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THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA

INSTITUTE FOR FISHERIES RESOURCES; PACIFIC COAST FEDERATION OF FISHERMEN'S ASSOCIATIONS; GOLDEN GATE SALMON ASSOCIATION; KENNEBEC REBORN; FRIENDS OF MERRYMEETING BAY; CASCADIA WILDLANDS; CENTER FOR BIOLOGICAL DIVERSITY; ECOLOGY ACTION CENTRE; FRIENDS OF THE EARTH; FOOD AND WATER WATCH; THE QUINAULT INDIAN NATION; and CENTER FOR FOOD SAFETY, *Plaintiffs,* v. SYLVIA MATHEWS BURWELL, Secretary of the United States Department of Health and Human Services; DR. ROBERT M. CALIFF, M.D., Commissioner of the United States Food And Drug Administration; the UNITED STATES FOOD AND DRUG ADMINISTRATION; and the UNITED STATES FISH AND WILDLIFE SERVICE, *Defendants.*	Case No. 3:16-cv-01574-VC **AMENDED COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF**

INTRODUCTION

1. This case challenges the United States Food and Drug Administration's approval of a novel genetically engineered salmon for human consumption without considering or fully disclosing the environmental and other risks of this unprecedented decision.

2. Plaintiffs Institute for Fisheries Resources, Pacific Coast Federation of Fishermen's Associations, Golden Gate Salmon Association, Kennebec Reborn, Friends of Merrymeeting Bay, Cascadia Wildlands, Center for Biological Diversity, Ecology Action Centre, Friends of the Earth, Food and Water Watch, the Quinault Indian Nation, and Center for Food Safety (collectively Plaintiffs), on behalf of their adversely affected members, challenge Defendants' November 19, 2015, decision to approve an application by AquaBounty Technologies, Inc. (AquaBounty) to develop, market, and sell for human consumption genetically engineered (GE) salmon.

3. AquaBounty's GE salmon (AquAdvantage salmon) is a novel, man-made animal: an Atlantic salmon genetically engineered with genes from a deep water ocean eelpout and a Pacific Chinook salmon in order to make it grow unnaturally fast.

4. The approval of GE salmon by the United States Food and Drug Administration; Sylvia Mathews Burwell, Secretary of the United States Department of Health and Human Services; and Dr. Robert M. Califf, Commissioner of the United States Food and Drug Administration (collectively FDA or the agency) marks the first occasion in history where any country has authorized the mass production of a GE animal of any variety to be sold as food. Accordingly, this action will serve as a precedent for the assessment and regulation of all potential future GE animals manufactured for human consumption, and for review of their impacts on public health and the environment.

5. Pursuant to the FDA approval, AquaBounty will manufacture its GE salmon at a facility located on Prince Edward Island, Canada, and then transport, by land and air, the resulting eggs to a separate facility located in Panama, where the GE eggs will be grown to maturity, before being processed and shipped back to the United States for sale. Those two operational sites present substantial environmental risks, as discussed below.

6. Importantly, this case concerns more than these two sites; it has much broader implications. In order to gain FDA approval and downplay risks and concerns from the public, AquaBounty sought to limit its application to just these two facilities; yet, since at least 2010, the company has been engaged in efforts to expand the production of GE salmon to facilities around the world, repeatedly telling its investors that it plans to raise GE salmon at other locations, in both other foreign markets and the United States, beginning in 2016, and to sell the salmon in other markets, including Canada, Argentina, Brazil, and China. In fact, AquaBounty has already communicated its intent to import GE salmon eggs into the U.S. to be grown at other sites, and has recently expanded its operations on Prince Edward Island. These expansions are a necessary outgrowth of the AquaBounty business plan, since large-scale aquaculture is not economically viable if it relies solely upon the highly convoluted, 5,000-mile multinational journey that AquaBounty has initially proposed. This constitutes merely the company's effort to open the regulatory door. Yet, despite the company's public statements, FDA approved the AquaBounty application without disclosing or analyzing the significant environmental effects from this foreseeable expansion.

7. The challenged decision is unlawful because FDA has not adequately assessed the full range of potentially significant environmental and ecological effects presented by the AquaBounty application, and/or significant changed circumstances since that application was submitted, in violation of the Federal Food, Drug, and Cosmetics Act, 21 U.S.C. §§ 301-399(f) (FFDCA); the National Environmental Policy Act, 42 U.S.C. §§ 4221-4370h (NEPA); the Endangered Species Act, 16 U.S.C. §§ 1531-1544 (ESA); and the Administrative Procedure Act, 5 U.S.C. §§ 701-706 (APA). FDA has created a GE animal program that is a major federal action, without preparing or engaging in a programmatic or other analysis of the impacts of that program as required by NEPA. FDA also arbitrarily and capriciously denied the 2011 citizen petition filed by several of the Plaintiffs by not preparing a full Environmental Impact Statement (EIS) pursuant to NEPA on the foreseeable impacts of its decision.

8. Instead, FDA completed an extremely limited environmental assessment (EA) and made a finding of no significant impact (FONSI) for the approval of AquaBounty's GE salmon,

which together fail to discuss or adequately evaluate myriad scientific questions regarding the risk of significant and irreversible environmental, ecological, and intertwined socioeconomic harms related to the production, commercialization, and proliferation of AquaBounty's GE fish. These threats include: the risk that GE salmon will escape from the facilities where they are manufactured or grown and interbreed with wild endangered salmon, compete with them for food and space, or pass on infectious diseases; the interrelated impacts to salmon fisheries and the social and economic well-being of those who depend on them; and the risks to ecosystems from the introduction of an invasive species. Expert scientists, including those within other federal agencies charged with the protection of fish and marine ecosystems, repeatedly cited these risks and expressed great concern with FDA's narrow, incomplete, unsubstantiated, and outdated analysis of the potential environmental and ecological threats posed by GE salmon. But, FDA ignored those concerns in its decisionmaking.

9. The inadequate EA, FONSI, and attendant decision not to prepare a comprehensive EIS are the result of FDA's failure to take the legally required "hard look" at these direct, indirect, and cumulative impacts of the agency's decision to allow mass production of AquaBounty's GE salmon, and are arbitrary, capricious, and contrary to NEPA. In addition, the agency's review was improperly segmented from AquaBounty's broader plan; it failed to adequately consider or assess numerous other reasonable alternatives to the proposed action; FDA has not supplemented that analysis based on AquaBounty's expanded Canadian facilities and operations; and it improperly relied on AquaBounty's proposed mitigation.

10. The challenged decision is also unlawful, in violation of the ESA, because FDA failed to consult with the federal fish and wildlife agencies to insure that its approval of AquaBounty's application was not likely to jeopardize endangered and threatened species or adversely modify critical habitat. The expert biologists at the wildlife and fisheries agencies, the National Marine Fisheries Service and U.S. Fish & Wildlife Services (collectively Services), urged FDA to engage in ESA consultation in association with its review of AquaBounty's application. These agencies' scientists described the very real potential that approval of the application may affect endangered Atlantic salmon populations. FDA's determination that its

action would have "no effect" on any endangered or threatened species or critical habitat—and consequently, its refusal to complete ESA consultation with the expert agencies—was based on the faulty assumption that GE salmon could not escape from AquaBounty's facilities, FDA's outdated risk analysis methods, and the agency's unlawfully constricted view of the foreseeable impacts of its approval decision.

11. Even apart from these vital considerations, FDA's decision to approve AquaBounty's GE salmon application should be vacated and set aside because FDA lacks the statutory authority to regulate GE animals as a "new animal drug" under the FFDCA. The FFDCA does not explicitly grant FDA authority to regulate GE animals. Indeed, Congress never intended or provided a means for FDA to regulate twenty-first century GE animals using its 1938 authority over veterinary animal drugs. To the contrary, GE animals present enormously different risks and impacts than drugs, requiring different expertise, analyses, and regulation than were contemplated when Congress enacted the FFDCA. Nevertheless, FDA issued Guidance for Industry 187, *The Regulation of Genetically Engineered Animals Containing Heritable Recombinant DNA Constructs* (GE Animal Guidance or the Guidance), interpreting the definition of "new animal drug" under the FFDCA to include GE animals, asserting exclusive authority over GE animals under the new animal drug provisions of the FFDCA, and purportedly outlining the steps that FDA will follow when considering applications for GE animals. FDA's approval of AquaBounty's application and the issuance of its GE Animal Guidance represent an unlawful effort to extend FDA's regulatory reach far beyond the statutory mandates of the FFDCA. FDA's assertion of jurisdiction under the GE Animal Guidance and its approval of the AquaBounty application are thus *ultra vires* and contrary to law in violation of the APA and the FFDCA.

12. Finally, even if FDA had the authority to issue the GE Animal Guidance, the guidance itself fails to explain how FDA will substantively incorporate important environmental considerations into its assessment of safety and effectiveness as a part of the review and approval of GE animals. As a practical result of the inadequacies of the GE Animal Guidance, FDA failed

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