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THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA

INSTITUTE FOR FISHERIES RESOURCES, *et al.*, *Plaintiffs,* v. ALEX M. AZAR II, *et al.*, *Defendants,* and AQUABOUNTY TECHNOLOGIES, INC., *Intervenor-Defendants.*	Case No. 3:16-cv-01574-VC **PLAINTIFFS' OPPOSITION TO DEFENDANTS' MOTION FOR JUDGMENT ON THE PLEADINGS AND CROSS MOTION FOR SUMMARY JUDGMENT ON CLAIMS 1, 8, 12, AND 13** Date: August 15, 2019 Time: 10:00 a.m. Location: Courtroom 4 – 17th Floor The Honorable Vince Chhabria

NOTICE OF CROSS-MOTION FOR PARTIAL SUMMARY JUDGMENT

PLEASE TAKE NOTICE Please take notice that the following Motion for Partial Summary Judgment will be heard by the Honorable Vince Chhabria of the United States District Court for the Northern District of California on August 15, 2019, at 10:00 a.m. in Courtroom 4, on the 17th floor of the Philip E. Burton Courthouse and Federal Building, 450 Golden Gate Avenue, San Francisco, California, or as soon thereafter as counsel can be heard.

REQUESTED RELIEF

Pursuant to Rule 56 of the Federal Rules of Civil Procedure, Plaintiffs Institute for Fisheries Resources (IFR), Pacific Coast Federation of Fishermen's Associations (PCFFA), Golden Gate Salmon Association (GGSA), Kennebec Reborn, Friends Of Merrymeeting Bay, Cascadia Wildlands (Cascadia), Center for Biological Diversity (the Center), Ecology Action Centre (EAC), Friends of The Earth (FoE), Food and Water Watch (FWW), Quinault Indian Nation, and Center For Food Safety (CFS), hereby move for partial summary judgment on Claims 1, 8, 12, and 13 raised in their Amended Complaint for Declaratory and Injunctive Relief, on the grounds that there is no genuine issue as to any material fact and that Plaintiffs are entitled to judgment as a matter of law. This motion is based upon the pleadings and administrative record on file in this case, the points and authorities herein, and the declarations submitted herewith.

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INTRODUCTION

Plaintiffs oppose the Food and Drug Administration (FDA)'s Motion for Judgment on the Pleadings on Claims 1, 8, 12, and 13, and cross move for Summary Judgment on those Claims. Based on review of the administrative record and the applicable legal standards, the Court should deny FDA's motion and grant Plaintiffs' summary judgment motion.

FDA insists that Congress authorized it to oversee genetically engineered food, animals, and fish as "drugs," pursuant to the Federal Food Drug and Cosmetic Act (FFDCA) of 1938. FDA has historically regulated veterinary substances used to treat individual animals as drugs under the FFDCA. Here, FDA is contorting its authority to assert broad jurisdiction over novel and unprecedented genetically engineered (GE) organisms and their lineage. GE animals simply are not "drugs," and FDA's attempt to assert authority to regulate them under statutory provisions never intended for that purpose is *ultra vires* and should be vacated.

Even if the Court concludes that FDA has jurisdiction to regulate GE animals as drugs, it still must ensure that the agency is accountable for the significant environmental risks of GE animals. The FFDCA allows FDA to approve new animal drugs only if they are "safe and effective." In both its guidance decision to regulate all GE animals as drugs and in its subsequent approval of the GE salmon, FDA failed to ensure the environmental safety of these novel organisms. Instead, FDA now argues that its environmental safety review is essentially voluntary and limited to its National Environmental Policy Act (NEPA) process. That is contrary to law, the record, and the agency's past practices. Allowing such an approach would set a dangerous precedent and turn consideration of environmental risks for GE animals into a pointless box-checking exercise.

Finally, FDA created its new GE animal program though a mere guidance document, without issuing formal regulations or evaluating the environmental impact of this new regulatory pathway under the National Environmental Policy Act (NEPA). NEPA requires FDA to complete an environmental impact statement (EIS) that evaluates the environmental effects of any "major federal action." The Administrative Procedure Act (APA) requires FDA to promulgate new rules using formal rulemaking procedures, culminating in binding regulations.

FDA's GE animal guidance was a legislative rule that amended existing law and created legal rights, and thus was a final agency action. Yet the agency did not complete any NEPA analysis of the environmental impacts of the GE animal program it created through the guidance, and did not adopt its new regulatory framework though a formal rulemaking as required by the APA.

In both its decision to regulate GE animals as "drugs" and its application of its new framework to approve GE salmon, FDA exceeded its authority, and violated the APA, the FFDCA, and NEPA. Plaintiffs seek summary judgment on claims 1, 8, 12, and 13, and ask the Court to set aside FDA's GE animal guidance and its GE salmon approval.

FACTUAL BACKGROUND

Sometime in the 1990s, FDA and AquaBounty began discussions about AquaBounty's novel GE salmon. *See* FDA-000001, FDA-000185.[1] At the time, neither FDA, nor any other agency, had a regulatory framework, or formally explained how federal agencies would regulate GE animals. *See* FDA-003696 (stating that FDA was "awaiting clear guidance from the highest levels of the agency with respect to how transgenic animals will be regulated"). In 2008, FDA developed a draft guidance document, which formally announced for the first time that the agency would extend its jurisdiction under the FFDCA to regulate GE animals as new animal drugs, 21 U.S.C. § 321, *et seq*. FDA-018743. FDA finalized the GE animal guidance in January 2009. 74 Fed. Reg. 3057 (Jan. 16, 2009). FDA never conducted an analysis of the environmental impacts of this GE animal regulatory program under NEPA.

In the GE animal guidance, FDA justified its assertion of regulatory jurisdiction by interpreting the term "new animal drug" to include the "rDNA construct" that genetically engineers the animal as an article "intended to affect the structure or function" of the animal. FDA-G187-00599. FDA did not define "rDNA construct," but referred to the artificially made DNA sequence that exists in a GE animal as part of its genetic code. *Id.* However, as FDA

[1] Because many of these record documents may contain "confidential information," Plaintiffs have not attached them as exhibits in accordance with the December 23, 2016 Protective Order (ECF No. 87) and the July 9, 2018 Amended Protective Order (ECF No. 140). As partially provided for in those orders, *see, e.g.*, ECF 87 No. at 5, at the close of briefing, Plaintiffs will confer with the parties regarding any needed redactions and the parties will compile the documents in a joint appendix to be filed publicly.

necessarily acknowledged, such integral DNA sequences are not items or objects that can be manipulated or regulated separate and apart from the animal itself. The rDNA is not even introduced into the individual GE animal, but rather is a part of the animal that is passed along to its progeny which inherit the rDNA, along with the animal's other genetic material. FDA-G187-00600. In short, an "rDNA construct" cannot be separated from the GE animal of which it is a part. *See id*. Rather than conclude that an inseparable "rDNA construct" does not meet the definition of a drug, and despite asserting that the "rDNA construct" is what is intended to affect the GE animal, FDA made a remarkable leap and asserted that a GE animal *itself* should therefore also be considered a "drug." FDA-G187-00596–97. By bootstrapping "animals" into the definition of a "drug," FDA enacted a sweeping—and unsupported—expansion of its jurisdiction.

In the GE animal guidance, FDA interpreted the FFDCA's requirement to ensure "safety and effectiveness" to include an evaluation of environmental risks, categorizing three components of safety to be considered as part of the pre-approval assessment: food safety, feed safety, and environmental safety. FDA-G187-00617–19. The record also demonstrates that FDA considered environmental safety to be a key part of its FFDCA review for a GE animal application. *See infra* at 16-19. Further, in its specific approval of the GE salmon under the FFDCA, FDA believed that it must address environmental risks and implement mitigation measures it concluded would reduce those risks. *See infra* at 17-19. Yet despite this record evidence, FDA now claims that environmental safety is not part of its FFDCA calculus, and that it need not address or ensure environmental safety, for the GE salmon or any other GE animal.

Applying the GE animal guidance's pathway and rubric, FDA approved AquaBounty's new animal drug application to produce and market its GE salmon on November 19, 2015. 80 Fed. Reg. 73,104 (Nov. 24, 2015). This was the first occasion in history when any country had authorized the production of a GE animal to be sold as food. In conjunction with that approval, FDA prepared an environmental assessment (EA) under NEPA, but not an environmental impact statement. FDA-022313–520.

STANDARDS OF REVIEW

Judgment on the pleadings is only appropriate when "there is no issue of material fact in dispute, and the moving party is entitled to judgment as a matter of law." *Fleming v. Pickard*, 581 F.3d 922, 925 (9th Cir. 2009). Under Fed. R. Civ. P. 12(d) where, as here, "the district court must go beyond the pleadings to resolve an issue on motion for judgment on the pleadings, the proceeding is properly treated as a motion for summary judgment." *See, e.g.*, *Jensen Fam. Farms, Inc. v. Monterey Bay Unified Air Pollution Control Dist.*, No. C 08-05003 JW, 2009 WL 10678847, at *3 (N.D. Cal. July 14, 2009) (citing Fed. R. Civ. P. 12(d)); *Bonilla v. Oakland Scavenger Co.*, 697 F.2d 1297, 1301 (9th Cir. 1982); *Bach v. Bambaren*, No. C09-1787RSL, 2010 WL 11565186, at *1 (W.D. Wash. June 4, 2010) (holding that "[t]he plain language of the rule explicitly permits a party to submit additional evidence. If a party does so, the Court may either disregard the evidence, or if it chooses to consider it, then the motion is converted into a motion for summary judgment."). *See also* ECF No. 163. Summary judgment is appropriate for the four claims at issue because the pleadings and the record evidence presented below show there is "no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56.

The APA provides the basic framework for judicial review of agency action and requires the Court to "hold unlawful and set aside" decisions that are (1) "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law," or (2) "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right," or (3) adopted "without observance of procedure required by law." 5 U.S.C. § 706(2). In determining whether an action is "arbitrary and capricious" the Court evaluates whether the agency "examine[d] the relevant data and articulate[d] a satisfactory explanation for its action including a 'rational connection between the facts found and the choice made.'" *Motor Vehicle Mfrs. Ass'n of U.S. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983) (quoting *Burlington Truck Lines v. U.S.*, 371 U.S. 156, 168 (1962)). An action is arbitrary and capricious if the agency "has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is

so implausible that it could not be ascribed to a difference in view or the product of agency expertise." *Id.*

Review of documents in the record is required to determine whether an action is "arbitrary and capricious," or "in excess of statutory jurisdiction." 5 U.S.C. § 706(2) ("the court shall review the whole record or those parts of it cited by a party"). Evidence in the administrative record, including of the agency's prior positions or interpretations of its own authority, is particularly important where the agency has adopted an inconsistent litigation position. *See e.g.*, *Beno v. Shalala*, 30 F.3d 1057, 1071 (9th Cir. 1994) (full deference is not appropriate for "statutory interpretations which appear to have been adopted for purposes of litigation, and which are not supported by any other evidence in the record" and "'[a]n agency interpretation of a relevant provision which conflicts with the agency's earlier interpretation is 'entitled to considerably less deference' than a consistently held agency view.") (citations omitted); *Stewart v. Azar*, 313 F. Supp. 3d 237, 249 (D.D.C. 2018) ("agency 'litigating positions' are not entitled to deference when they are merely [agency] counsel's '*post hoc* rationalizations' for agency action, advanced for the first time in the reviewing court.") (citations omitted).

ARGUMENT

I. THE FFDCA'S DRUG PROVISIONS DO NOT GRANT FDA JURISDICTION OVER GENETICALLY ENGINEERED ANIMALS.

FDA has asserted jurisdiction to approve and regulate GE animals under the FFDCA. FDA-G187-00598–600. The agency approved AquaBounty's GE salmon based on this asserted authority to regulate these animals as "new animal drugs." FDA-023113. Genetically engineered animals, however, are not drugs: they are fundamentally different and carry different risks, environmental impacts, and socioeconomic ramifications. Congress authorized FDA to regulate veterinary animal drugs under the FFDCA's new animal drug provisions. It did not authorize the agency to cantilever from that an entirely new regulatory regime for the entire life cycle and commercial sale of GE animals for food. FDA's GE salmon approval, and the GE animal program established by the GE animal guidance, exceed FDA's authority and violate the APA. 5 U.S.C. § 706(2)(C). FDA itself has accurately described GE animals as not "fit[ting] any current paradigms" of FDA regulatory authority. FDA-004192 (Letter to AquaBounty recognizing that

"the 'product' [GE salmon] clearly doesn't fit any current paradigms" and recommending steps AquaBounty could take to define the product "regardless of whether the new animal drug rubric or any other would be employed"). This Court should reject FDA's attempt to read into the FFDCA a sweeping new authority to regulate GE animals.

A. The FFDCA's Plain Text and Statutory Scheme Show GE Animals Are Not "Drugs."

As the Supreme Court has instructed "[a]n agency has no power to tailor legislation to bureaucratic policy goals by rewriting unambiguous statutory terms." *Util. Air Regulatory Group v. EPA*, 573 U.S. 302, 325 (2014). FDA's attempt to transform an animal into a "drug" flies in the face of the plain language of the FFDCA and the term's ordinary meaning. Under the FFDCA, Congress charged FDA with the broad duty to "promote public health by ensuring," among other things, that "human and veterinary drugs are safe and effective." 21 U.S.C. § 393(b).[2] Under the FFDCA, the term "drug" includes, among other things, "articles (other than food) intended to affect the structure or any function of the body of man or other animals." *Id.* § 321(g)(1)(C). Contrary to FDA's assertion, the GE animal itself is not an "article intended to affect the structure or function" of the animal, 21 U.S.C § 321(g)(1)(C), it *is* the animal. Nor does the FFDCA provide FDA the broad authority to extend the drug provisions to construct a new permitting scheme for the production and commercialization of GE food animals. In fact, the drug provisions do not even mention genetic engineering. *See, e.g.*, 21 U.S.C. § 321(g)(1)(C) (defining drugs as "articles (other than food) intended to affect the structure or function of the body of man or other animals …"); § 321(v) (new animal drugs are "any drug intended for use for animals"); *id.* § 360b (no mention of authority to regulate animals themselves in requirements of drug approval process).

"'A fundamental canon of statutory construction is that, unless otherwise defined, words will be interpreted as taking their ordinary, contemporary, common meaning.'" *Gulf Fishermen's Ass'n v. Nat'l Marine Fisheries Serv.*, 341 F. Supp. 3d 632, 640 (E.D. La. 2018) (quoting *Perrin*

[2] As FDA has recognized, public health is a broad term that incorporates environmental health. FDA-004899 (stating "public health" is an "encompassing term that refers to the health" of not only the target animals and humans/other animals consuming food from the target animals, but also "other organisms in the environment in which [the target animals] are likely to be found").

v. United States, 444 U.S. 37, 42 (1979)). Congress and society commonly understood the word "drug" in the 1930s, when Congress enacted the FFDCA, and later in the 1960s, when Congress amended it, to be a *medicine* for the treatment of disease, not a fundamental and heritable alteration of an organism itself. *See e.g.*, *Guest v. Horace Mann Ins. Co.*, 168 Ga. App. 714, 715 (1983) (citing Webster's Third New International Dictionary from 1961 for definition of "drug," then defined as "a substance used as a medicine or in making medications for internal or external use . . . a substance intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animal. . . .").[3] Understood in the context of its plain terms and their ordinary meaning, the new animal drug framework was intended to regulate a familiar scenario: an animal is administered medication, like antibiotics, that is temporarily present but metabolized. FDA cannot credibly contend that Congress in the 1930s or 1960s could foresee that this same authority could be applied to regulate the life cycle of an entirely new organism, permanently altered and capable of passing its traits on to the next generation. "If the intent of Congress is clear, that is the end of the matter." *Chevron v. Nat. Res. Def. Council, Inc.*, 467 U.S. 837, 842 (1984).

Other provisions of the FFDCA's new animal drug framework underscore that Congress did not intend this authority to encompass the comprehensive regulation of animals produced as food.[4] First, and most obviously, the FFDCA's definition of "drug" expressly excludes "food." 21 U.S.C. § 321(g)(1)(C). Yet FDA used this authority to approve AquaBounty's GE salmon as

[3] Other contemporary definitions confirm that "drug" was defined as a medicinal substance administered to cure disease, not an "rDNA construct." Webster's Seventh New Collegiate Dictionary (1963), at 255 (defining "drug" as "a substance used as a medicine or in medicines"), https://archive.org/details/webstersseventhn00unse/page/254;1933 Black's Law Dictionary (3d ed.) ("Drug**.** The general name of substances used in medicine … any substance used as a medicine"); Oxford English Dictionary (vol. III 1933), at 687, available at https://bit.ly/2EPzoNT_(Drug is defined as: "An original, simple, medicinal substance, organic or inorganic, whether used by itself in its natural condition or prepared by art, or as an ingredient in a medicine or medicament.").

[4] Courts assess Congressional intent based on the "design and structure of the statute as a whole." *See Util. Air Regulatory Grp. v. EPA*, 573 U.S. 302, 320 (2014) (quoting *United Sav. Ass'n of Tex. v. Timbers of Inwood Forest Assocs., Ltd.*, 484 U.S. 365, 371 (1988)); *Robinson v. Shell Oil Co.*, 519 U.S. 337, 341 (1997); *Ariz. Pub. Serv. Co. v. EPA*, 211 F.3d 1280, 1287 (D.C. Cir. 2000) (holding court must "exhaust[] traditional tools of statutory construction" at *Chevron* Step 1).

an animal drug—despite the fact that it is solely intended to be grown and sold as food. FDA has not and cannot explain how these mutually exclusive categories can apply to the same organism. Similarly, the FFDCA provides that new animal drugs may only be deemed "safe" and exempt from the misbranding provisions if "such intended use is by or on the lawful written or oral order of a licensed veterinarian within the context of a veterinarian-client-patient relationship, as defined by the Secretary." 21 U.S.C. §§ 360b(a)(4) and (5); FDA-G187-00599 (same provisions cited by FDA in its GE animal guidance). Of course, this cannot apply to GE animals because a genetic engineer (not a veterinarian) transforms the DNA of a GE animal and neither the transgenic "rDNA construct" nor the GE animal itself is ordered by a veterinarian in the context of a client-patient relationship (a process of course reserved for the ordinary administration of animal drugs).[5]

FDA's actions here mirror those of the National Marine Fisheries Service (NMFS) in a recent decision related to a rulemaking that asserted jurisdiction over commercial aquaculture under the agency's statutory authority to regulate "fishing." *Gulf Fishermens Ass'n.*, 341 F. Supp. 3d. 632.[6] In that case, NMFS argued that the statutory definition of "fishing" included fish farming or aquaculture, even though the statute was silent on the question. *Id*. at 637. The Court determined that, just like GE animals and drugs, aquaculture is unambiguously not the same thing as fishing, and instead raised a host of different risks and considerations. *Id*. at 639. The Court rejected the Defendants' request for *Chevron* deference, *id.* at 641-42, because the plain language, statutory purposes, statutory scheme, and legislative history illustrated the "nonsensical" results of the agency's assertion that fish farming and fishing were the same. *Id.* at 640. Accordingly, the Court held that the agency "acted outside its statutory authority in shoehorning an entire regulatory scheme into a single unambiguous word" and vacated the

[5] Even if the FFDCA was ambiguous, FDA established its new interpretation in a guidance document, which the agency contends is "non-binding." *But see infra* at 23-28 (disputing FDA's characterization). Such policy documents are not eligible for *Chervon* Step 2 deference. This interpretation is only given "respect proportional to its 'power to persuade.'" *Northern California River Watch v. Wilcox*, 633 F.3d 766, 780 (9th Cir. 2011)(citations omitted); *Christensen v. Harris Cnty.*, 529 U.S. 576, 587 (2000).

[6] Unlike FDA's attempt to regulate by guidance here, Commerce engaged in a ten-year formal rulemaking to enact an entire new set of regulations for the aquaculture permitting scheme.

regulations and permitting scheme as *ultra vires*.[7] *Id.* at 642. *See also Sierra Club v. Pruitt*, 293 F. Supp. 3d 1050, 1059-60 (N.D. Cal. 2018) (vacating *ultra vires* agency action); *Northwest Environmental Advocates v. EPA*, 537 F.3d 1006, 1021-22 (9th Cir. 2008) (vacating an EPA regulation as *ultra vires*).

Defendants scaremonger when they imply that if the Court finds FDA's decisions were *ultra vires*, AquaBounty could sell its GE salmon without any oversight. ECF No. 145 at n.4. Vacating an unlawful regulatory program does not mean that a Wild West free-for-all will follow. First, this characterization conflicts with FDA's argument that the GE animal guidance lacks any legal effect, *see infra* at 23-28. If the GE animal guidance implementing FDA's alleged authority is truly voluntary, then the unregulated market FDA professes to fear already exists. Second, GE animal manufacturers count on the imprimatur of regulatory approval and any associated protection from liability risks, as evidenced by regulation of other GE organisms. FDA-003696 (memo on 2004 conference noting that "that the biotech industry was diametrically opposed to voluntary regulation… [because] a voluntary system would be insufficient to provide the confidence that the public would need to accept the technology.").[8] Third, while further Congressional action may eventually be necessary to comprehensively regulate GE animals in the long-term, this does not translate to a complete absence of oversight in the short-term as multiple other laws and agencies govern GE salmon. For example, Congress has previously prohibited importation of GE salmon pending labeling and could again enact a temporary ban pending fuller legislation. Consolidated Appropriations Act of 2017, Pub. L. No. 115-31, § 761, 131 Stat. 135, 179 (2017). *See also* F1-00267590 (2011 letter to FDA from U.S. House of Representative members, FDA should "delay consideration until an appropriate federal process is developed"). In addition, because AquaBounty's facilities are located outside the United

[7] *Ultra vires* means action that is "unauthorized," or "beyond the scope of power allowed or granted … by law." *Ultra Vires*, Black's Law Dictionary (10th ed. 2014). The term is applied to federal agencies when they act in excess of their delegated power, because "an agency's power is no greater than that delegated to it by Congress." *Lyng v. Payne*, 476 U.S. 926, 937 (1986).

[8] *See, e.g.*, Brendan Pierson, *U.S. farmers seek approval of $1.51 bln GMO corn settlement with Syngenta*, Reuters (Mar. 12, 2018), available at https://reut.rs/2Sb4XF7 (last visited Feb. 18, 2019) (detailing $1.5 billion settlement for market damages caused by unregulated GE plant).

States, the U.S. Fish and Wildlife Service would be required to exercise its authority under the Lacey Act to approve a permit for importation of GE fish eggs or fish as well as consult under the ESA for that decision. 50 C.F.R § 16.13(a)(3). FDA itself could also exercise oversight of GE food animals under its authority to regulate food additives. 21 U.S.C. §§ 321(s), 348. And other agencies, such as EPA and the Department of Agriculture, with relevant scientific and regulatory expertise (and which already regulate other aspects of agricultural biotechnology), also have statutory authority over GE organisms.[9] Finally, even if vacatur of FDA's *ultra vires* actions *could* result in a temporary regulatory void, that is not a legal rationale to uphold FDA's illegal actions. Nor is any void likely to last long: once American consumers know unregulated novel GE animals are on grocery store shelves or are allowed in U.S. waters, public pressure would require individual states, other federal agencies, and Congress to act.

In sum, the plain language of the FFDCA and the ordinary meaning of its terms are unambiguous: Congress made plain that the agency's new animal drug authority applied to a limited and, at the time these provisions were enacted, well-understood series of practices to provide medicine or other supplements to animals. It was not a blank check to regulate the cradle-to-grave (or cradle-to-plate) manufacture, culture, containment, and use of those animals.

B. Subsequent FFDCA Legislative History Undermines FDA's Interpretation.

FDA points to recent Congressional attempts intended to prevent the agency from approving GE salmon as nonetheless evincing Congressional approval of its authority to regulate all GE animals as drugs. ECF No. 145 at 22. But, if anything, these bills support Plaintiffs because they show Congress's *concern* about FDA's assertion of authority, not acquiescence to it. In addition to being counter-intuitive, FDA's argument violates the interpretative maxim that "'failed legislative proposals are a particularly dangerous ground on which to rest an interpretation of a prior statute.'" *Federal Trade Comm'n v. AT&T Mobility*, 883 F.3d 848, 857 (9th Cir. 2018) (quoting *United States v. Craft*, 535 U.S. 274, 287 (2002)).

The agency also points to narrow supplemental revisions of the FFDCA from 2004 that

[9] *See Coordinated Framework for the Regulation of Biotechnology*, 51 Fed. Reg. 23,302 (Jun. 26, 1986).

mention new animal drugs contained in "transgenic animals," in the context of prohibiting expedited approval or conditional authorization of these animals. *See* 21 U.S.C. § 360ccc(j). Notably this provision came *before* FDA's 2009 promulgation of a regulatory scheme in the GE animal guidance and *before* the more recent Congressional pronouncements expressing concern and alarm. But, regardless, this provision is not evidence of Congressional acquiescence in FDA's actions because it does not address the "precise issue" before the Court: whether FDA may regulate GE animals using its 1938 veterinary animal drug authority. *See Bob Jones University v. United States*, 461 U.S. 574, 600 (1983). When such amendments do not directly address the "precise issue," courts are typically reticent to glean any intent, and "[a]bsent such overwhelming evidence of acquiescence, [courts] are loath to replace the plain text and original understanding of a statute with an amended agency interpretation." *Solid Waste Agency v. United States Army Corps of Eng'rs*, 531 U.S. 159, 169-70 (2001); *id.* at 170-71 (rejecting an argument for congressional intent based on an amendment to a different part of the Clean Water Act that only indirectly addressed the issue). Early Congressional concern over FDA's expedited approval of GE animals simply does not translate to Congressional approval of the agency's subsequently-adopted GE animal guidance. *Northwest Environmental Advocates*, 537 F.3d at 1025 (rejecting such arguments and explaining that "the standard for a judicial finding of congressional acquiescence is extremely high").

Likewise, FDA's invocation of a 2007 amendment directing FDA to consult with NMFS and produce a report on the environmental risks of genetically engineered seafood products does not bless FDA's assertion of authority to regulate GE animals, or GE salmon specifically, as "animal drugs." ECF No. 145 at 21; 21 U.S.C. § 2106. It does just the opposite: it demonstrates significant Congressional *concern* about the limits of FDA's expertise and authority, and explicitly directs the involvement of other federal agencies with relevant expertise.

FDA's claims of Congressional acquiescence are also belied by the numerous letters from Congress to FDA expressing significant apprehension and alarm about any approval of GE salmon, and expressly questioning the agency's assertion of authority to do so. *See, e.g.*, F1-00267592 (2011 letter to FDA from eight Senators, "strongly urg[ing] [FDA] to immediately

cease your approval process" because, *inter alia*, "We are concerned that FDA's review of GE salmon uses the same criteria as it would for approving a veterinary drug. This level of genetic manipulation is *clearly not a veterinary drug*.").[10]

The Supreme Court has warned repeatedly that "Congress does not, one might say, hide elephants in mouseholes." *Puerto Rico v. Franklin California Tax-Free Tr.*, 136 S. Ct. 1938, 1947 (2016) (internal quotation omitted). Yet this is what FDA's actions amount to: shoving a genetically engineered fish through the eye of a veterinary animal drug needle. It is an untenable expansion of the FFDCA. *FDA v. Brown & Williams Tobacco Corp.*, 529 U.S. 120, 160 (2000) ("Congress could not have intended to delegate a decision of such economic and political significance to an agency in so cryptic a fashion."). The Court should reject it as *ulta vires* and grant summary judgment to Plaintiffs.

II. FDA'S FAILURES TO ENSURE ENVIRONMENTAL SAFETY WERE ARBITRARY AND CAPRICIOUS.

Even if FDA has authority to regulate GE animals under the FFDCA, it must ensure that its oversight is correspondingly meaningful and comprehensive. FDA's GE animal guidance, however, failed to fully or rationally explain how it would evaluate, assess, or weigh as a factor the environmental safety of GE animals in determining that GE animals meet the statutory requirement that new animal drugs are "safe and effective." In its GE salmon approval, FDA likewise failed to explain or ensure that GE salmon was "environmentally safe" as part of its "safe and effective" determination. These failures render FDA's decisions arbitrary and capricious.

FDA does not defend the adequacy of its FFDCA environmental risk review. Instead, it claims that judgment on the pleadings is warranted for two ill-defined reasons. First, although

[10] *See also* F1-00267590 (2011 letter to FDA from House of Representative members, "At present, the FDA currently does not have adequate means to assess the GE salmon as an animal intended for human consumption" and should "delay consideration until an appropriate federal process is developed" not "proceed[] with the approval of the GE fish using the agency's existing process designed to review new drugs meant for use on animals"); F1-00267587 (2010 Senate letter: "FDA is considering this GE fish through its process for reviewing a new drug to be used by animals, not for creation of a new animal, especially one intended for human consumption. *Clearly, this is inappropriate*." (emphasis added)); F1-00267583 (2010 House letter).

FDA apparently does not dispute that it may consider environmental safety under the FFDCA, it implies it is not obligated to account for those impacts. *See* ECF No. 145 at 23. Second, FDA argues that, instead of ensuring environmental safety under the FFDCA, its consideration of environmental risks is relevant only in its NEPA process. *Id* at 3, 23. These assertions are contrary to NEPA and the FFDCA. Contrary to FDA's litigation position, the record demonstrates that FDA itself actually determined environmental safety considerations were highly relevant to its FFDCA statutory safety analysis, and the agency did consider environmental risk as part of its FFDCA safety evaluation (albeit inadequately) in the guidance and its GE salmon approval. NEPA does not replace or limit FDA's responsibility to ensure environmental safety under the FFDCA. NEPA merely provides a procedural vehicle for considering environmental concerns pursuant to FDA's underlying substantive authority, thereby informing the agency's eventual substantive decision. And under FFDCA, FDA cannot approve an "animal drug" that is not environmentally safe.

A. FDA Failed to Adequately Consider Environmental Safety in the GE Animal Guidance or the GE Salmon Approval.

The APA requires FDA to consider all relevant factors and rationally explain its decisions. Despite the requirements of the APA and FFDCA, there are no criteria or explanatory rationale in the GE animal guidance or the GE salmon approval detailing how FDA will consider environmental safety or otherwise consider environmental impacts as part of its FFDCA safety assessment. In the GE animal guidance, FDA specified that some information would be needed to demonstrate a GE animal "drug" would, overall, be safe and effective. *See* FDA-G187-00589-90. While FDA said environmental safety is part of this determination, FDA-G187-00619, it did not outline *how* it would evaluate environmental risks in its FFDCA safety determinations. Instead, FDA merely stated that it would evaluate environmental safety through its NEPA review. FDA-G187-00605; FDA-G187-00619. This conclusory statement fails to provide any indication how that *NEPA* review will factor into its substantive *FFDCA* safety determination. FDA did not, among other things, set standards for determining when GE animals pose ecological risks, detail what environmental safety evidence would be required for its review,

identify situations where it may be necessary to protect wild populations or ecosystems from risks posed by GE animals, or what measures may be available. In short, the agency failed to detail what criteria it would apply to weigh and combine environmental factors in its new animal drug approval decision to ensure that environmental risks were adequately addressed such that a GE animal could be found "safe and effective." FDA-G187-00606. FDA's failure to rationally explain how it will substantively consider environmental risks renders the guidance arbitrary and capricious. *See, e.g.*, *Northwest Envt'l Defense Ctr. v. Bonneville Power Admin.*, 477 F.3d 668, 691 (9th Cir. 2007) ("The United States Supreme Court has declared that we must require that an agency 'cogently explain why it has exercised its discretion in a given manner.'") (citation omitted).

The GE salmon approval demonstrates the consequences of these omissions. In making this decision, FDA failed to consider all of the relevant environmental factors when evaluating whether GE salmon will be "safe and effective" and never explained how it ensured the GE salmon was environmentally safe under the FFDCA. FDA instead leaned exclusively on its NEPA environmental assessment to assert that it considered environmental concerns. FDA-022784.[11] Yet as discussed below, that NEPA assessment is procedural and is intended to *inform*—not replace—the substantive consideration the FFDCA requires. These failures to consider important factors, make a rational connection between the facts found and the agency's "safe and effective" conclusion, and to explain how the NEPA analysis supported and informed FDA's ultimate FFDCA safety determination, renders FDA's decision to approve GE salmon arbitrary and capricious under the APA and the FFDCA. *State Farm*, 463 U.S. at 43.

[11] FDA's NEPA assessment itself was unlawful because, among other things, the agency failed to adequately assess the environmental effects of escape or release of GE salmon, or the reasonably foreseeable expansion inherent in AquaBounty's business model. ECF No. 53 at ¶¶ 167-215. The full extent of FDA's failures to adequately consider environmental risks as part of its "safety and effectiveness" review is tied inextricably to Plaintiffs' arguments related to the inadequacy of FDA's environmental review under NEPA and the ESA and should be considered together with these remaining claims. ECF No. 169 ("The Court will consider whether adjudication of parts of th[e current] motion should be delayed for consideration with the remaining claims.").

B. FDA's Position is Contrary to the FFDCA.

While FDA now contends that the FFDCA does not specifically include environmental safety as part of the new animal drug approval process, ECF No. 145 at 23, the plain language of the FFDCA, and FDA's consistent interpretation, demonstrates that the review of a new animal drug's "safety and effectiveness" must include an evaluation of environmental safety. And the record demonstrates that environmental safety is inextricably linked to FDA's new animal drug approvals, including its approval of GE salmon.

Congress charged FDA with the broad duty to "promote the public health" by ensuring, among other things, that "human and veterinary drugs are safe and effective." 21 U.S.C. § 393(b)(2)(B). "Safe" is not separately defined, but is determined with "reference to the health of man or animal." 21 U.S.C. § 321(u) (emphasis added). In the animal drug context, "safety" encompasses any factor relevant to the approval of the drug. *See* 21 U.S.C.§ 360b(d)(2) (providing that "[i]n determining whether such drug is safe for use … the Secretary shall consider …[several non-exclusive factors], *among other relevant factors…*") (emphasis added); *id.* at § (d)(1)(D) (FDA must consider safety based on information in the application "or upon the basis of any other information before" FDA).

Given this broad charge, FDA does not dispute (nor could it) that it has authority to consider environmental impacts as part of its "safety and effectiveness" review; instead, it twists the issue, asserting "FDA [only] considers whether a drug is safe for the target animal and whether it is safe for humans to eat food from the animal, not whether it is safe for the environment." ECF No. 145 at 23. To the contrary, none of the provisions FDA cites in any way limit the factors the agency must consider. *See, e.g.*, 21 U.S.C. § 360b(a)(1) (listing types of applications for new animal drugs); *id.* at § (b)(1)(H) (listing required contents of an application, including a "proposed tolerance or withdrawal period" if these are "required … to assure the proposed use of such drug is safe").[12] FDA's *post hoc* argument in its motion also contradicts its

[12] FDA's regulations are similarly broad. 21 C.F.R. § 514.1(b)(8) outlines the evidence that an applicant should submit to establish safety and effectiveness, but far from limiting such information to specific topics, the regulations broadly require submission of "[a]ll information pertinent to an evaluation of the safety and effectiveness" available "from any source." 21 C.F.R. § 514.1(b)(8)(iv). Although Section 514.1(b)(14) also specifically requires an applicant to submit

own past practice and interpretation of the statute. The record demonstrates FDA has consistently interpreted the FFDCA to encompass environmental safety and demonstrates that the agency *did* evaluate environmental safety (albeit inadequately) for GE salmon. If, as FDA admits throughout this record, evaluation of environmental risk is a "relevant factor[]" for determining safety under the FFDCA, then it follows that FDA must ensure that GE animals will be environmentally safe under the FFDCA before approving a new animal drug. 21 U.S.C.§ 360b(d)(2) (requiring Secretary to consider any "relevant factors" when determining drug safety).

In the GE animal guidance, FDA interpreted "safety and effectiveness" to include an evaluation of environmental risks, including three components of safety to be considered as part of the pre-approval assessment: food safety, feed safety, and environmental safety. FDA-G187-00617–19.[13] FDA stated that "environmental risks are among the factors we intend to consider in determining whether to exercise enforcement discretion" to require a new drug application in the first place. FDA-G187-00600. And FDA outlined (but did not explain how it would weigh or consider) some of the factors it would consider to determine whether to take enforcement action as a result of "safety concerns," including whether the GE animal poses a "human, animal, or *environmental* risk." FDA-G187-00599–600 (emphasis added).

In a case study, authored by FDA and other federal agencies, ECF No. 145 at 5, FDA also explicitly found that environmental safety must be considered as part of its safety assessment. ECF No. 145-3 at FDA-2001CP-00092 ("Under the FFDCA, a new animal drug's

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an environmental assessment, that provision is not a substitute for the information that an applicant must submit to establish safety or, more specifically, a limitation on the environmental evidence submitted or considered to establish safety. *See* 21 C.F.R. § 514.1(14).

[13] FDA now claims that the placement of the term "environmental safety" as part of the specific seven steps the guidance outlines is coincidental. ECF No. 145 at 23-24. The guidance speaks for itself. It uses the terminology "Environmental Safety," which is not a NEPA term of art, but instead refers by context to the FFDCA "safety" determination (since that is the only safety determination). And it places the environmental safety determination directly in and part of the new animal drug approval process, not set off apart as FDA now claims. FDA-G187-00619 ("This portion of Step 6 addresses the *environmental component of your NADA*") (emphasis added). FDA notes that it discusses the NEPA analyses for evaluation, but as discussed below, *infra* at 19-21, that is unsurprising given NEPA's informative role. Further, in developing a hierarchical approach to its approval of applications for GE animals, FDA demonstrated that it would evaluate environmental safety as part of its safety assessment. *See* FDA-014754.

safety is defined as having 'reference to the health of man or animal' . . . The agency considers, *as part of its safety assessment of the drug contained in a transgenic fish (or any other new animal drug)*, environmental effects that directly or indirectly affect the health of humans or animals as a result of FDA's allowing the new animal drug's 'use.'" (emphasis added)). FDA also stated that it "*relies on its authority under the FFDCA* to require, where appropriate, environmental safety instructions on product labels, to enforce compliance with mitigations that are required as a condition of the product approval, and to refuse to approve or to withdraw approval of products that cause unexpected and unmitigable environmental impacts." *Id.* at FDA-2001CP-00093 (emphasis added).[14]

FDA repeatedly stated that it considered environmental safety *one of the most important parts* of its review of GE animals—and in particular, of GE salmon. *See, e.g.*, F1-00183309 (management team meeting acknowledging that "[t]he primary risk issue posed by the [AquAdvantage] salmon is environmental."). In response to comments from a State concerned about the environmental risks of GE salmon, FDA emphasized that its approval "requires that the GE salmon with the rDNA construct meets our safety standards not only for the animal, but also for the environment and for any food derived from the animal." F1-00065842.

FDA also expressly stated it needed to ensure environmental safety in order to approve GE Salmon under the FFDCA. In early meetings with AquaBounty, FDA explained how the company could satisfy environmental safety requirements under the FFDCA. *See* FDA-001025; FDA-001427 (FDA "discussed the environmental safety framework under the FFDCA, NEPA, and FDA environmental regulations"); FDA-001435-37 (laying out the environmental safety framework as part of FFDCA and separate from NEPA); FDA-001382-83. AquaBounty submitted evidence to support its assertions of environmental safety, in accordance with the FFDCA, 21 U.S.C. § 360b(b)(1)(A). FDA-0007362; FDA-013978. FDA reviewed that evidence

[14] FDA may argue that these and other statements from FDA officials and scientists are somehow discountable because they touch on matters not within the individual's formal title. But the record demonstrates that FDA considered the team it assembled for these decisions to consist of its "most senior and experienced staff" and "[t]hese CVM scientists not only fully understand the safety and effectiveness standards at an expert level but understand how these standards can be met taking into account the characteristics of this technology." FDA-014623.

and raised questions about "environmental safety," before it eventually determined (incorrectly) that it had "adequate support to conclude the environmental safety step of [the] review." FDA-013978; *see also* FDA-013948 (stating that after reviewing the EA, Canadian environmental review, and site visit report, FDA "concluded that no additional environmental safety information" was needed to support the animal drug application); FDA-013973 (characterizing NEPA Environment Assessment as only one of several documents and pieces of information that FDA considered with respect to "environmental safety"); FDA-014756 (listing all the information evaluated as part of environmental safety review); FDA-000635 (stating that triploidy would not be sufficient to "ensure environmental safety" for GE animals).

Finally, in issuing the final approval, FDA exercised its statutory obligation to ensure environmental safety under the FFDCA by imposing environmental "conditions of use" or "limitations" on the AquaBounty salmon.[15] When amending its regulations to approve GE salmon, FDA imposed environmental limitations on the approval, including restrictions on facilities, containment, and production methods. 80 Fed. Reg. at 73,104 (Nov. 24, 2015); 21 C.F.R. § 528.1092 (listing limitations). Under FDA's own regulations, those environmental limitations are those FDA "deems necessary to assure the safe and effective use" of the GE salmon drug. 21 C.F.R. § 514.105. FDA specified that its approval was predicated upon compliance with each of these environmental safety conditions and that "[d]eviations from these commitments and requirements will result in the article being considered an unsafe new animal drug" under the FFDCA. FDA-023113. And in the Final EA, FDA stated that it reviewed environmental safety and effectiveness under the "specified conditions of use" and concluded that they would "serve to mitigate environmental risks." FDA-022328.[16] None of these

[15] FDA has broad authority to impose environmental conditions of use in order to assure safety and effectiveness. 21 U.S.C. § 360b(i) (authority to impose conditions of use which FDA "deems necessary to assure the safe and effective use of such drug"). FDA's authority to oversee and enforce new animal drug approvals is also tied to the continued "safety" of the drug. A drug is considered "unsafe" if the use does not conform to the approved application. 21 U.S.C. § 360b(a)(1)(A). FDA has authority to withdraw approval of a new animal drug if it finds that its use is "unsafe" for the environment, even under the approved conditions or if the applicant makes any changes from the standpoint of "safety or effectiveness." 21 U.S.C. § 360b(e)(1) (granting broad authority to withdraw approval if a drug is "unsafe for use").

[16] Despite these statements about the importance of environmental safety, FDA did not

conditions would be necessary—and none would be enforceable—if under the FFDCA, FDA does not consider whether a new animal drug is safe for the environment under the FFDCA, as it now asserts.

Given this extensive record, FDA's inconsistent litigation position that the FFDCA does not require the agency to address environmental safety deserves little deference. *See e.g., Beno v. Shalala*, 30 F.3d at 1071; *Stewart v. Azar*, 313 F. Supp. 3d at 249.

C. FDA's Position is Contrary to NEPA.

FDA's argument—that NEPA is somehow a separate vehicle under which "environmental safety is considered"—is both legally and factually incorrect. ECF No. 145 at 23. It is settled law (undisputed by FDA, *see id*. at 10) that NEPA is a procedural statute, which requires federal agencies to take a "hard look" at the environmental consequences of its actions and "carefully consider" them before deciding whether to take that action. *See, e.g., Alliance for the Wild Rockies v. U.S. Forest Service*, 899 F.3d 970, 975 (9th Cir. 2018). While it can inform an agency's decision, NEPA by itself "does not provide any substantive protections, only procedural ones." *See, e.g., Conservation Congress v. Environmental Protection Information Ctr.*, 774 F.3d 611, 615 (9th Cir. 2014). And, as demonstrated *infra*, it is factually false that the environmental aspects of FDA's decision were limited to its NEPA document.

Agencies do not comply with NEPA in a vacuum: it is only triggered by another underlying substantive agency action which the agency must analyze. *Kern v. Bureau of Land Management*, 2084 F.3d 1062, 1066 (9th Cir. 2002) (NEPA's procedures are "action-forcing"). NEPA's procedural safeguards ensure that the agency's consideration of environmental effects is *meaningful*, as Congress intended; that is, that the required NEPA analysis informs the ultimate substantive agency decision. *Robertson v. Methow Valley Citizens Council*, 490 U.S. 332, 350 (1989) (NEPA procedures "almost certain to affect the agency's substantive decision"). *See also Oregon Nat'l Desert Ass'n v. Bureau of Land Management*, 625 F.3d 1092, 1099 (9th Cir. 2010).

Accordingly, agencies do not undertake NEPA analyses in connection with decisions for

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adequately assess GE salmon risks in either its approval or its NEPA analysis. *See supra* at 13-14 & n.10.

which they have no underlying statutory authority to prevent environmental harm (such as by denying or conditioning a permit); such endeavors would be a charade of meaningless paperwork, vitiating NEPA's core "action-forcing" purpose. *Department of Transp. v. Public Citizen*, 541 U.S. 752, 7708 (2004); *Oregon Nat'l Resources Council Fund v. Brong*, 492 F.3d 1120, 1134 n.20 (9th Cir. 2007) (distinguishing *Public Citizen* in situations where the agency had statutory authority to address the environmental impacts).

The record demonstrates that FDA itself specifically acknowledged that its duty to consider environmental safety as part of the review and approval of GE animals comes from outside of NEPA. In its GE animal guidance, the agency explained that it will not conduct NEPA review in connection with its decision to require a new animal drug application or to exercise its enforcement authority, but made clear that it must still consider environmental safety concerns in making those decisions. FDA-G187-00600 (specifying environmental criteria the agency will consider). FDA's argument here (that NEPA is the *source* of its environmental safety considerations) confuses the duty to consider environmental safety with the vehicle FDA chose to do that work. They are not the same thing.

Further, the record demonstrates FDA did not in fact limit its environmental safety evaluation in its GE salmon approval to its NEPA evaluation. *See also supra* at 17-19 (citing numerous examples of FDA's consideration of environmental safety under the FFDCA, not just NEPA). Rather, as outlined in its guidance, FDA used the NEPA process as a means to facilitate its environmental safety review under the FFDCA. In its presentation at the VMAC meeting, FDA stated that, although the EA was part of FDA's environmental safety review, the agency would go beyond the EA to look at the product definition and conditions of use, FDA's inspection of the facilities, a validation study on triploidy, and information on phenotypic characterization in order to evaluate environmental safety. FDA-014756. *See also* FDA-013948 (describing all the information FDA evaluated in its review of environmental safety, including the EA, site visit reports, and other studies).[17] *See also* ECF No. 145-3 at FDA-2001CP-00092

[17] The fact of the agency's consideration is not to imply that it did so adequately, only that it recognized its duty to do so in the approval process.

(FDA clarified that an environmental assessment under NEPA is meant to "facilitate" FDA's safety review under the FFDCA, not to replace that review entirely as FDA now asserts).

Contrary to what FDA argues here, without substantive underlying authority sufficient to mitigate environmental harm from new animal drug approvals, neither its NEPA review or the agency regulations requiring such review would have any meaning. As detailed above, that substantive underlying authority comes from the FFDCA's requirement to determine whether a drug is "safe and effective" for its intended use. 21 U.S.C. § 321(v), 360b(a)(1); 21 C.F.R. § 514.1(b)(8); 21 C.F.R. § 514.105; *see supra* at 14-19.

Allowing FDA to both argue that NEPA does not grant the agency substantive environmental authority and that the agency's environmental safety considerations may be undertaken exclusively under NEPA has dangerous consequences. Compare ECF No. 145 at 10 with *id*. at 23. It gives the public the illusion that the agency is accounting for the environmental risks of GE animals, while at the same time disavowing any authority to regulate or mitigate those impacts. If FDA has authority to oversee GE animals, then it must also consider and mitigate their environmental effects in a meaningful way by ensuring environmental safety as part of its new animal drug approval process for GE animals.

III. FDA'S PROMULGATION OF THE GE ANIMAL GUIDANCE WAS CONTRARY TO LAW.

In adopting the GE animal guidance, FDA failed to evaluate the environmental impacts of the guidance under NEPA and failed to promulgate the guidance, a legislative rule, as binding and codified regulation adopted in compliance with APA formal rulemaking procedures.

A. FDA Violated NEPA When it Promulgated the GE Animal Guidance.

The GE animal guidance was a major federal action significantly affecting the environment, triggering FDA's duty to comply with NEPA. NEPA requires agencies to prepare an EIS for *any* major federal action significantly affecting the human environment. 42 U.S.C. § 4332(C). This requirement ensures NEPA's environmental protection policies are integrated into agency decision making, 40 C.F.R. § 1501.1(a), and provides a means for decision makers and the public to evaluate the environmental (and intertwined socioeconomic) impacts of government

proposals. 40 C.F.R. § 1502.1; *Kern*, 284 F.3d at 1066. Triggering NEPA compliance is a "low standard:" the threshold requiring an EIS is simply whether significant effects "may occur." *See, e.g. League of Wilderness Defs. v. Connaughton*, 752 F.3d 755, 760 (9th Cir. 2014). NEPA applies to a range of actions, including regulations, interpretative rules, policies, procedures, or program proposals. 40 C.F.R. § 1508.18(a) (defining "major federal action"); *id.* § 1508.18(b)(1) ("interpretations" subject to NEPA); *id.* § 1502.4(b) (programmatic EIS required for "broad Federal actions such as the adoption of new agency programs or regulations"). *See also Cal. Wilderness Coalition v. Dept. of Energy*, 631 F.3d 1072, 1097-1100 (9th Cir. 2011).

FDA did not prepare any NEPA analysis when it promulgated the new GE animal program. There is no real dispute that this program could have significant environmental effects: these are novel organisms that will be introduced into the environment and the food supply. Indeed, FDA acknowledges this by discussing (albeit in general terms) the environmental risks posed by GE Animals, FDA-G187-00601, and its duty to comply with NEPA for individual new animal drug applications. FDA-G187-00605.

By failing to comply with NEPA, FDA sidestepped NEPA's core purposes of informing the public and the decision maker about its new GE animal program's environmental impacts and viable alternatives. In crafting the GE animal guidance, FDA had other options that would have met its objectives. It could have considered alternatives that would assert non-exclusive authority to regulate GE animals, formally including the wildlife or other federal agencies with expertise in environmental risk assessment in the GE animal review process. It could have crafted detailed requirements for containment, monitoring, or other mitigation that would apply to ensure that any approved GE animals do not escape or otherwise impact the environment. It could have considered limiting the number and scope of approvals it would issue to limit environmental risk from this novel technology.[18] The "heart" of NEPA is the comparison and evaluation of such alternatives. 40 C.F.R. § 1502.14.

[18] Identification and analysis of such alternative types must be accomplished at the programmatic level, where FDA is best able to consider the aggregate impacts of the proposed policy or program. Courts reject attempts to "defer [programmatic-level] analysis to future site-specific consultations" because doing so risks masking or missing collective impacts. *See, e.g., Pac. Coast Fed'n of Fishermen's Ass'ns v. NMFS*, 482 F. Supp. 2d 1248, 1267 (W.D. Wash. 2007).

Given the foreseeable adverse environmental impacts that may flow from FDA's decision to apply the new animal drug provisions to GE animals as outlined and adopted in the guidance, FDA was required to either prepare an EIS or justify a decision that impacts were insignificant through an EA and FONSI. 40 C.F.R. § 1501.4. The agency did neither, in violation of NEPA.

B. The GE Animal Guidance is A Legislative Rule.

FDA's attempt to shoehorn GE animals into its drug authority created a new "regulatory pathway" for the GE salmon approval and others to follow that both: (1) changed existing law by amending FDA's existing regulations; and (2) conferred rights and responsibilities to GE animal developers by creating a mechanism to approve GE animals and imposed obligations on FDA to accept such applications and apply specific criteria to these applications. FDA's failure to promulgate and codify this new regulatory regime as a rulemaking violates the APA.

Legislative rules are agency decisions that "create rights, impose obligations or effect a change in existing law pursuant to authority delegated by Congress." *Hemp Industries Ass'n v. Drug Enforcement Admin.*, 333 F.3d 1082, 1087 (9th Cir. 2003); *see also, e.g., Erringer v. Thompson*, 371 F.3d 625, 630 (9th Cir. 2004). The Ninth Circuit employs a three-part test to make this determination:

> (1) when, in the absence of the rule, there would not be an adequate legislative basis for enforcement action;
> (2) when the agency has explicitly invoked its general legislative authority; or
> (3) when the rule effectively amends a prior legislative rule.

Wilson v. Lynch, 835 F.3d 1083, 1099 (9th Cir. 2016). FDA's guidance easily satisfies the first and third of these criteria, either one of which makes it a legislative rule.

FDA's new "regulatory pathway"[19] for GE animals did not exist in the statute or the agency's new animal drug regulations. The statute itself predated the technology by many decades and does not mention GE animals as drugs, let alone reflect any Congressional intent that GE animals be exclusively regulated by FDA under this authority. *See supra* at 6-12. Nor do FDA's codified animal drug regulations contain any provisions regarding GE animals. *See e.g.,*

[19] F1-00240932, FDA response to Congress, July 15, 2011 letter draft (explaining this "regulatory pathway established for GE animals" and referencing the 2009 guidance that "clarified our statutory authority"); F1-00240929 (same).

21 C.F.R. § 510.3. The guidance fundamentally changed this regulatory process by expanding the definition of a new animal drug to include a *whole new class of substances*: GE animals.[20] FDA established it was: (1) interpreting its animal drug classification to include GE animals and asserting authority to regulate them under this classification; and (2) explained to stakeholders exactly how that process would work, including the data required and the criteria FDA would apply. FDA "developed the following approach for submitting data for an application for GE animals," and detailed how "it fulfills the regulatory requirements described in the preceding section." FDA-G187-00614. The guidance laid out a seven-step process, including "product identification," "molecular characterization," and "food/feed safety and environmental safety assessments." FDA-G187-00614–18.

It is axiomatic "that an amendment to a legislative rule must itself be legislative." *Sierra Club v. Envtl. Protec. Agency*, 873 F.3d 946, 952 (D.C. Cir. 2017); *Erringer*, 371 F.3d at 632 (action that "effectively amends a prior legislative rule" is a legislative rule). In clearing the path for FDA to assert exclusive regulatory authority over GE animals, the guidance significantly expanded FDA's reach and effected a sweeping "change in existing law or policy." *Mendoza v. Perez*, 754 F.3d 1002, 1021 (D.C. Cir. 2014) ("A rule is legislative if it supplements a statute . . . or otherwise effects a substantive change in existing law or policy.").

The new and detailed provisions in the GE animal guidance did far more than provide helpful advice for complying with an existing regulatory process; it expanded FDA's responsibilities and created new legal rights for GE animal developers. This specifically included the process, data requirements, criteria, and factors FDA will apply to exercise its enforcement authority to require new animal drug applications, as well as what factors and processes would

[20] FDA did not see it necessary to amend its regulations in order to create a whole new program, but in sharp contrast has seen it fit to amend its regulations to denote the individual GE animal approvals. The regulations nowhere set forth generally how GE animals will be regulated as animal drugs—processes, data requirements, labeling, restrictions on use, and so forth. But they do include a Part that briefly *lists* the approved individual GE animals and the limitations on use for each. *See* 21 C.F.R. Part 528 (listing the 3 approved so far, the AquaBounty salmon, the GE goat and a GE chicken). This further shows that the guidance amended existing law. In other words, FDA believes it must treat GE animal approvals as final agency action codified in regulation, but not the regulatory framework which produces those approvals. FDA cannot so easily escape review of its guidance as final agency action.

and would not apply to those decisions. FDA-G187-00600–01.[21] *Am. Mining Cong.*, 995 F.2d at 1110 (holding rules are legislative where they are based on the "agency's power to exercise its judgment as to how best to implement a general statutory mandate")(citing *United Technologies Corp. v. EPA*, 821 F.2d 714, 719-20 (D.C. Cir. 1987)).

FDA's promulgation of these factors created a corresponding obligation for the agency to then follow these criteria when reviewing new animal drug applications for GE animals. The record demonstrates that FDA believed and acted as if it was bound to follow this new legal framework for regulating GE animals when approving GE salmon. *See, e.g.*, F1-00212559 ("FDA will announce a regulatory policy for genetically engineered animals. Under the new draft guidance, genetically engineered animals would be subject to regulatory oversight under the new animal drug review process. … The Draft Guidance communicates a clear path for industry to follow…."); F1-00219691("*Under the draft guidance*, in those cases where the GE animal is intended for food use, producers will have to demonstrate that food from the GE animal is safe to eat." (emphasis added)). *See also, e.g.*, FDA-005300 (2007 meeting with AquaBounty detailing that FDA "continues to work on the policy for the regulation of genetically engineered animals").

FDA's subsequent actions prove that the standards and processes detailed in the guidance were a necessary precursor to the use of its new animal drug authority for GE animal approvals. The guidance had an immediate effect that tangibly changed the relationship between FDA and the regulated entities. Prior to the guidance, FDA had never approved a GE animal. And yet, immediately after finalizing and issuing the guidance in 2009, FDA approved the first limited and experimental GE animals,[22] and began the approval process for the GE salmon.[23] This is not

[21] This applicability decision itself carries legal consequences because the agency committed not to apply an otherwise available and required tool. A decision that provides the "legislative basis for enforcement action on third parties …. necessarily creates new rights and imposes new obligations." *Erringer*, 371 F.3d at 630 ; *American Mining Congress v. Mine Safety & Health Administration*, 995 F.2d 1106 (D.C. Cir. 1993) (rule is legislative if in the absence of the rule there would not be an adequate legislative basis for enforcement action or other agency action to confer benefits or ensure the performance of duties).

[22] *See* GE Goat press release, available at https://bit.ly/2DFErzO (Feb. 6, 2009) (last visited Apr. 5, 2019) ("[FDA] today issued its first approval for a biological product produced by genetically engineered (GE) animals.").

coincidental but telling, and reflects the practical reality: that the guidance *established* this approval process; it was necessary before FDA could begin to approve these animals under its claimed new animal drug authority.[24] *Grand Canyon Trust v. Williams*, 38 F. Supp. 3d 1073, 1078 (D. Ariz. 2014) (finding that Forest Service's mineral rights determination was final agency action because it had practical consequence of allowing mining to proceed).

Nor is it coincidental that FDA waited until the very same day it issued the guidance in 2009 to finally respond to Plaintiffs' 2001 rulemaking petition regarding FDA's authority over GE animals. FDA-2001CP-00805 (denying petition to, *inter alia*, "establish[] a comprehensive regulatory framework" for GE fish because "[s]ince submission of your petition, FDA released a final guidance, Regulation of Genetically Engineered Animals [], describing how the new animal drug provisions of the FFDCA and its implementing regulations apply to transgenic animals"). FDA explained that it denied the rulemaking request because the agency "has published a final guidance detailing how FDA's existing [new animal drug] regulations apply to GE animals, including GE fish" and thus the agency "believes it is accomplishing what the petitioners request [i.e., a regulatory framework]." FDA-2001CP-00809. FDA's actions show that the guidance had legal consequences, and hence it was a legislative rule. *Ctr. For Envt'l Health v. Vilsack*, No. 15-cv-01690-JSC, 2016 WL 3383954, at *4 (N.D. Cal. June 20, 2016) (finding guidance legislative where, among other things, conduct prohibited before its adoption became permissible because it created an exception to the existing regulations).[25]

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[23] FDA-014622 (Presentation by FDA, explaining the length of time between the AquaBounty application and the 2010 hearings and saying, "CVM [FDA] worked for several years to achieve consensus with the rest of the federal government that this technology should be regulated as [new animal drugs.] Now that we have secured that decision, the review process has proceeded expeditiously.").

[24] F1-00219664 (GE Animals Fact Sheet, stating need for "regulatory approval" for GE animals "before they can be marketed"); *id*. ("The FDA is, therefore, issuing and inviting public comment for 60 days on [the draft guidance].").

[25] While there are APA rulemaking exceptions for general statements of policy, these exceptions "will be narrowly construed and only reluctantly countenanced." *Ctr. for Envtl. Health*, 2016 WL 3383954, at *4 (quoting *Alcaraz v. Block*, 746 F.2d 593, 612 (9th Cir. 1984)). The guidance is not a general statement of policy. *Mada-Luna v. Fitzpatrick*, 813 F.2d 1006, 1014 (9th Cir. 1987) (stating policy statement may not establish a "binding norm"). The "critical factor" is whether "the challenged [directive] leaves the agency . . . free to exercise discretion to follow, or not to follow, the [announced] policy in an individual case." *Id.* at 1013 (emphasis added)

IV. FDA's JURISDICTIONAL ARGUMENTS FAIL.

The Court should reject FDA's attempt to dismiss Claims 1 and 12 (to the extent they challenge the guidance), and Claims 8 and 13 for lack of jurisdiction. ECF No. 145 at 14-18. The guidance is a final agency action, reviewable for substantive and procedural violations. Moreover, the GE animal guidance itself—and as applied through the GE salmon approval—injures Plaintiffs' concrete environmental, economic, and consumer interests and these injuries would be redressed by an order requiring FDA to comply with the FFDCA, NEPA, and the APA.

A. The Guidance is a Final Agency Action.

Two conditions indicate an agency's action is "final" for purposes of judicial review: (1) "the action must mark the 'consummation' of the agency's decisionmaking process . . . it must not be of a merely tentative or interlocutory nature;" and (2) "the action must be one by which 'rights or obligations have been determined,' or from which 'legal consequences will flow[.]'" *Bennett v. Spear*, 520 U.S. 154, 178 (1997) (internal citations omitted). Courts evaluate both the "the practical and legal effect" of an action because the finality requirement is interpreted in a "pragmatic and flexible manner." *Or. Nat. Desert Ass'n v. Forest Serv.*, 465 F.3d 977, 982 (9th Cir. 2006). FDA's GE animal guidance satisfies both prongs of the *Bennett* finality test.

FDA does not seriously contest the first *Bennett* factor. ECF No. 145 at 16. The guidance was the consummation of a years-long debate and decision-making process about whether and how to expand its new drug authority to regulate GE animals. *Navajo Nation v. U.S. Dep't of Interior*, 819 F.3d 1084, 1091 (9th Cir. 2016) ("An agency's determination of its jurisdiction is the consummation of agency decisionmaking regarding that issue.").[26]

(quoting *Jean v. Nelson*, 711 F.2d 1455, 1481 (11th Cir. 1983)). There is no such flexibility here: FDA no longer has the option to treat GE animals as anything other than new animal drugs. Instead, the guidance established a new binding norm and the substance and procedures that FDA will apply to regulate GE animals. FDA explained what data the agency will need, and what findings it will need to make to approve any such drugs as well as the sponsors' responsibilities. Neither FDA nor any GE animal applicants are free to ignore the animal drug mandates. The Court should not credit FDA's statements that the guidance is "not binding" or that it "does not establish any rights." FDA-G187-00596. "[A]n agency's characterization of its action as being provisional or advisory is not dispositive, and courts consider whether the practical effects of an agency's decision make it a final agency action, regardless of how it is labeled." *Columbia Riverkeeper v. Coast Guard*, 761 F.3d 1084, 1094-95 (9th Cir. 2014). *See also Hemp Industries*, 333 F.3d at 1087.

[26] The Court need not credit FDA's protests that the guidance represents only its "current

The inquiry under the second *Bennett* prong is "essentially the same" as whether the agency action is a legislative/substantive rule, and these two questions are frequently answered in the same context. *Nat. Res. Def. Council v. EPA*, 643 F.3d 311, 321 (D.C. Cir. 2011). Thus, for all of the reasons that the GE animal guidance is a legislative rule discussed *supra* at 23-26, it is a final agency action reviewable by this court. *Ctr. for Auto Safety v. Nat'l Highway Traffic Safety Admin.*, 452 F.3d 798, 807 (D.C. Cir. 2006) (finding that if the challenged guidance "constitute[s] a de facto rule" it is also a final agency action).[27]

B. Plaintiffs Have Standing to Challenge the GE Animal Guidance.[28]

FDA's standing argument fails primarily because it manufactures an artificial distinction between the GE animal guidance and the GE salmon approval. Claims 1 and 12 challenge the guidance both facially and as applied to the GE salmon approval. FDA does not, and cannot, demonstrate that Plaintiffs have not plead injury regarding these claims—it is the guidance that made the GE salmon approval possible and FDA applied the inadequate procedures in the guidance in approving GE salmon, harming Plaintiffs in a concrete way. *See* ECF No. 53 at ¶ 30.[29] As pled in the complaint, the "practical result" of the violations in the guidance is that the agency failed to adequately assess the risks of approving GE salmon and violated NEPA, the FFDCA, the APA, and the ESA. *Id.* ¶ 12. For these claims, there has been not only procedural injury, but also *actual* injury to Plaintiffs from FDA's application of the guidance in the GE

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thinking" and "recommendations." ECF No. 145 at 15. *Appalachian Power Company v. EPA*, 208 F.3d 1015,1023 (D.C. Cir. 2000) (refusing to assign significance to "boilerplate" language that guidance did "not represent final Agency action, and cannot be relied upon to create any rights enforceable by any party"); *Cal. ex rel. Harris v. Fed. Hous. Fin. Agency*, No. C 10-03084 CW, 2011 WL 3794942, at *11 (N.D. Cal. Aug. 26, 2011) ("[A] court need not accept an agency's characterization of its rule at face value.").

[27] *See also Ass'n of Flight Attendants-CWA, AFL-CIO v. Huerta*, 785 F.3d 710, 716 (D.C. Cir. 2015) ("In litigation over guidance documents, the finality inquiry is often framed as the question of whether the challenged agency action is best understood as a non-binding action, like a policy statement or interpretive rule, or a binding legislative rule."); *Sierra Club v. EPA*, 699 F.3d 530, 535 (D.C. Cir. 2012) ("As will often be the case where an agency action is clearly final, the question whether [it] 'is a legislative rule that required notice and comment is easy.'" (quoting *Nat. Res. Def. Council*, 643 F.3d at 320)).

[28] *See* Burd Decl., Friedman Decl., Hanson Decl., James Decl., Lovera Decl., McManus Decl., Perls Decl., Sakashita Decl.,White Decl.

[29] Burd Decl. ¶¶ 7-12; Friedman Decl. ¶¶ 5-6; Hanson Decl. ¶¶ 11-13, 19-24; James Decl. ¶¶ 12-15; Lovera Decl. ¶¶ 8-9, 14-19; McManus Decl. ¶¶ 8-9, 11; Perls Decl. ¶¶ 7-14; Sakashita Decl. ¶¶ 9-12; White Decl. ¶¶ 18-20.

salmon approval.[30] For standing purposes, this is no different than an "as applied" challenge to a regulation or program and a specific approval done pursuant to it. Indeed, Plaintiffs would have standing to challenge the guidance *without* the GE salmon approval. *Ctizens for Better Forestry v. USDA*, 341 F.3d 961 (9th Cir. 2003) (challenge to programmatic forest plan cognizable even without as applied individual timber sale); *id.* at 975 ("[W]e reaffirm . . . that environmental plaintiffs have standing to challenge not only site-specific plans, but also higher-level, programmatic rules that impose or remove requirements on site-specific plans."); *see also Idaho Conservation League v. Mumma*, 956 F.2d 1508, 1516 (9th Cir.1992) (cautioning that "if the agency action only could be challenged at the site-specific development stage, the underlying programmatic authorization would forever escape review"). Here, where there is a discrete individual application of the entire program being challenged, standing is even stronger.[31]

Standing to challenge FDA's procedural violations of NEPA and the APA in Claims 8 and 13 are evaluated under a significantly "relaxed" standard. For these procedural claims, "[o]nce plaintiffs … establish a concrete injury, 'the causation and redressability requirements are relaxed.'" *WildEarth Guardians v. Dep't of Agric*., 795 F.3d 1148, 1154 (9th Cir. 2015) (quoting *W. Watersheds Project v. Kraayenbrink*, 632 F.3d 472, 485 (9th Cir. 2011)). Plaintiffs need only show that that completion of the withheld action "may" remedy their injuries. *Salmon Spawning & Recovery Alliance v. Gutierrez*, 545 F.3d 1220, 1226-27 (9th Cir. 2008).

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[30] Burd Decl. ¶¶ 7-12; Friedman Decl. ¶¶ 4-10; Hanson Decl. ¶¶ 11-28; James Decl. ¶¶ 9-15; Lovera Decl. ¶¶ 8-19; McManus Decl. ¶¶ 5-11; Perls Decl. ¶¶ 4-14; Sakashita Decl. ¶¶ 9-12; White Decl. ¶¶ 4-20.

[31] FDA's argument that setting aside the guidance would not redress Plaintiffs' injuries for these Claims misrepresents the relationship of the guidance to the GE salmon approval. ECF No. 145 at 17-18. Contrary to its assertion in the motion, FDA has elsewhere recognized that the resolution of these claims could "eliminate" the need to consider any other claims in this case: if FDA lacks authority to regulate GE animals as a drug, for example, there may be no need to evaluate its GE salmon approval. ECF No. 160 at 2-3. Moreover, Plaintiffs have standing to independently pursue their claims against the guidance even without also challenging the GE Salmon approval. Plaintiffs have standing "to challenge programmatic management direction [even] without also challenging an implementing project that will cause discrete injury." *Cottonwood Envtl. L. Ctr. v. U.S. Forest Serv.*, 789 F.3d 1075, 1081 (9th Cir. 2015) (holding that plaintiff "was not required to challenge directly any specific project because, as in *Sierra Forest Legacy*, the "procedural injury [was] complete" when the programmatic decision was made) (citing *Sierra Forest Legacy v. Sherman*, 646 F.3d 1161, 1179 (9th Cir. 2011)).

FDA's argument that Plaintiffs have not been injured because the guidance does not have any effect, ECF No. 145 at 18, merely repeats the incorrect characterization that underpins its final agency action arguments and "improperly conflate[s]… standing with whether [the plaintiff] would prevail on the merits." *Kirola v. City & County of San Francisco*, 860 F.3d 1164, 1175 (9th Cir. 2017). The guidance established a new regulatory program and did so in a manner that violated NEPA and the APA. Plaintiffs, whose interests include protecting the environment, fisheries, and food supply, and ensuring the proper regulation of GE organisms, *see e.g.*, ECF No. 53 ¶¶ 17-28, are each injured by the inadequate regulation of GE animals, including the failure to adequately assess their environmental risks under NEPA.[32]

Where, as here, an agency's failure to comply with these requirements injures their interests, plaintiffs "must show only that they have a procedural right that, if exercised, could protect their concrete interests and that those interests fall within the zone of interests protected by the statute at issue." *Defs. of Wildlife v. EPA*, 420 F.3d 946, 957 (9th Cir. 2005), *rev'd and remanded on other grounds, Natl. Ass'n of Home Builders v. Defs. of Wildlife*, 551 U.S. 644 (2007). The required showing that vacating the guidance and ordering NEPA and APA compliance "may" redress the injuries, *Salmon Spawning*, 545 F.3d at 1226-27, is easily met. FDA's failure to comply with the procedural requirements of NEPA and the APA are redressible by a court order setting aside the guidance. Requiring compliance with these laws could result in both additional protection for the environment and better regulation of GE Animals.

CONCLUSION

FDA has failed to show it is entitled to judgment as a matter of law on Plaintiffs' Claims 1, 8, 12, and 13. To the contrary, based on review of the administrative record and the applicable legal standards, the Court should deny FDA's motion and instead grant Plaintiffs' motion for summary judgment on all four claims.

[32] Burd Decl. ¶¶ 7-11; Friedman Decl. ¶¶ 5-6, 8; Hanson Decl. ¶¶ 11-13, 19-25; James Decl. ¶¶ 10-15; Lovera Decl. ¶¶ 8-9, 14-19; McManus Decl. ¶¶ 8-9, 11; Perls Decl. ¶¶ 7-14; Sakashita Decl. ¶¶ 9-12; White Decl. ¶¶ 18-20.

Respectfully submitted this 24th day of April, 2019 in San Francisco, California.

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