ADAM KEATS (CSB No. 191157)
GEORGE KIMBRELL (*Pro Hac Vice pending*)
Center for Food Safety
303 Sacramento Street, 2nd Floor, San Francisco, CA 94111
T: (415) 826-2770 / F: (415) 826-0507
Emails: akeats@centerforfoodsafety.org
gkimbrell@centerforfoodsafety.org

STEPHEN D. MASHUDA (*Pro Hac Vice pending*)
Earthjustice
705 Second Avenue, Suite 203, Seattle, WA 98104
T: (206) 343-7340 / F: (206) 343-1526
Email: smashuda@earthjustice.org

BRETTNY HARDY (*Pro Hac Vice pending*)
Earthjustice
50 California Street, Suite 500, San Francisco, CA 94111
T: (415) 217-2142
Email: bhardy@earthjustice.org

Counsel for Plaintiffs

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; 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. **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, 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 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. 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, 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); the Federal Food and Drug Amendments Act of 2007, Pub. L. No. 110–85, 121 Stat. 823 (2007), 21 U.S.C. § 2106 (FDA Amendments Act); 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; 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, 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 to adequately consider environmental risks as part of its statutory "safety" evaluation when reviewing and approving AquaBounty's GE salmon application in this case.

13. Accordingly, Plaintiffs ask this Court to: (1) declare that FDA's decision to approve the AquaBounty application for GE salmon is arbitrary, capricious, and in violation of the APA, NEPA, ESA, and the FDA Amendments Act; (2) declare that the FDA GE Animal Guidance is unlawful under the APA and the FFDCA, that FDA has no jurisdiction to regulate GE animals under the new animal drug provisions of the FFDCA, and that FDA's approval of AquaBounty's application is *ultra vires* and contrary to law under the APA and the FFDCA; (3) vacate FDA's November 19, 2015 approval decision; and (4) enjoin FDA to withdraw its assertion of jurisdiction over GE animals and enjoin FDA from taking further action on AquaBounty's GE salmon application or any other application for commercialization of a genetically engineered food animal until Congress provides explicit statutory authority governing regulation of such products and vests clear authority for such regulation in a named agency of the Executive Branch of the United States.

JURISDICTION AND VENUE

14. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1331 (federal question), 28 U.S.C. § 1346 (United States as a defendant), 28 U.S.C. §§ 2201-02 (declaratory and injunctive relief) and 5 U.S.C. §§ 701-706 (APA). An actual controversy exists between the parties within the meaning of 28 U.S.C. § 2201.

15. The Court has jurisdiction to review FDA's failure to consult with the Services under the citizen-suit provision of the ESA, 16 U.S.C. § 1540 (g)(1), which provides that the "district courts shall have jurisdiction…to enforce any such provision or regulation" of the ESA. As required by the ESA, Plaintiffs provided sixty days' notice of their intent to sue by letter sent to FDA and the Services on December 22, 2015 and January 25, 2016. Copies of those letters are appended as Exhibit 1. FDA has not remedied the violations set out in those sixty-day notices. *See* 16 U.S.C. § 1540(g)(2)(A).

16. Venue is properly vested in this judicial district under 28 U.S.C. § 1391 (e)(1)(C) because no real property is involved in this action, several of the Plaintiffs reside in and/or maintain places of business in this district, and members of the Plaintiff organizations reside in this district.

PARTIES

Plaintiffs

17. Plaintiff **Institute for Fisheries Resources** (IFR) is a nonprofit public interest marine resources protection and conservation organization. IFR's members, most of whom are commercial salmon fishermen or women, have personal interests in the restoration of salmon fisheries.

18. Plaintiff **Pacific Coast Federation of Fishermen's Associations** (PCFFA) is a nonprofit membership organization composed of trade associations of commercial fisherman on the West Coast, from San Diego to Alaska. PCFFA is separate from, but closely related to, IFR. PCFFA is incorporated in and headquartered in California. For over 30 years, PCFFA has advocated to ensure the rights of individual fishermen and to fight for the long-term survival of commercial fishing as a livelihood and way of life. PCFFA's port and member associations and at-large members represent nearly 1,200 commercial fishing families who are small and mid-sized commercial fishing boat owners and operators, most of whom derive all or a portion of their income from the harvesting of Pacific salmon.

19. Plaintiff **Golden Gate Salmon Association** (GGSA) is a coalition of salmon advocates, including commercial and recreational fishermen, businesses, restaurants, tribes, environmentalists, and communities that rely on salmon, from Oregon to the Central Coast, through the Bay-Delta and into the Central Valley. GGSA seeks to protect and restore California's largest salmon producing habitat in the Central Valley for the benefit of the Bay-Delta ecosystem and the diverse communities that rely on salmon as a long-term, sustainable commercial, recreational and cultural resource.

20. Plaintiff **Center for Food Safety** (CFS) is a public interest, nonprofit organization whose mission is to empower people, support farmers, and protect the earth from the adverse impacts of industrial food production. CFS has more than 750,000 members across the country and offices in San Francisco, California, Portland, Oregon, Washington, D.C., and Honolulu, Hawaii. CFS is a recognized national leader on the issue of genetically engineered

crops and other GE organisms, and has worked to improve their regulation and address their impacts continuously since the organization's inception in 1997.

21. Plaintiff **Friends of the Earth, U.S.** (FoE) is a national, nonprofit environmental advocacy organization founded in 1969 and incorporated in the District of Columbia, with its headquarters in Washington, D.C. and an office in Berkeley, California. FoE's mission is to defend the environment and champion a healthy and just world. To this end, FoE promotes policies and actions that address the climate change crisis, minimize the negative impacts of environmental pollution, keep toxic and risky technologies out of the food we eat and products we use, and protect marine ecosystems and the people who live and work near them. FoE has more than 175,000 members in all 50 states.

22. Plaintiff **Center for Biological Diversity** (CBD) is a nonprofit incorporated in California and headquartered in Tucson, Arizona, with field offices throughout the United States, including Arizona, New Mexico, California, Nevada, Oregon, Washington, Alaska, Minnesota, Vermont, Florida, and Washington, D.C. The Center uses science, law, and media to secure a future for all species, great or small, hovering on the brink of extinction.

23. Plaintiff **Food and Water Watch** (FWW) is a national, non-profit consumer advocacy organization with its headquarters in Washington, D.C. and several offices throughout the United States, including in Oakland, California. FWW works to ensure safe food and clean water, advocating for safe, wholesome food produced in a humane and sustainable manner, and public, rather than private control of water resources, including oceans, rivers, and groundwater. For more than five years, FWW has advocated for stronger regulation and labeling of genetically engineered organisms, including salmon. FWW has approximately 76,000 members and 900,000 supporters in the United States.

24. Plaintiff **Ecology Action Centre** (EAC), established in 1971, is Nova Scotia's largest and oldest environmental organization, serving Nova Scotia in a variety of capacities for over forty years. EAC has over 3,000 members who reside predominantly in Nova Scotia, with some members residing in the other Atlantic provinces, the rest of Canada and internationally. Drawing on current science and public policy, staff and members of the organization work to

protect and conserve terrestrial and aquatic ecosystems in Nova Scotia and Atlantic Canada. EAC has played a pivotal role in protecting important ecological areas in Nova Scotia including some of the remaining Atlantic salmon rivers and their surrounding habitat. EAC has a strong track record when it comes to marine conservation, with staff participating in a range of provincial, national and international processes and fora to advance sustainable fishing practices and the protection of endangered or threatened species such as Atlantic salmon. In early 2014 EAC, along with Living Oceans Society, challenged the Canadian government's decision to allow AquaBounty Canada Inc. to manufacture and export genetically modified salmon eggs. EAC considers genetically modified salmon and genetic contamination a serious threat to Atlantic salmon in Nova Scotia and throughout its range.

25. Plaintiff **Cascadia Wildlands** ("Cascadia") is a nonprofit organization incorporated in Oregon, with a field office in Cordova, Alaska, that focuses on conservation of the wildlife and communities of the Cascadia bioregion (*i.e.*, the Pacific coastal temperate rainforest, stretching from northern California to southeast Alaska). Cascadia has approximately 5,000 members throughout the United States, including subsistence, commercial, and recreational fishermen, and, processors, marketers, and consumers of salmon. Cascadia educates, agitates, and inspires a movement to protect and restore Cascadia's wild ecosystems, including healthy wild salmon populations. Salmon are widely acknowledged as a keystone species in the bioregion, and so Cascadia members, like most residents, have a special relationship with salmon.

26. Plaintiff **Kennebec Reborn** is a 501(c)(3) Maine nonprofit conservation organization founded in 2011 to advocate and promote the restoration of Atlantic salmon and other native sea-run fish to their historic habitat in the rivers of New England. Kennebec Reborn and its board members work closely with allied national, regional and local conservation groups at various levels of formality to bring native sea-run fish back to their homes by advocating for fish passage and improved habitat conditions within the Kennebec and Maine's other coastal watersheds. Kennebec Reborn members have been involved as plaintiffs and citizen intervenors since 1996 in successful litigation to protect native Atlantic salmon in Maine under the

Endangered Species Act, including litigation to expand Endangered Species Act protections to Atlantic salmon in the Kennebec, Androscoggin, and Penobscot Rivers. Kennebec Reborn also is the caretaker of the Atlantic Salmon History Project, an on-line archive of historic documents and records that describe the former abundance of sea-run fish in New England rivers and their progressive diminution since the late 1700s.

27. Plaintiff **Friends of Merrymeeting Bay** is a nonprofit organization, incorporated in Maine, dedicated to preserving the ecological, aesthetic, biological, and commercial values of Merrymeeting Bay, its watershed, and the Gulf of Maine (the part of the Northwest Atlantic Ocean where Merrymeeting Bay is located). Friends of Merrymeeting Bay and its members work to protect these waters and their fish and wildlife through research, advocacy, education, and land conservation. Friends of Merrymeeting Bay and its members are dedicated to the protection of the last remaining Atlantic salmon populations in Maine and were instrumental in the fight to secure the Endangered Species Act listing for Atlantic salmon in the Kennebec, Androscoggin, and Penobscot Rivers.

28. Members of the plaintiff organizations use and enjoy salmon and salmon habitats on both the east and west coasts of the United States and Canada for recreational, scientific, aesthetic, cultural, subsistence, and commercial purposes. Plaintiffs' members observe and interact with Atlantic and Pacific salmon and their marine and freshwater habitats through wildlife observation, study and photography, and recreational, commercial, and subsistence fishing. These activities require viable populations of wild Atlantic and Pacific salmon that contribute to healthy, functioning ecosystems. The identity and genetic integrity of wild salmon runs, populations, and fisheries is itself an asset that is used and valued by Plaintiffs' members. Plaintiffs and their members derive or, but for the threatened and endangered status of many Atlantic and Pacific salmon species, would derive recreational, scientific, aesthetic, and commercial benefits from the existence of these species in the wild.

29. FDA's approval of the AquaBounty GE salmon harms these Plaintiff organizations and their members' past, present, and future enjoyment of salmonids and salmonid habitat by allowing production of GE salmon to proceed without adequate regulation and

analyses of associated, and potentially irreversible, environmental and ecological impacts. These aesthetic, conservation, recreational, commercial, subsistence, scientific, and procedural interests of Plaintiffs and their respective members have been, are being, and, unless the relief prayed for herein is granted, will continue to be adversely affected and irreparably injured by FDA's failure to comply with NEPA, the APA, the ESA, the FDA Amendments Act, and the FFDCA, as described below. Plaintiffs have no adequate remedy at law.

Defendants

30. Defendant Sylvia Mathews Burwell is the Secretary of the United States Department of Health and Human Services, which includes the United States Food and Drug Administration. The Secretary of the U.S. Department of Health and Human Services, "through the Commissioner" of FDA, regulates new animal drugs. 21 U.S.C. § 393(d)(2). Secretary Burwell is named a defendant solely in her official capacity.

31. Defendant Dr. Robert M. Califf, M.D. is the Commissioner of the U.S. Food and Drug Administration. In that capacity, he is directly responsible for overseeing the FDA review process for the AquaBounty application and is tasked with the authority to approve or deny AquaBounty's application upon a finding that applicable legal requirements have or have not been met. Commissioner Califf is named as a defendant solely in his official capacity. Commissioner Califf is responsible for the approval of AquaBounty's application on November 19, 2015, through Bernadette M. Dunham, D.V.M., Ph.D., Director, Center for Veterinary Medicine, who formally signed the agency's approval letter.

32. Defendant U.S. Food and Drug Administration is a federal agency within the U.S. Department of Health and Human Services. FDA is charged with the regulation of medical products, tobacco, foods, and veterinary medicine. As described by the agency itself, FDA is responsible for protecting public health by assuring that foods (except for meat from livestock, poultry and some egg products which are regulated by the U.S. Department of Agriculture) are safe, wholesome, sanitary, and properly labeled; ensuring that human and veterinary drugs, vaccines and other biological products, and medical devices intended for human use are safe and effective; protecting the public from electronic product radiation; assuring cosmetics and dietary

supplements are safe and properly labeled; regulating tobacco products; and advancing the public health by helping to speed product innovations. FDA's November 19, 2015, approval of the AquaBounty new animal drug application is the only existing federal agency approval of AquaBounty's GE salmon.

33. Defendant United States Fish and Wildlife Service (FWS) is a federal agency within the Department of the Interior authorized and required by law to protect and manage fish, wildlife, and native plant resources of the United States, including enforcing the ESA. FWS has been delegated authority by the Secretary of the Interior to implement the ESA for many endangered fish species, including shared responsibility for making decisions and promulgating regulations for endangered Atlantic salmon.

STATUTORY AND REGULATORY BACKGROUND

I. Federal Food Drug and Cosmetic Act

34. In enacting the FFDCA in 1938, Congress provided FDA the authority and obligation to protect public health and safety by overseeing certain food products, drugs, and cosmetics. Through the FFDCA, Congress charged FDA to "promote the public health" by ensuring that "human and veterinary drugs are safe and effective." 21 U.S.C. § 393.

35. The FFDCA does not explicitly authorize FDA to assert exclusive jurisdiction over the production and commercialization of GE animals or their food products. *See, e.g.*, 21 U.S.C. § 321 (providing definitions for the FFDCA, and not defining "animals" or making any reference to "genetic engineering"); *id.* §§ 341-350*l* (establishing food safety and testing laws, with no mention of genetic engineering); *id.* §§ 351-360ddd-2. Instead, FDA has asserted such jurisdiction under the "new animal drug" provisions of the FFDCA. *Id.* § 360b.

36. 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…." 21 U.S.C. § 321(g)(1)(C). "New animal drug" is any drug intended for use in animals that has not been used to a material extent or for a material time, and is not recognized by "experts qualified by scientific training and experience" as safe and effective for use under the conditions prescribed. *Id.* § 321(v).

37. Generally, under the FFDCA, a new animal drug is deemed "unsafe" unless FDA has approved a new animal drug application for the drug and its use conforms to its labeling and the conditions of the approved application. 21 U.S.C. § 360b(a)(1).

38. The FFDCA requires an applicant to submit reports to demonstrate whether the drug is "safe and effective for use." 21 U.S.C. § 360b(b)(1)(A); *see also* 21 C.F.R. § 514.1(8) (FDA regulations requiring applicant to submit evidence to establish the "safety and effectiveness" of a new animal drug). The applicant must also submit "other use restrictions . . . in order to assure that the proposed use of such drug will be safe." 21 U.S.C. § 360b(b)(1)(H).

39. A new animal drug application must also contain either an environmental assessment or present an analysis and justification for why the applicant believes that it qualifies for a categorical exemption under NEPA. 21 C.F.R. § 514.1(b)(14). Consideration of this information is integral to FDA's review of the application. *See* 21 C.F.R. § 514.110(b)(10). Indeed, FDA shall disapprove the application if "[t]he applicant fails to submit an adequate environmental assessment under § 25.40 of this chapter or fails to provide sufficient information to establish that the requested action is subject to categorical exclusion under § 25.30 or § 25.33 of this chapter." 21 C.F.R. § 514.111(a)(9).

40. FDA's approval of an application hinges upon the agency's finding that the new animal drug is "safe and effective" for the purposes intended and for use under the prescribed conditions. *See, e.g.*, 21 U.S.C. §§ 360b(d)(1)(A),(B),(D),(E).

41. The FFDCA does not define the phrases "safe and effective," or "safety and effectiveness," or the term "effective." The statute states generally that the term "safe" "has reference to the health of man or animal." 21 U.S.C. § 321(u). In considering whether a drug is "safe," FDA may consider, among other things: (1) "the cumulative effect on man or animal of such drug;" (2) "safety factors" which experts consider appropriate; and (3) whether the conditions in the proposed labeling are reasonably certain to be followed. 21 U.S.C. § 360b(d)(2).

42. When FDA approves a new animal drug application, it must publish in the Federal Register any "conditions and indications of use of the new animal drug … and such other

information, … as the Secretary deems necessary to assure the safe and effective use of such drug." 21 U.S.C. § 360b(i); *see also* 21 C.F.R. § 514.105.

43. FDA's authority to oversee and enforce new animal drug approvals is 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 also has authority to withdraw approval of a new animal drug if it finds that its use is "unsafe" 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).

44. FDA's regulations provide that an applicant may make "minor," "moderate," or "major" changes to the manufacturing process for a previously approved new animal drug. 21 C.F.R. §§ 514.8(b)(2), (3), (4). FDA regulations do not precisely define these terms, but provide a non-exclusive list of examples. *Id.* An applicant can make "minor changes" to the manufacture of a drug without seeking any additional approval from FDA. 21 C.F.R. § 514.8(b)(4). An applicant is only required to inform FDA of these "minor changes" on an annual basis. *Id.* §§ 514.8(a)(iii), (b). FDA is not required to review, evaluate, or approve any such minor changes. *Id.*

45. "Moderate" or "major" manufacturing changes require an applicant to submit a supplemental application. 21 C.F.R. §§ 514.8(b)(2), (3). The agency's regulations leave it to the applicant to determine independently whether its changes are "major" or "moderate" and therefore require submission of a supplemental application. *Id.* The regulations do not require FDA to review or evaluate an applicant's changes in order to determine whether it has correctly classified those changes under the regulations. *See* 21 C.F.R. § 514.8. In addition, an applicant may proceed with making "moderate" changes before receiving approval for a supplemental application submitted to FDA. *Id.* § 514.8(b)(3).

46. Once an applicant submits a supplemental application, FDA determines whether to reevaluate the safety or effectiveness of the drug as part of the approval process. 21 C.F.R. § 514.106(b). The regulations allow FDA to determine what type of environmental analysis to apply when reviewing the application, including whether a new EA or other additional NEPA

analysis is required, or if an applicant can rely on the original EA for the new application. *See* FDA, Guidance for Industry 82, Development of Supplemental Applications for Approved New Animal Drugs (2002), at 8, 10-22.

47. FDA's approval of a new animal drug application is a major federal action subject to the requirements of NEPA. *See* 21 § C.F.R. § 25.20(m).

II. The National Environmental Policy Act

48. NEPA is our "national charter for protection of the environment." 40 C.F.R. § 1500.1(a). Its purpose is to "promote efforts which will prevent or eliminate damage to the environment." 42 U.S.C. § 4321. Regulations promulgated by the Council on Environmental Quality (CEQ) implement NEPA and govern FDA's decisionmaking. *See* 40 C.F.R. §§ 1500-1508; 21 C.F.R., Part 25.

49. When enacting NEPA, Congress expressed great concern for the "profound impact of man's activity on the interrelations of all components of the natural environment, particularly the profound influences of … new and expanding technological advances …." 42 U.S.C. § 4331(a). Congress was specifically wary of "[a] growing technological power which is far outstripping man's capacity to understand and ability to control its impact on the environment." S. Rep. No. 91-296, 91st Cong., 1st Sess., at 6, 1969 U.S. Code Con. & Admin. News 1969.

50. The twin pillars of NEPA are the requirements that agencies (1) carefully evaluate the environmental impacts of proposed actions before undertaking the action, and (2) fully advise the public of the potential impacts of those actions, and of alternatives. NEPA requires federal agencies to fully consider and disclose the environmental consequences of an agency action before proceeding with that action—to take a "hard look." 42 U.S.C. § 4332(2)(C); 40 C.F.R. §§ 1501.2, 1501.4, 1502.5. An agency's evaluation of environmental consequences must be based on "accurate scientific" information of "high quality." 40 C.F.R. § 1500.1(b). If there are not sufficient data available, the agency must follow the requisite procedure for addressing or evaluating the impacts in view of incomplete or unavailable information. *Id*. § 1502.22.

51. NEPA requires federal agencies to prepare an EIS for all "major Federal actions significantly affecting the quality of the human environment." 42 U.S.C. § 4332(2)(C); 40 C.F.R. § 1501.4. Under certain circumstances, the agency can prepare an EA that provides "sufficient evidence and analysis for determining whether to prepare" an EIS and that contributes to the agency's compliance with NEPA. 40 C.F.R. §§ 1508.9, 1501.4.

52. In determining whether an action "significantly" affects the environment, the agency must analyze significance in several contexts "such as society as a whole (human, national), the affected region, the affected interests, and the locality." 40 C.F.R. § 1508.27(a). Determining the significance of an action also requires the agency to consider the intensity of the impact by evaluating factors enumerated at 40 C.F.R. § 1508.27(b).

53. Federal agencies cannot segment or manipulate the scope of their actions in order to avoid a finding of significance and evade the full environmental impact study NEPA demands. 40 C.F.R. § 1508.27(b)(7) ("Significance cannot be avoided by … breaking [an action] down into small component parts."). Rather, when determining the scope of its environmental review under NEPA, an agency must consider "connected, cumulative, and similar actions" together to prevent an agency from "dividing a project into multiple 'actions,' each of which individually has an insignificant environmental impact, but which collectively have a substantial impact." 40 C.F.R. § 1508.25; *see, e.g.*, *Earth Island Inst. v. U.S. Forest Serv.*, 351 F.3d 1291, 1305 (9th Cir. 2003). Actions are connected if they: "(i) Automatically trigger other actions which may require environmental impact statements; (ii) Cannot or will not proceed unless other actions are taken previously or simultaneously; or (iii) Are interdependent parts of a larger action and depend on the larger action for their justification." 40 C.F.R. § 1508.25.

54. In a NEPA analysis, the federal agency must identify the direct, indirect, and cumulative impacts of the proposed action, consider alternative actions and their impacts, and identify all irreversible and irretrievable commitments of resources associated with the proposed action. 42 U.S.C. § 4332(2)(C); 40 C.F.R. §§ 1508.7, 1508.8, 1502.14. Direct effects are those "which are caused by the action and occur at the same time and place." 40 C.F.R. § 1508.8(a). Indirect effects are "caused by the action and are later in time or farther removed in distance, but

are still reasonably foreseeable." *Id.* § 1508.8(b). Cumulative impacts are impacts from "past, present and reasonably foreseeable future actions regardless of what agency (Federal or non-Federal) or person undertakes such other actions." *Id.* § 1508.7. "Cumulative impacts can result from individually minor but collectively significant actions taking place over a period of time." *Id.* "Effects" or "impacts" (synonymous) include "ecological (such as the effects on natural resources and on the components, structures, and functioning of affected ecosystems), aesthetic, historic, cultural, economic, social, or health, whether direct, indirect, or cumulative." 40 C.F.R. § 1508.8.

55. NEPA also requires agencies to evaluate economic or social and natural or physical environmental effects that are interrelated. 40 C.F.R. § 1508.14.

56. NEPA requires agencies to consider "alternatives to the proposed action." 42 U.S.C. § 4332(2)(C)(iii) & (E); 40 C.F.R. § 1508.25. The analysis of alternatives is the "heart" of the NEPA process and must provide "a clear basis for choice among options by the decisionmaker and the public." 40 C.F.R. § 1502.14.

57. NEPA also requires agencies to disclose and analyze measures to mitigate the impacts of proposed actions. 40 C.F.R. §§ 1502.14(f), 1502.16(h). An agency's analysis of mitigation measures must be reasonably complete in order to properly evaluate the severity of the adverse effects of an agency's proposed action prior to the agency making a final decision.

58. CEQ guidance allows an agency to consider and rely on mitigation when making its significance determination. This includes both mitigation measures proposed by the agency and those included in the action "where the proposal itself so integrates mitigation from the beginning that it is impossible to define the proposal without including the mitigation." 46 Fed. Reg. 18,026, 18,038 (Mar. 23, 1981). Particularly in situations where the agency is relying upon mitigation to support a decision to rely upon an EA and a FONSI—and therefore not to prepare an EIS—the agency must carefully evaluate any proposed mitigation, and engage in on-going monitoring in order to ensure that mitigation measures are being followed. Mitigation measures used to support a FONSI must be enforceable and the agency must have sufficient resources to perform or ensure performance of mitigation measures.

59. CEQ regulations require the preparation of a programmatic EIS "for broad Federal actions such as the adoption of new agency programs or regulations." 40 C.F.R. § 1502.4(b); *see also* 40 C.F.R. § 1508.18(b)(4) (definition of major federal action includes "[a]doption of programs, such as a group of concerted actions to implement a specific policy or plan"). Under the CEQ regulations, a programmatic EIS is appropriate for a program that exists in fact, but is not necessarily declared by the agency. *See id*. § 1508.23 (defining "proposal" to include that a "proposal may exist in fact as well as by agency declaration that one exists").

60. A programmatic EIS should be "relevant to policy and [] timed to coincide with meaningful points in agency planning and decisionmaking," and "shall be prepared on such programs and shall be available before the program has reached a stage of investment or commitment to implementation likely to determine subsequent development or restrict later alternatives." 40 C.F.R. § 1502.4.

61. NEPA requires that an agency incorporate its environmental analysis into its decision making process. "NEPA's purpose is not to generate paperwork—even excellent paperwork—but to foster excellent action." 40 C.F.R. § 1500.1(c); *see also id*. ("Ultimately … it is not better documents but better decisions that count."); 40 C.F.R.§ 1502.1 ("primary purpose" of an EIS is to "serve as an action-forcing device to insure that the policies and goals defined in the Act are infused into the ongoing programs and actions of the Federal Government…. An environmental impact statement is more than a disclosure document. It shall be used by Federal officials in conjunction with other relevant material to plan actions and make decisions.").

III. The Endangered Species Act

62. When a species is listed as threatened or endangered under the ESA, section 7(a)(2) of the Act requires that all federal agencies "insure" that their actions "are not likely to jeopardize the continued existence of any endangered species or threatened species or result in the destruction or adverse modification of" their critical habitat. 16 U.S.C. § 1536(a)(2). The "institutionalized caution" embodied in the ESA requires federal agencies to give the benefit of the doubt to listed species and places the burden of risk and uncertainty on the proposed

action. *See Sierra Club v. Marsh*, 816 F.2d 1376, 1386 (9th Cir. 1987); *Tennessee Valley Auth. v. Hill*, 437 U.S. 153, 180 (1978).

63. The Act establishes an interagency consultation process to assist federal agencies in complying with their substantive section 7(a)(2) duty to guard against jeopardy to listed species or destruction or adverse modification of critical habitat. Under section 7(a)(2), federal agencies must consult with the appropriate expert fish and wildlife agency to determine whether their actions will jeopardize any listed species' survival or adversely modify designated critical habitat and, if so, to identify ways to modify the action to avoid that result. *See* 50 C.F.R. § 402.14. The National Marine Fisheries Service (NMFS) is the expert fish and wildlife agency with respect to most anadromous and marine species and FWS is the expert agency with respect to many terrestrial and freshwater species.

64. The Services have adopted joint regulations governing the section 7(a)(2) consultation process. Under the joint regulations, a federal agency must initiate a section 7(a)(2) consultation with NMFS or FWS whenever it undertakes an "action" that "may affect" a listed species or critical habitat. 50 C.F.R. § 402.14(a). The threshold for a "may affect" determination and the required ESA section 7(a)(2) consultation is low. *See* 51 Fed. Reg. 19,926, 19,949 (June 3, 1986) ("Any possible effect, whether beneficial, benign, adverse, or of an undetermined character, triggers the formal consultation requirement."). *See also* FWS, *Endangered Species Consultation Handbook* at 3-13, 4-26 (1998). An agency is relieved of the obligation to consult only if the action will have "no effect" on listed species or designated critical habitat.

65. The joint regulations broadly define the scope of agency actions subject to ESA section 7(a)(2) mandates to encompass "all activities or programs of any kind authorized, funded, or carried out, in whole or in part, by [f]ederal agencies," including the promulgation of regulations and the granting of licenses. 50 C.F.R. § 402.02 (definition of "action"). Courts interpret the term "agency action" broadly under the ESA. *See, e.g.*, *Karuk Tribe of California v. U.S. Forest Service*, 681 F.3d 1006, 1020 (9th Cir. 2012) (en banc).

66. Under the ESA, the "action area" is broadly defined as "all areas to be affected directly or indirectly by the federal action and not merely the immediate area involved in the action." 50 C.F.R. § 402.02. The potential "effects" of an agency action that an agency must consider are similarly broad and include both the "direct" and "indirect" effects of the action and all activities "interrelated or interdependent" with that action. *Id.*

67. In insuring that any action is not likely to jeopardize a listed species or result in the adverse modification of critical habitat, the ESA requires every agency to use only the best scientific and commercial data available at every step of the process. 16 U.S.C. § 1536(a)(2); 50 C.F.R. § 402.14(g)(8).

68. If an agency determines that its action "may affect" but is "not likely to adversely affect" a listed species or its critical habitat, ESA regulations permit "informal consultation," in which there is no requirement for a biological opinion so long as NMFS or FWS concurs in writing with the "not likely to adversely affect" determination. 50 C.F.R. § 402.13. If the Service(s) do not concur in the "not likely to adversely affect" determination or if the action agency determines that the action is "likely to adversely affect" the listed species, the agencies must engage in "formal consultation." 50 C.F.R. §§ 402.12; 402.14(a), (b).

69. Formal consultation "is a process between the Service and the [f]ederal agency that commences with the [f]ederal agency's written request for consultation under section 7(a)(2) of the Act and concludes with the Service's issuance of the biological opinion under section 7(b)(3) of the Act." 50 C.F.R. § 402.02.

70. Compliance with the procedural provisions of the ESA—identifying the likely effects of the action through the consultation process—is integral to compliance with the substantive requirements of the Act. Under the statutory framework, federal actions that "may affect" a listed species or critical habitat may not proceed unless and until the federal agency ensures, through completion of the consultation process, that the action is not likely to cause jeopardy or adverse modification of critical habitat. 16 U.S.C. § 1536(a); 50 C.F.R. §§ 402.14; 402.13; *see also* 16 U.S.C. § 1536(d).

IV. The Food and Drug Administration Amendments Act of 2007

71. In 2007, Congress amended the FFDCA. Pub. L. No. 110–85, 121 Stat. 823 (2007).

72. Section 1007 of those amendments requires that FDA "shall consult with the Assistant Administrator of the National Marine Fisheries Service of the National Oceanic and Atmospheric Administration to produce a report on any environmental risks associated with genetically engineered seafood products, including the impact on wild fish stocks." 21 U.S.C. § 2106.

V. The Administrative Procedure Act

73. The APA grants a right of judicial review to "[a] person suffering legal wrong because of agency action, or adversely affected or aggrieved by agency action…." 5 U.S.C. § 702.

74. Under the APA, a court must "hold unlawful and set aside agency action … found to be … arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law…." *Id.* § 706(2)(A). An agency 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." *Motor Vehicle Mfrs. Assoc. v. State Farm Mutual Auto. Ins. Co.*, 463 U.S. 29, 43 (1983).

75. Under the APA, a court must also "hold unlawful and set aside" any agency action taken that is "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right." 5 U.S.C. § 706(2)(C).

76. Finally, under the APA, a court shall also "hold unlawful and set aside" any agency action that was promulgated "without observance of procedure required by law." *Id.* § 706(2)(D).

FACTUAL BACKGROUND AND ALLEGATIONS

I. FDA's Highly Controversial and Opaque Review of the AquaBounty GE Salmon

77. AquaBounty's GE salmon is a genetically engineered Atlantic salmon that is manipulated to produce an insulin-like growth factor hormone (IGF-1) year-round, allowing it purportedly to reach full size in less time than most conventional farmed salmon. The engineered genetic construct combines a growth hormone protein from the unrelated Pacific Chinook salmon (*Oncorhynchus tshawytscha*) with regulatory sequences from an antifreeze protein gene derived from an ocean pout (*Macrozoarces americanus*, also known as an eelpout), which AquaBounty inserts into the genome of Atlantic salmon. The ocean pout promoter acts like a switch, keeping the growth hormone protein from turning off, which allows for continued growth of the fish. According to AquaBounty, its GE salmon grows to commercial size in half the time of conventional Atlantic salmon and is therefore desirable for commercialization.

78. Although AquaBounty began developing its GE salmon in 1989, the public did not learn about the GE salmon or that FDA was evaluating AquaBounty's GE salmon for potential commercial approval until 2001. At that time, FDA reviewed a draft EA prepared by AquaBounty in support of the investigational use of the GE salmon and issued a finding of no significant impact for this investigational use. Plaintiffs and the public were not provided with notice or an opportunity to comment on either of these documents.

79. In 2001, neither FDA, nor any other agency, had or had developed a regulatory framework for GE animals, or formally explained how U.S. federal agencies would regulate GE animals and GE fish or products created from them. Upon learning that the federal government was considering a commercial approval of GE salmon, Plaintiff CFS and a coalition of other groups filed a suite of legal petitions in 2001 with multiple agencies, including FDA, the Department of the Interior, the Department of Commerce, the U.S. Army Corps of Engineers, and the Department of Agriculture. These petitions called on FDA and these other agencies to, *inter alia*, establish new regulations specific to GE fish; establish regulations requiring monitoring, reporting, and inspection procedures for any producers; require labeling of any GE fish; prohibit any approval of GE fish until and unless an EIS and/or Programmatic EIS was

completed; permanently prohibit such activities should they be shown to harm the environment; and prohibit any approval until and unless FDA or any other agency charged with oversight consulted with the expert wildlife agencies pursuant to the Endangered Species Act. No agency responded in any fashion to any of these petitions for roughly eight years.

A. Development of FDA's GE Animal Guidance

80. On September 18, 2008, FDA released a draft of its GE Animal Guidance for a 60-day public comment period. This draft GE Animal Guidance formally announced for the first time that the agency would extend its jurisdiction to cover GE animals, including those produced for food like AquaBounty's GE salmon, purportedly pursuant to its statutory authority to regulate new animal drugs, 21 U.S.C. § 321, *et seq*. CFS and other public interest groups filed extensive comments related to the GE Animal Guidance, pointing out the flaws in FDA's guidance and the inapposite nature of the animal drug provisions when applied to the risks of genetically engineered animals. These included comments specific to the risks of GE fish filed by a coalition of commercial fishing organizations. The U.S. Fish and Wildlife Service also submitted comments urging FDA to consult with its fish experts before taking action on any application involving the production of GE fish.

81. FDA published the GE Animal Guidance on January 16, 2009. Guidance for Industry #187, Regulation of Genetically Engineered Animals Containing Heritable Recombinant DNA Constructs, 74 Fed. Reg. 3057 (Jan. 16, 2009). In response to comments, FDA provided only generic short statements about the adequacy of the new animal drug process and claimed that the GE Animal Guidance offered only "non-binding recommendations" and did "not establish legally enforceable responsibilities."

82. Relying on the GE Animal Guidance, FDA denied Plaintiff CFS's 2001 legal petition requesting, among other things, that FDA establish a comprehensive regulatory framework under the FFDCA to fully address the environmental impacts caused by GE fish. In the January 15, 2009, denial letter, FDA stated its belief that regulations were not necessary because the GE Animal Guidance details how FDA's existing new animal drug application requirements apply to GE fish.

83. In the GE Animal Guidance, FDA invokes and interprets the FFDCA definitions of "drug" and "new animal drug" to encompass the recombinant DNA (rDNA) construct engineered into a GE animal because it is "intended to affect the structure or function" of the GE animal. GE Animal Guidance at 6.

84. Although the GE animal itself cannot possibly be a drug, FDA also asserted that the new animal drug provisions of the FFDCA allow it to regulate the GE animals carrying the rDNA construct. As asserted by the agency, its interpretation of "drug" covers all GE animals, regardless of their intended use, even those produced as food for human consumption. The GE Animal Guidance states:

> Each new animal drug approval covers all animals containing the same rDNA construct (the regulated article or new animal drug) derived from the same transformation event, including, for example, animals containing that rDNA construct as a result of breeding between a non-GE animal and a GE animal.

GE Animal Guidance at 7.

85. FDA's GE Animal Guidance also explains how the agency would extrapolate the existing "new animal drug" requirements to apply to applications for approval of GE animals, including AquaBounty's GE salmon, such as the types of data and other information needed to fulfill the new animal drug regulatory requirements in the GE animal context.

86. In the GE Animal Guidance, FDA interprets "safety and effectiveness" to include an evaluation of environmental risks. FDA includes three components of safety to be considered as part of the pre-approval assessment: food safety, feed safety, and environmental safety. GE Animal Guidance at 24.

87. Despite FDA's finding that environmental risks are a part its evaluation of "safety and effectiveness," the guidance does not further detail or address precisely how FDA will evaluate environmental safety or otherwise consider environmental impacts as a factor in its safety and effectiveness evaluation. *See, e.g.*, GE Animal Guidance at 20, 26.

88. Although the Guidance purports to establish FDA authority over all GE animals, FDA also attempts to retain unbridled discretion to determine whether or not to enforce new

animal drug application requirements for some GE animals, in some instances, as it sees fit. GE Animal Guidance at 7-8. In exercising this discretion, FDA states that NEPA does not apply to its decision whether to require a new animal drug application for certain GE animals (a decision FDA calls its "enforcement discretion"). GE Animal Guidance at 8. Nevertheless, FDA states that "environmental risks are among the factors we intend to consider in determining whether to exercise enforcement discretion" and outlines some of the factors it will consider in determining whether to require a new animal drug application, including whether the GE animal poses a "human, animal, or environmental risk." *Id.* (stating that environmental risks are among the "safety questions" FDA considers when exercising its enforcement discretion).

89. FDA revised the GE Animal Guidance in June 2015 in order to change language regarding what transparency measures and public meetings would be conducted for future GE animal determinations. The revised guidance now purports to assign FDA the unfettered discretion to decide whether or not to convene public meetings in advance of decisions on applications.

90. Although the Guidance establishes for the first time a regulatory approval framework for all GE animals, FDA did not prepare a programmatic EIS or any other NEPA review for the expansive framework it describes in the GE Animal Guidance and the establishment of a GE animal approval process under the FFDCA.

B. FDA's Failure to Consider the Environmental Impacts of GE Salmon

91. In August 2010—ten years after the public first learned of AquaBounty's GE salmon—FDA finally released to the public AquaBounty's draft EA for the company's GE salmon new animal drug application. AquaBounty's EA contained limited information about the GE salmon and the application for approval that had been pending with the FDA.

92. AquaBounty's draft EA did, for the first time, describe the far-flung, international, and unusual production processes the company proposed for GE salmon in its application. Specifically, the draft EA revealed that GE salmon was first generated by injecting the genetically engineered rDNA construct into fertilized eggs, which were subsequently bred for at least eight generations to produce the fertile GE salmon adults (broodstock). In the draft EA,

AquaBounty proposed to produce eggs using fertile GE salmon broodstock at a facility located on Prince Edward Island, Canada, and then ship the live GE eggs by air to an undisclosed site in Panama for grow-out. In Panama, the GE salmon would be raised to commercial size and slaughtered, then processed and shipped back to the U.S. for sale as a food product.

93. AquaBounty's draft EA asserted that its GE salmon would pose no environmental or ecological risks because the proposed production processes at the Prince Edward Island and Panama sites would be subject to physical, biological, and geographic/geophysical containment measures designed to prevent the GE salmon from escaping into and establishing in the natural environment. According to FDA, these proposed limitations on the production and grow-out of AquaBounty's GE salmon were designed to "mitigate potential adverse environmental impacts."

94. The draft EA relied on the approach it outlined in FDA's GE Animal Guidance to review AquaBounty's application, including assessment under the new animal drug provisions of the FFDCA and the environmental review required by NEPA and FDA's regulations.

95. Shortly after the release of AquaBounty's draft EA, FDA announced it would convene a public meeting of its Veterinary Medicine Advisory Committee (VMAC) in September 2010, to consider the science, safety, and effectiveness of the AquaBounty application, and hold a separate public hearing regarding the labeling of food derived from AquaBounty's GE salmon. *See* Notice of Public Hearing, 75 Fed. Reg. 52,602 (Aug. 26, 2010) (labeling hearing); Notice of Meeting, 75 Fed. Reg. 52,605 (Aug. 26, 2010) (VMAC meeting).

96. In advance of and during the VMAC meeting, representatives of numerous environmental and public health organizations, including Plaintiffs CFS, FWW, and FoE, and non-FDA scientists voiced serious and specific concerns about both the environmental safety of the GE salmon and FDA's review of AquaBounty's application, in both written comments and oral testimony.

97. The preeminent scientific experts on GE fish, Dr. Anne Kapuscinski and Dr. Frederick Sundström, provided written comments to FDA before the VMAC meeting detailing the various significant deficiencies in the science (and scientific approach) underlying AquaBounty's and FDA's assessment of the potential environmental and ecological risks

presented by AquaBounty's GE salmon. In particular, these scientists explained the kinds of failures that FDA should account for in its evaluation of AquaBounty's proposed containment measures, using the best available quantitative failure mode analysis, and recommended that FDA undertake a "failure mode analysis for the full range of facilities that may obtain AquaBounty's GE salmon eggs in the foreseeable future, as part of a full EIS." They also explained that the draft EA did not provide all of the information needed to predict the environmental effects of GE salmon, and the need for an EIS. Their comments were summarized in oral testimony at the VMAC during the public meeting held on September 19, 2010.

98. Even members of FDA's own VMAC recognized the flaws and gaps in FDA's environmental analysis. The only fish scientist on the VMAC concluded that in light of these concerns, "considering this issue in a comprehensive way, together with other agencies through an environmental impact statement, would be the best way to proceed."

99. Over the next two years, from the end of 2010 to the end of 2012, members of the public, commercial fishermen, environmental and consumer groups, and members of U.S. Congress and state legislatures, continued to raise serious concerns regarding the sufficiency and limited scope of FDA's review and the agency's lack of environmental expertise. These stakeholders specifically called on FDA to halt its consideration of GE salmon, and to prepare a comprehensive EIS assessing the full range of environmental and ecological risks it posed.

100. During this time, scientists with expertise in fish biology and GE fish from FWS and NMFS also expressed serious concerns about the scope of FDA's review and its failure to properly analyze relevant risks associated with AquaBounty's GE salmon, particularly as such risks relate to wild salmon stocks and aquatic ecosystems. One FWS scientist noted, for example, that FDA's 2010 VMAC Briefing Packet for AquaBounty's GE salmon "falls short of providing an actual risk assessment of putative environmental damages in the event of escapement" and that he was troubled by the apparent lack of any policy for monitoring or enforcement with respect to operations and escapement at these facilities.

101. FWS's comments on AquaBounty's 2010 draft EA, stated that "it must be assumed that escape will … occur," and that "any interaction between wild and [GE] salmon must be considered a serious threat." FWS concluded that "we do not feel enough evidence has been provided to conclude the risks to natural populations of Atlantic salmon in Canada and the U.S. are negligible." Dr. Gregory Moyer, a FWS regional geneticist sent FDA a letter in 2010 expressing criticisms and concerns with FDA's risk assessment.

102. In 2010, a body of FWS fish conservation geneticists comprising the Conservation Genetics Community of Practice (COP) also expressed "great concern" with respect to the risk of escapement and "possible interaction of [AquaBounty's GE] salmon with endangered wild salmon stocks" citing, in particular, historical evidence of massive escapes of commercially reared fish from aquaculture farms. The COP stated further that the EA lacked needed information and that its conclusions are based on limited data that must be supplemented with a number of studies, observing that the EA "is overly simplistic and does not adequately capture the actual risk of environmental damages to wild Atlantic salmon or the ecosystem."

103. A number of other FWS scientists, from numerous regional offices, expressed concerns similar to those presented by the COP, revealing that the concerns were pervasive throughout the agency. On October 29, 2010, it was reported internally at that agency that "all but one Region oppose[] FDA approval" of AquaBounty's GE salmon application.

104. NMFS expressed similar concerns in 2010. NMFS sent a letter to FDA raising serious questions regarding containment of fertile GE salmon broodstock at the Prince Edward Island facility and the future marketing of GE salmon eggs. NMFS also questioned FDA's decision to narrowly limit the analyzed "action area" to Canada and Panama only, noting that "the action area as defined in the ESA (50 CFR 402.02), should be identified as all areas of potential impacts as a result of this action. The topics of selling commercially and rearing fertile adult males at the Canadian production facility both potentially increase the size of the action area to include the United States."

105. In particular, NMFS pointed out the inconsistency between FDA's statements that (1) its approval would be limited to particular restrictions and locations, as stated in the current

application; and (2) the agency's discussion of GE eggs produced for commercial sale. NMFS explained that "[b]ecause the egg production facility and the grow-out facility are owned by AquaBounty Technologies, Inc., there would be no reason to sell the eggs unless another aquaculture facility was involved."

106. NMFS expressed other significant concerns about the potential implications of the AquaBounty application, including that the sterilization process for the GE salmon eggs would not be 100% effective, that the GE salmon could indeed escape containment, and that the escaped GE fish could catastrophically harm native salmon populations.

107. Between 2010 and 2012, FDA held closed-door meetings with various agencies, including the Council on Environmental Quality, FWS, and NMFS about the adequacy of its environmental review. Presumably faced with concerns from sister agencies, FDA characterized its approval decision as confined strictly to the Panama and Prince Edwards Island sites and the conditions presented in AquaBounty's application. FDA emphasized in those meetings that environmental impacts of plans to alter or expand the production of its GE salmon, including requests to produce the GE fish in the United States, could be assessed in later supplemental approvals.

108. On December 26, 2012, FDA released its own draft EA and FONSI for the AquaBounty new animal drug application for public review and comment. Despite the ongoing substantial scientific controversy and the repeated calls for a more comprehensive environmental review, FDA's draft EA varied only slightly from the 2010 EA prepared by AquaBounty; it did not include new or additional data or environmental analyses regarding the environmental risks or other potential impacts that could occur if AquaBounty's GE salmon escaped containment.

109. Many organizations and individuals submitted extensive comments on FDA's draft EA, explaining, among other things, that FDA lacks the legal authority to approve GE salmon for production and commercialization, and that the agency's extremely inadequate draft EA renders FDA's FONSI and decision not to prepare an EIS arbitrary and unlawful. These submissions included comments from yet another independent scientist with expertise in fish biology, ecology, and genetic introgression, who provided detailed concerns regarding FDA's

failure to assess the potentially significant and irreparable harm GE salmon could pose to any environment in which they may be released.

110. Comments on FDA's 2012 draft EA from Drs. Kapuscinski and Sundström explained that FDA continued to ignore their 2010 recommendations for conducting an adequate risk assessment that is consistent with current science, a failure that rendered the draft EA "weak and scientifically unacceptable." These comments highlighted that FDA continued its indefensible use of outdated risk methods, which Dr. Kapuscinski herself developed in the 1990s, but which she and others have had since replaced with improved, science-driven, rigorously reviewed methodologies.

111. By the close of the comment period on FDA's draft EA on April 26, 2013, over 1.8 million comments had been submitted to FDA objecting to the proposed approval of AquaBounty's GE salmon application on the basis of environmental and public health risks.

112. Despite these objections, FDA announced its final approval of the AquaBounty new animal drug application to produce and market its GE salmon on November 19, 2015. 80 Fed. Reg. 73,104 (Nov. 24, 2015). FDA did not require labeling of AquaBounty's GE salmon, but instead allowed for voluntary labeling of the product.

113. FDA purported to sufficiently consider environmental safety as part of its approval process, and concluded that the GE animal and conditions presented in the application did not present "safety concerns" to the environment. In the final EA, FDA stated that GE salmon would be considered "unsafe" if AquaBounty did not conform with the "specific set of conditions enumerated and described in the [new animal drug application] and the approval letter." In the final EA, FDA stated that it reviewed environmental safety and effectiveness under these "specified conditions of use" and concluded that they would "serve to mitigate environmental risks."

114. In its approval letter to AquaBounty, FDA also included a detailed set of conditions that the agency placed on the approval—including restrictions on facilities, containment, breeding and production methods, and shipment of eggs—each of which relates to environmental safety. *See also* 21 C.F.R. § 514.105 (also listing several of these conditions and

a prohibition on the use of net pens as among those FDA "deems necessary to assure the safe and effective use of the drug."). FDA's approval letter specifies that its approval is predicated upon compliance with each of these conditions and that "[d]eviations from these commitments and requirements will result in the article being considered an unsafe new animal drug" and an adultered animal drug and food under the FFDCA.

115. FDA's limited consideration of environmental risks, however, was based on a final EA and FONSI that, like the draft EA, are improperly limited in scope, devoid of sound scientific analyses, and replete with unsupported assumptions. Despite receiving significant and substantive comments, the passage of five years since the original AquaBounty 2010 draft EA, and three years since the FDA draft EA, the final EA was substantially similar to, and in many cases virtually indistinguishable from, FDA's 2012 draft EA.

116. FDA's final EA included numerous unsubstantiated, misleading assumptions about environmental risk. For example, neither FDA nor AquaBounty has studied the potential biological fitness of the specific GE salmon that FDA has approved for commercialization; instead the agency relied on—and extrapolated from—studies about the fitness of other types of GE fish, which do not adequately support FDA's conclusions.

117. Similarly, FDA did not provide sufficient evidence or analysis to support the presumed sterility of AquaBounty's GE salmon. In fact, FDA acknowledged that up to five percent of the GE salmon produced at Prince Edward Island may not be sterile, following implementation of AquaBounty's biological containment process (induction of triploidy), and that "there are no specific data demonstrating that triploid [AquaBounty] salmon are indeed sterile, that is incapable of producing viable offspring." FDA also admitted the existence of fertile GE salmon broodstock at the Prince Edward Island facility, noting that approximately one half of them are fertile males. Nonetheless, the agency arbitrarily assumed, for purposes of its EA and FONSI, that *all* GE salmon will be functionally sterile, and therefore did not provide any relevant analysis regarding possible risks presented by fertile GE salmon.

118. Moreover, the final EA lacked analysis of risks associated with Infectious Salmon Anemia Virus (ISAV). ISAV is a viral disease in salmon that causes severe anemia in the fish,

and has spread quickly among Atlantic salmon in salmon farms, causing wide-spread losses in many locations. In December 2011, through Canadian proceedings regarding a separate matter, it was discovered for the first time that fish eggs at AquaBounty's Prince Edward Island facility were infected with ISAV in 2009. In the 2012 draft EA, FDA for the first time acknowledged that this outbreak occurred, but it never attempted to explain how the ISAV entered the facility, how to prevent it from happening again, or what might happen if a similar outbreak occurs again and an infected GE salmon were to escape into the natural environment.

C. AquaBounty's Plans for Expansion

119. With FDA's approval in hand, absent judicial intervention, AquaBounty is now able to begin production and commercialization of its GE salmon for sale in the U.S.

120. AquaBounty has publicly and repeatedly confirmed its intent to expand capacity and begin field trials with prospective customers in the United States. Public statements and financial disclosures from AquaBounty demonstrate that the company will not limit the manufacture of GE salmon to the facilities approved in this application, but rather plans to expand its production operations to other countries. AquaBounty's chief executive officer has stated that the company has been moving forward with field trials in several foreign countries to import and grow its GE salmon eggs.

121. The company's own annual reports further detail and confirm its expansion efforts. For example, in its 2014 Form 10 to the Securities and Exchange Commission, AquaBounty stated "we currently plan to increase our supply of unfertilized Atlantic salmon eggs through either expansion of our existing Canadian hatchery or through the purchase of an existing egg producer." In that Form 10, the company stated, "we currently plan to apply for regulatory approval of a second hatchery that would likely be located in the United States."

122. In a recent February 2016 financial disclosure document, AquaBounty stated that it was "finalizing its proposed commercialization strategy," and "exploring capital raising opportunities to fund expansion."

123. FDA knew about these existing requests for government action, but failed even to mention them in its draft or final EA, and neither document analyzed the impacts from the

foreseeable expansion of AquaBounty's production, manufacturing, and sale of GE salmon eggs and fish.

124. Even FWS recognized internally that "[AquaBounty's] Canada-Panama scenario seems far-fetched as a business strategy" and that AquaBounty "may be using it as a means of gaining FDA approval in anticipation of a wider operation."

D. FDA's Failure to Ensure Approval Would Not Jeopardize Protected Species

125. Beginning at least as early as 2001, both NMFS and FWS urged FDA to engage in ESA consultation in connection with AquaBounty's application to produce and market GE salmon. In a joint October 30, 2001, letter to FDA about AquaBounty's application, FWS and NMFS stated that "[t]here is a large body of scientific evidence that clearly indicates genetic and ecological interactions between wild and aquaculture salmon can adversely affect wild populations…. The introduction and use of genetically modified salmon by the salmon farming industry has the potential to adversely affect endangered wild salmon and thus, is of concern to the Services."

126. As of 2009, FDA had finally asked the Services to consult under Section 7 of the ESA on the impacts of GE salmon on several ESA-listed species. In response to FDA's request to initiate consultation, NMFS stated that it had an interest in the consultation because AquaBounty's proposal "may have effects on endangered species and species that support commercial fisheries."

127. In August 2010, FDA sent both of the Services letters, concluding that approval of AquaBounty's application "may affect" but was "not likely to adversely affect" endangered Atlantic salmon populations.

128. In or around October 2010, FWS suggested that FDA should clarify the approval would have "no effect" on listed salmon. FDA amended its ESA determination a few months later. In subsequent letters to the Services, FDA stated that it now believed that approval of AquaBounty's application under the proposed conditions of use would instead have "no effect" on endangered Atlantic salmon populations. FDA requested that the Services send a written response to FDA's determination.

129. At the end of 2010, FWS sent a letter to FDA accepting its "no effect" determination and stating that concern for endangered Atlantic salmon would exist if there was even a "detectible probability" that the GE salmon could interbreed with or consume Atlantic salmon, but discounted those outcomes as unlikely.

130. In July 2011, after numerous "technical discussions" with FDA, NMFS sent FDA a letter acknowledging only that FDA had terminated the consultation process. Internal NMFS email correspondence indicated that NMFS staff did not agree with FDA's "no effect" determination.

E. Citizen Petition for Comprehensive Analysis

131. On May 25, 2011, Plaintiffs CFS, FoE, and FWW, along with other groups filed a legal petition with FDA requesting that the agency refrain from taking final action on the AquaBounty new animal drug application until the agency completed a comprehensive EIS fully analyzing the potential environmental and ecological impacts associated with GE salmon and until FDA developed regulations that included mandatory consideration of environmental safety when approving GE animals.

132. On November 19, 2015, the same day that it approved the AquaBounty GE salmon, FDA denied Plaintiffs' legal petition. FDA stated that the GE salmon approval would not have a significant impact on the environment, relying entirely on its conclusion that containment would prevent release. FDA refused to consider cumulative impacts, stating that any future sale of eggs or additional production facilities were not foreseeable because the agency had not received any additional formal proposals or applications from AquaBounty at that time.

II. Risks to Aquatic Ecosystems, Wild Fish Populations, and Fisheries

133. Of particular concern to Plaintiffs are the potential impacts of FDA's approval of AquaBounty's GE salmon application upon already vulnerable wild fish populations, including, but not limited to, members of genera *Salmo* (Atlantic salmon and trout) and *Oncorhynchus* (Pacific salmon and trout). Over time, these species have been decimated by a variety of human-induced pressures.

134. In 2000, NMFS and FWS issued a final rule designating the Gulf of Maine Distinct Population Segment (GOM DPS) of Atlantic salmon as endangered under the ESA. A final rule designating critical habitat for the GOM DPS was published in the Federal Register on June 19, 2009. 74 Fed. Reg. 29,300 (June 19, 2009).

135. According to the National Oceanic and Atmospheric Association's (NOAA's) Office of Protected Resources, "[t]he populations of Atlantic salmon present in the Gulf of Maine DPS represent the last wild populations of U.S. Atlantic salmon." Of the New England rivers in which Atlantic salmon runs were historically found, only 16% currently support salmon. In these rivers, Atlantic salmon are considered to be in "critical condition."

136. As FDA acknowledges, the migratory range of the endangered Gulf of Maine Atlantic salmon includes areas surrounding Prince Edward Island, Canada, where AquaBounty will house GE fertile broodstock fish, including fertile males, and eggs. Indeed, these salmon populations spend "as many as five winters at sea, thousands of miles away." They "leave Maine rivers sometime in April or May, and can be found in the waters off Labrador and Newfoundland by mid-summer. They then migrate to take advantage of available food supplies and generally spend their first winter at sea off the coast of Greenland."

137. Atlantic salmon continue to face many threats that may jeopardize their environment and continued existence. Although salmon fishing is currently prohibited in Maine, illegal harvest, bycatch, habitat destruction and modification, incidental take, and other pressures still represent significant risks to the recovery of Atlantic salmon in the United States. NMFS recognizes aquaculture practices as one of the threats facing the Maine DPS Atlantic salmon population as they "pose ecological and genetic risks." In 2003, citing the need for greater protections for the endangered Atlantic salmon population from growing risks, NMFS issued a biological opinion stating, *inter alia*, that production of GE fish species in net-pen aquaculture off the coast of Maine is prohibited.

138. Like Atlantic salmon, Pacific salmon populations on the west coast of the United States have faced significant declines. Many Pacific salmonids are listed as endangered or threatened under the Endangered Species Act, including certain populations of Chinook salmon

(*Oncorhynchus tshawytscha*), chum salmon (*Oncorhynchus keta*), coho salmon (*Oncorhynchus kisutch*), sockeye salmon (*Oncorhynchus nerka*), and steelhead trout (*Oncorhynchus mykiss).* NMFS has listed the following Pacific salmon and steelhead Evolutionarily Significant Units (ESUs) and Distinct Population Segments (DPSs)[1] as threatened or endangered: California coastal Chinook salmon, Central Valley spring-run Chinook salmon, Lower Columbia River Chinook salmon, Puget Sound Chinook salmon, Sacramento River winter-run Chinook salmon, Snake River fall-run Chinook salmon, Snake River spring/summer-run Chinook salmon, Upper Columbia River spring-run Chinook salmon, Upper Willamette River Chinook salmon, Columbia River chum salmon, Hood Canal summer run chum salmon, Central California Coast coho salmon, Southern Oregon and Northern Coastal California coho salmon, Lower Columbia River coho, Oregon Coast coho salmon, Snake River sockeye salmon, Central California Coast steelhead, California Central Valley steelhead, Lower Columbia River steelhead, Middle Columbia River steelhead, Northern California steelhead, Snake River Basin steelhead, South-Central California Coast steelhead, Southern California steelhead, Upper Columbia River steelhead, and Upper Willamette River steelhead. The few wild Pacific salmon runs that remain healthy enough support vibrant subsistence, recreational, and commercial fisheries, which in turn support vibrant coastal communities. Pacific salmon fisheries constitute some of the best and most valuable remaining wild fisheries on earth.

139. All five species of wild Pacific salmon live in the western U.S. and Alaska: Chinook (King); Coho (Silver); Pink; Sockeye (Red), and Chum (Dog). While there are

[1] In order for an imperiled species to be protected by the ESA, it must first be placed on the Act's "threatened" or "endangered" species lists. 16 U.S.C. § 1533(c). A "species" that may be listed for protection under the ESA includes "any subspecies of fish or wildlife or plants, and any distinct population segment of any species of vertebrate fish or wildlife which interbreeds when mature." 16 U.S.C. § 1532(16). When deciding whether to list populations of Pacific salmon for protection as a "distinct population segment" under this definition, NMFS employs the concept of "evolutionarily significant unit" (ESU). A population of Pacific salmon is an ESU if it is "(1) … reproductively isolated from other population units of the same species, and (2) … an important component in the evolutionary legacy of the biological species." 64 Fed. Reg. 14,308 14,310 (Mar. 24, 1999). In 2006, NMFS issued revised listings for all west coast steelhead populations applying the joint Distinct Population Segment (DPS) policy developed by NOAA and the U.S. Fish and Wildlife Service in 1996. See 71 Fed. Reg. 834 (Jan. 5, 2006) (revised steelhead listings); 61 Fed. Reg. 4,722 (Feb. 7, 1996). Though the ESU and DPS policies are consistent, there are differences in emphasis between them. The different emphases are not relevant here.

variations between species, Pacific salmon generally spend from several months to several years in freshwater before migrating to the ocean for one to five years of feeding in the North Pacific Ocean as juveniles and sub-adults. Generally, little is known about marine behavior of salmon. They are known to travel vast distances, presumably in search of food, with wide variation in the behavior among runs and over time. After reaching maturity in the ocean, Pacific salmon return to their natal freshwater streams to spawn. As is the case with Atlantic salmon, Pacific salmon can cover thousands of miles during their fresh and saltwater migrations.

140. Among different populations and salmon runs, individual Pacific salmon populations have evolved distinctive characteristics, including various physical and physiological characteristics and behavioral differences, such as differences in size, color, shape, life span, and marine feeding patterns. These diverse adaptations can have ecological significance.

141. Salmon are rightly revered for their integral roles in their native ecosystems, as their sacrificial anadromous journeys transfer vast amounts of marine nutrients to freshwater and terrestrial species, including aquatic invertebrates, other fish, marine mammals, birds, and terrestrial mammals. The contribution of salmon to the quality of the environment is substantial and far-reaching. The Pacific Northwest rainforests are to a large extent fed by returning salmon. Studies have found that trees like the Sitka spruce alongside salmon rivers can grow more than three times faster than counterparts along rivers without salmon. Species such as bear and bald eagle feed on salmon, as do myriad other species.

142. Wild Pacific salmon fisheries constitute an important source of jobs and enjoyment for thousands of U.S. citizens and hundreds of coastal communities, including many members of the Plaintiff organizations that work in the salmon industry as fishers, producers, processors, marketers, and chefs. Recreational salmon fishing is an economic engine along the U.S. West Coast and Alaska, in addition to contributing greatly to the quality of life for thousands of enthusiasts. Subsistence salmon fisheries remain an important source of food for many rural residents and tribal members. Families up and down the U.S. West Coast still depend on healthy wild fish stocks for their livelihoods, as was once the case for Atlantic salmon fisheries on the East Coast.

143. These fisheries rely on the health and diversity of Pacific salmon. The various populations and runs of Pacific salmon have developed distinctive identities, many of which have substantial aesthetic, cultural, social, and economic significance. Connoisseurs and consumers of salmon appreciate the distinctive physical and socio-cultural characteristics of each different run, and so too has the salmon industry profitably capitalized on this aesthetic appreciation. The "Copper River salmon" is one famous, and profitable, example. Copper River salmon have a distinct taste, color, and texture, as well as timing and cultural context, which are prized in the marketplace and by discerning consumers.

144. The environmental risks of GE fish are both very real and potentially disastrous. Studies have found that GE fish may be more competitive, less discriminate in choosing prey, more likely to attack novel prey, and better at using lower quality food when compared to wild salmon. When the GE salmon do escape, the impacts on the environment are significant and irreversible, in the form of, *inter alia*, (1) ecological impacts on native species via predation and/or competition for limited food and space; (2) transfer of exotic pathogens or an increase in the amount of pathogens present in the environment; (3) ecological disturbance through interference competition or the disruption of ecological processes like predator/prey interactions or migration patterns; and (4) genetic impacts via hybridization and genetic introgression. Additionally, GE salmon's over-production of the growth hormone, IGF-1, may lead to behavioral changes, such as increased aggressiveness and altered breeding and migration patterns.

145. If GE salmon breed with wild fish, these and other traits ultimately impact the fitness of wild salmon. The introduction of GE salmon with any mating success into a wild population would affect the genetic makeup of the population. This can have two consequences. First, successful mating of GE salmon with wild salmon would spread the altered gene throughout the wild population, with each successive generation, until the wild, unaltered population no longer exists. Second, GE salmon reportedly have reduced viability—i.e., they are less fit to survive in the wild than wild salmon—and successful mating with wild salmon could pass along this genetic heritage to the next generation, reducing the overall survival of the

salmon population as a whole. It is survival of the "unfittest:" engineered salmon may successfully mate, but because of unexpected physiological havoc caused by the new genes, their offspring might die more often or sooner than wild salmon. While these effects are detrimental to any population of fish, they are especially problematic for smaller, imperiled populations where every individual member makes a difference.

146. Once engineered organisms escape or are released into the environment, it is impossible to recall or eliminate them. Unlike chemical pollution, GE contamination is a living pollution that can propagate itself over space and time via gene flow. As federal courts have found in the context of GE plants, "once the gene transmission occurs and a farmer's seed crop is contaminated with the [engineered] gene, there is no way for the farmer to remove the gene from the crop or control its further spread." *Geertson Seed Farms v. Johanns*, No. Civ 06–01075, 2007 WL 518624, at *5 (N.D. Cal. 2007).

147. As detailed above, scientists with FWS (which, unlike FDA, has expertise in fish biology and ecology) found that FDA's assessment of the risks of escape was "overly simplistic," and failed to "adequately capture the actual risk of environmental damages" to wild salmon in the event of escape. Independent fisheries scientists and those with NMFS echoed these concerns. Because containment measures cannot guarantee that GE salmon will not escape into the wild, and because survival and reproduction of escaped GE salmon is possible, any escape or release event would be significant and irreparable. The GE salmon, once in rivers or the ocean, are free to reproduce, and mutate to adapt to their environment; in other words, to do what fish in the wild do. Their ability to affect already decimated wild salmon populations will continue, and may even increase, over time.

148. Distinct from effects on the viability of wild salmon populations themselves, escaped engineered fish contaminating salmon populations or salmon fisheries would adversely impact those resources and humans' relationship with them. First, escapes will have secondary adverse economic effects on the commercial fishing industry by further straining already imperiled salmon populations, thus affecting salmon fishermen's livelihoods. Contamination of wild runs could also result in fishing closures. Second, commercial, subsistence, and

recreational fisheries that are linked with the identity of particular populations or fisheries would suffer immediate and irreparable harm if an engineered fish found its way into a fishing net or a market. Market and public perceptions of even a small, isolated release of GE salmon—even in the absence of any negative physical effect on wild salmon populations—would disproportionately impact these fisheries. Polls repeatedly conclude that U.S. consumers reject the approval of GE salmon, or at a minimum, demand they be labeled. Many major U.S. grocery chains have already agreed not to sell the GE salmon for this very reason. FDA's approval and the lack of any point-of-sale labeling requirements for GE salmon could reduce consumers' confidence in and purchasing of salmon, causing negative effects on salmon markets and further affecting fishing men and women. FDA refused to consider, let alone analyze, these intertwined economic and environmental effects.

149. Yet, the incalculable worth of the species cannot be measured solely in scientific or monetary terms. Harm to wild salmon runs further degrades or destroys the profound cultural identity and social and aesthetic values supported by salmon as well. The cultural values of salmon are profound. Salmon are a sacred animal in many cultural traditions, including Native American traditions, as well as regional traditions. On the U.S. West Coast, salmon have been the centerpiece of cultural and spiritual life for thousands of years. GE contamination of salmon runs would have significant adverse effects on the cultural identities associated with those wild stocks. FDA did not consider these impacts.

FIRST CLAIM FOR RELIEF
VIOLATION OF THE FFDCA AND APA
ULTRA VIRES ACTIONS OF THE GE SALMON APPROVAL AND GE ANIMAL PROGRAM

150. Plaintiffs re-allege, as if fully set forth, each and every allegation set forth in paragraphs 1 through 149 of this Complaint.

151. As described above, FDA has asserted exclusive jurisdiction over the approval of GE animals, including GE salmon, under its FFDCA authority to approve new animal drugs. 21 U.S.C. § 360b.

152. Genetically engineered animals are not animal drugs. The FFDCA does not explicitly or implicitly authorize the FDA to approve for production and commercialization GE food animals intended for human consumption. *See* 21 U.S.C. §§ 321(g)(1)(C), 321(v). FDA has erroneously overextended its drug authority to encompass these novel organisms and their concomitant novel significant risks.

153. The FFDCA defines the term "drug," *inter alia*, as "articles (other than food) intended to affect the structure or function of the body of man or other animals…" 21 U.S.C. § 321(g)(1)(C). The FFDCA defines the term "new animal drug" as "any drug intended for use for animals…" 21 U.S.C. § 321(v).

154. In the GE Animal Guidance, and as applied in its approval of AquaBounty's GE salmon, FDA interprets the definition of "new animal drug" to include the "rDNA construct" that genetically engineers the animal as an article that is "intended to affect the structure or function" of the animal. The GE Animal Guidance does not define "rDNA construct," but states that "[t]he rDNA construct at a specific site in the genome is the subject of the [new animal drug application]." FDA is likely referring to the artificially made DNA sequence that exists in a GE animal as an integral part of its genome, or genetic code. Such integral DNA sequences, however, 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 GE animal, but is rather a part of the animal that is passed along to its progeny which inherit the rDNA along with the animal's other genetic material.

155. An "rDNA construct" is not a "drug" that is separate and apart from the body of an animal or something that is "intended for use for animals," but rather is a part of the animal itself. The "rDNA construct" in a GE animal does not meet the FFDCA definition of "drug" or "new animal drug."

156. In the GE Animal Guidance, FDA also asserted its authority over the entire GE organism containing the "drug," not merely the rDNA construct that exists inside the GE animal. The GE animal itself is not a "new animal drug" either because it is not an article that is intended to affect the structure or function of another animal under the FFDCA's definition.

157. Neither the FFDCA nor the FDA's regulations support FDA's assertion that either the "rDNA construct" or the entire GE animal fits within its statutory authority over "new animal drugs." These provisions were instead intended to regulate the far more familiar scenario where an animal is provided with medication that is temporary in the sense that it can be metabolized and is not passed on to its offspring.

158. The FFDCA definition of "drug" also expressly excludes "food." 21 U.S.C. § 321(g)(1)(C). However, AquaBounty's GE salmon is clearly intended for use as food, and thus, by the statute's own plain language, FDA lacks the authority to regulate GE salmon, or other future GE animals to be produced as food, solely as a "drug." The terms are mutually exclusive in the statutory scheme.

159. FDA's assertion of exclusive authority to regulate GE animals as new animal drugs in its GE Animal Guidance, its application of its GE Animal Guidance, and its approval of GE salmon under its new animal drug authority are *ultra vires* actions "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right," and are "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law" in violation of the FFDCA and the APA. 5 U.S.C. §§ 706(2)(A),(C).

160. The actions and inactions of the Defendants described in this Cause of Action are causing injuries to the Plaintiffs, for which they have no adequate remedy at law.

SECOND CLAIM FOR RELIEF
VIOLATION OF NEPA AND APA:
FAILURE TO TAKE A HARD LOOK AT THE EFFECTS OF THE ACTION

161. Plaintiffs re-allege, as if fully set forth, each and every allegation set forth in paragraphs 1 through 160 of this Complaint.

162. NEPA requires that federal agencies take a "hard look" at the environmental consequences of their actions, before action is taken. *See, e.g.*, *Blue Mountains Biodiversity Project v. Blackwood*, 161 F.3d 1208, 1211 (9th Cir. 1998). NEPA's implementing regulations require FDA to assess the environmental impacts of the proposed action, including direct and indirect effects, which are reasonably foreseeable but removed in time or space. 42 U.S.C. § 4332(C); 40 C.F.R. §§ 1502; 1508.7. NEPA further requires FDA to use high quality, accurate

scientific information and to ensure the scientific integrity of this analysis. 40 C.F.R. §§ 1500.1(b); 1502.24.

163. In violation of these mandates, FDA's FONSI is based on an unlawfully narrow, incomplete, and inadequate EA that fails to take a hard look at the potential impacts of AquaBounty's GE salmon on the environment and aquatic ecosystems. The available information—including that provided by the public, independent scientific experts, and other federal agencies in comments on the EA—detail the extensive environmental and ecological threats posed by GE salmon, including the potential that the AquaBounty GE salmon will enter and survive in the natural marine and/or freshwater ecosystems, the potential impacts of escaped or otherwise released GE salmon on wild fish populations (including already imperiled Atlantic salmon and Pacific salmonids and other fish species such as trout) as well as potential socioeconomic impacts on commercial fisheries and subsistence fishing communities intertwined with and stemming from those environmental harms. The agency's EA and FONSI entirely failed to consider and/or to adequately analyze these substantial impacts associated with AquaBounty's application.

164. FDA's refusal to analyze or even consider the further effects of its approval was based on the agency's erroneous assumption and determination that any impacts would be insignificant because the proposed AquaBounty production processes at the Prince Edward Island and Panama facilities would be subject to physical, biological, and geographic/geophysical containment measures that would prevent any risk of the GE salmon escaping into and establishing in the natural environment. Based on this assumption, FDA acted contrary to basic principles of risk assessment and erroneously stopped its analysis, refusing to consider the reasonably foreseeable indirect effects of its approval if and when these containment measures fail.

165. FDA also made unsubstantiated assumptions about the biological fitness of AquaBounty's GE salmon and the sterility of the salmon, failing to investigate the risks of fertile GE salmon if they escaped into the environment, including the risk that GE salmon could be carrying infectious disease. As a consequence, FDA's risk assessment falls far short of

providing a scientifically defensible analysis of possible consequences should AquaBounty's GE salmon be released into any natural environment, including waters outside the Prince Edward Island and Panama facilities, or areas the GE salmon could enter upon proliferation.

166. FDA entirely failed to consider high quality, accurate scientific information as NEPA requires, including the standard practice of conducting a quantitative failure mode risk analysis, and instead relied on outdated risk analysis methods in analyzing the direct and indirect environmental effects of AquaBounty's GE salmon. Independent, expert scientists have made clear that the kind and extent of harm escaped or released GE salmon may impose on natural environments and ecosystems are unique and extremely uncertain. These scientists have warned, repeatedly, that FDA must utilize additional, more comprehensive studies and up-to-date scientific methods to assess risks.

167. NEPA also requires FDA to take a hard look at the potential aesthetic, historic, cultural, economic, social, and health impacts, including harm to commercial fisheries, recreational fishing, and fishery-dependent communities of its GE salmon approval. 40 C.F.R. § 1508.8. Genetic contamination of native salmon populations by released GE salmon could have devastating impacts on salmon fisheries and markets. Similarly, GE contamination of native salmon could cause irreparable damage to biodiversity and native and cultural traditions so venerating salmon. The agency refused to consider, let alone adequately analyze, these intertwined socioeconomic and environmental impacts of its approval decision.

168. For the above reasons, FDA violated NEPA, and the EA and FONSI are invalid because they fail to take a hard look at the direct and indirect effects arising from the potential for AquaBounty's GE salmon to enter the environment and adversely affect threatened and endangered fish species or marine ecosystems in either the United States or in any foreign jurisdiction.

169. By issuing an EA and FONSI that fail to meet the standards laid out in NEPA, its implementing regulations, and governing precedent, FDA has acted in a manner that is arbitrary, capricious, an abuse of discretion, and not in accordance with law, and without observance of

procedures required by law, in violation of NEPA, 42 U.S.C. § 4332, its implementing regulations, and the APA. 5 U.S.C. §§ 701-706.

170. The actions and inactions of the Defendants described in this Cause of Action are causing injuries to the Plaintiffs, for which they have no adequate remedy at law.

THIRD CLAIM FOR RELIEF
VIOLATION OF NEPA AND APA:
IMPROPER SEGMENTATION, FAILURE TO CONSIDER CONNECTED, CUMULATIVE, AND INTERDEPENDENT ACTIONS

171. Plaintiffs re-allege, as if fully set forth, each and every allegation set forth in paragraphs 1 through 170 of this Complaint.

172. NEPA and its implementing regulations require the scope of FDA's analysis to include "connected actions" that "automatically trigger other actions," "cannot or will not proceed unless other actions are taken previously," or "are interdependent parts of a larger action and depend on the larger action for their justification." 40 C.F.R. § 1508.25. FDA must also consider "cumulative actions," which include those that "when viewed with other proposed actions have cumulatively significant impacts," and "similar actions" that "when viewed with other reasonably foreseeable or proposed agency actions have similarities that provide a basis for evaluating their environmental consequences together." *Id*.

173. By contrast, NEPA prohibits an agency from doing what FDA did here: dividing a project into multiple actions, or "breaking it down into small component parts," in order to avoid a determination that "the action is related to other actions with individually insignificant but cumulatively significant impacts." 40 C.F.R. § 1508.27(b)(7).

174. FDA impermissibly segmented its review of the effects of AquaBounty's GE salmon by considering production only at the Panama and Canada sites, when this approval is only the first step in the company's public plans to commercially develop their GE salmon. This cabined scope of review prevented FDA from properly considering the potentially significant environmental and ecological impacts associated with known and reasonably foreseeable connected, similar, and cumulative actions to expand production of AquaBounty's GE salmon in

other areas and at other sites, including the United States, Canada, Argentina, Chile, China, and other parts of the world, as previously and repeatedly announced by the company.

175. FDA claims that changes to the approved process for producing AquaBounty's GE salmon, including expansions, will be subject to the agency's supplemental application process; however the FDA's own regulations do not support the agency's position. In fact, pursuant to the existing regulations, the agency cannot assure that such changes will be subject to additional environmental analysis and public review, even if they have the potential to cause significant impacts. *See* 21 C.F.R. § 514.8. FDA's overly constrained review risks that the broader impacts of the AquaBounty approval may never be analyzed, and violates NEPA's fundamental requirement that such impacts be analyzed at the earliest possible time, and before the agency makes a decision with far-reaching environmental impacts.

176. For the reasons described above, FDA has violated NEPA and the EA and FONSI are invalid because they fail to adequately assess connected, cumulative, and similar actions.

177. By issuing an EA and FONSI that fail to meet the standards laid out in NEPA, its implementing regulations, and governing precedent, FDA has acted in a manner that is arbitrary, capricious, an abuse of discretion, and not in accordance with law, and without observance of procedures required by law, in violation of NEPA, 42 U.S.C. § 4332, its implementing regulations, and the APA. 5 U.S.C. §§ 701-706.

178. The actions and inactions of the Defendants described in this Cause of Action are causing injuries to the Plaintiffs, for which they have no adequate remedy at law.

FOURTH CLAIM FOR RELIEF
VIOLATION OF NEPA AND APA:
FAILURE TO ADEQUATELY EVALUATE CUMULATIVE EFFECTS

179. Plaintiffs re-allege, as if fully set forth, each and every allegation set forth in paragraphs 1 through 178 of this Complaint.

180. NEPA and its implementing regulations require the FDA to analyze the cumulative effects of its actions. 40 C.F.R. §§ 1508.25 (a)(2), (c); 1508.7; 1508.8. A cumulative impact is the "incremental impact of the action when added to other past, present, and reasonably foreseeable future actions regardless of what agency (Federal or non-Federal) or person

undertakes such other actions. Cumulative impacts can result from individually minor but collectively significant actions taking place over a period of time." 40 C.F.R. § 1508.7. The duty to comprehensively evaluate cumulative impacts is distinct from FDA's duty to evaluate connected, cumulative, and interdependent actions in a single NEPA analysis. *Earth Island Inst. v. Forest Service*, 351 F.3d at 1306 ("Even if a single, comprehensive EIS is not required, the agency must still adequately analyze the cumulative effects of the projects within each individual EIS.").

181. To satisfy NEPA's cumulative impacts mandates, FDA was required to consider the cumulative impacts of its approval of this single new animal drug application in combination with other actions, including but not limited to, AquaBounty's reasonably foreseeable plans to expand production of GE salmon; other GE fish in development; and any other actions that could affect the marine and freshwater environments impacted by FDA's approval, regardless of what agency or entity is responsible for those actions. This should also have included an analysis of other current threats to Atlantic and Pacific salmon stocks; and other socioeconomic threats to fishing communities and those dependent on healthy ocean ecosystems, such as impacts from existing industrial aquaculture, or habitat changes due to climate change and how these impacts accumulate with the impacts of the company's existing and/or reasonably foreseeable plans to expand production beyond the sites proposed in its application.

182. Instead of casting the wide net NEPA requires, FDA took an extremely narrow and unlawful view of what potential cumulative impacts it had to consider and analyze, concluding that because there are no other pending or reasonably foreseeable new animal drug applications for GE salmon, there is thus no need for a cumulative impacts analysis. By focusing solely on formal, similar, new animal drug applications, FDA has unlawfully refused to analyze or provide any information concerning the cumulative impacts of its decision to approve AquaBounty's application, as required by 40 C.F.R. § 1508.7.

183. For the reasons described above, FDA has violated NEPA and the EA and FONSI are invalid because they entirely fail to consider and/or to adequately assess the cumulative

effects of FDA's actions in conjunction with past, present, and reasonably foreseeable future actions.

184. By issuing an EA and FONSI that fail to meet the standards laid out in NEPA, its implementing regulations, and governing precedent, FDA has acted in a manner that is arbitrary, capricious, an abuse of discretion, not in accordance with law, and without observance of procedures required by law, in violation of NEPA, 42 U.S.C. § 4332, its implementing regulations, and the APA. 5 U.S.C. §§ 701-706.

185. The actions and inactions of the Defendants described in this Cause of Action are causing injuries to the Plaintiffs, for which they have no adequate remedy at law.

FIFTH CLAIM FOR RELIEF
VIOLATION OF NEPA AND APA:
ALTERNATIVES ANALYSIS VIOLATIONS AND IMPROPER PURPOSE AND NEED

186. Plaintiffs re-allege, as if fully set forth, each and every allegation set forth in paragraphs 1 through 185 of this Complaint.

187. NEPA and its implementing regulations require an agency to "[r]igorously explore and objectively evaluate all reasonable alternatives." 40 C.F.R. § 1502.14(a). *See also* 42 U.S.C. § 4332(C), (E); 40 C.F.R. § 1508.25. Indeed, the alternatives analysis to the proposed action is "the heart" of the NEPA process, and is intended to provide a "clear basis for choice among options by the decision-maker and the public." 40 C.F.R. § 1502.14. *See also* 42 U.S.C. § 4332(C)(iii), (E); 40 C.F.R. § 1508.25.

188. The scope of a NEPA alternatives analysis is a function of the "purpose and need" for the agency action under review. 40 C.F.R. § 1502.13. The purpose and need statement in the EA is unclear. On the one hand, FDA states that the purpose and need is limited to whether to approve AquaBounty's new animal drug application. On the other hand, FDA describes the purported need for this GE fish to help address the world-wide overfishing crisis, and the attendant decline in wild stocks, including Atlantic salmon populations, as well as address increasing demand for fish protein. FDA has either erroneously defined its purpose and need, failed to consider an adequate range of alternatives for its stated justifications, or both.

189. To the extent that FDA's purpose and need is limited to whether to approve AquaBounty's application, FDA either too narrowly defined the purpose and need to be limited to its statutory obligations to review and approve a new animal drug application, or failed to consider any alternatives that would condition its approval to better protect the environment. The only alternative FDA considered was denial of AquaBounty's application. FDA explained that it dismissed this "no action" alternative based on its belief that the FFDCA required approval of the GE salmon application so long as there are no specific grounds under the FFDCA to deny approval.

190. However, even under this restrictive iteration of the purpose and need, numerous alternatives to FDA's approval of AquaBounty's application were available, but FDA failed to adequately evaluate any of them. For example, FDA failed to adequately consider the inclusion of additional regulatory conditions on the approval to protect the environment and sensitive marine and freshwater areas affected by AquaBounty's application including temporal, process, facilities, and transport restrictions; limiting the volume of GE fish that could be grown at once; imposing more stringent monitoring, recordkeeping, or reporting requirements; requiring additional training or qualifications for workers; refusing to permit facilities beyond FDA's jurisdiction; or granting only a limited, pilot project. FDA also failed to consider any alternatives that would require concurrent review and approval/restrictions by other agencies with relevant expertise in fisheries biology, such as NMFS or FWS. 40 C.F.R. § 1502.14(c) (alternatives discussion shall "include reasonable alternatives not within the jurisdiction of the lead agency").

191. To the extent that the purpose and need for this action includes addressing the world-wide overfishing crisis, the agency arbitrarily considered the proposed GE salmon approval as the only potential solution. FDA failed to consider any other options that could feasibly, effectively, and safely improve the world's overstressed fisheries and meet the demand for fish protein without the environmental risks of GE salmon. Such alternatives were presented to the agency by commenters, including development of new projects and policies designed to support and expand sustainable commercial fishing or aquaculture practices; actions to protect

and restore native Atlantic salmon populations; and non-GE alternatives to developing "faster growing" salmon, such as that developed by SalmoBreed in Norway. FDA ignored all of these reasonable alternatives that would have satisfied its purpose and need.

192. NEPA requires agencies to consider "a range of reasonable actions which might meet goals of the agency by using different approaches that might reduce the environmental impacts of the agency's action." *See, e.g.*, *Soda Mountain Wilderness Council v. Norton*, 424 F. Supp. 2d 1241, 1265 (E.D. Cal. 2006). *See also* 40 C.F.R. § 1508.25(b) (requiring agency to consider other reasonable courses of action and that include mitigation measures not in proposed action). By considering only one alternative—approval of AquaBounty's application as presented—the agency failed to adequately consider other reasonable alternatives to the proposed action that could fulfill either articulation of the agency's purpose and need for the action.

193. FDA has violated NEPA and its EA and FONSI are invalid because they fail to rigorously explore and evaluate a full range of reasonable alternatives. FDA has acted in a manner that is arbitrary, capricious, an abuse of discretion, and not in accordance with law, and without observance of procedures required by law in violation of NEPA, 42 U.S.C. § 4322, its implementing regulations, and the APA. 5 U.S.C. §§ 701-706.

194. The actions and inactions of the Defendants described in this Cause of Action are causing injuries to the Plaintiffs, for which they have no adequate remedy at law.

SIXTH CLAIM FOR RELIEF
VIOLATION OF NEPA AND APA:
FAILURE TO PREPARE AN ENVIRONMENTAL IMPACT STATEMENT

195. Plaintiffs re-allege, as if fully set forth, each and every allegation set forth in paragraphs 1 through 194 of this Complaint.

196. NEPA requires federal agencies to prepare an EIS for all "major Federal actions significantly affecting the quality of the human environment." 42 U.S.C. § 4332(2)(C); 40 C.F.R. § 1501.4. Under certain circumstances, the agency can prepare an EA that provides "sufficient evidence and analysis for determining whether to prepare" an EIS and that contributes to the agency's compliance with NEPA. 40 C.F.R. §§ 1508.9; 1501.4.

197. Determining the significance of an action in an EA or elsewhere requires the agency to consider the intensity of the impact by evaluating factors enumerated at 40 C.F.R. § 1508.27(b), including, *inter alia*, the degree to which the action affects public health or safety; the degree to which the effects are likely to be highly controversial; the degree to which effects are highly uncertain or involve unique or unknown risks; whether the action establishes a precedent for future actions or represents a decision in principle about a future consideration; the degree to which the action may affect endangered or threatened species; and whether the action is related to actions with individually insignificant but cumulatively significant impacts.

198. As detailed above and in the preceding claims for relief, FDA's decision to approve the AquaBounty application to manufacture GE salmon and sell it in the United States is highly controversial; it involves uncertain, unique, and unknown risks; it is precedent-setting, as the first-ever GE animal for human consumption and first GE fish; it involves significant cumulative impacts; it involves unanalyzed connected, cumulative, and similar action; it poses risks to ecologically critical areas and to species protected under the Endangered Species Act; and it could adversely affect significant cultural and native resources, in the form of protected salmon stocks and traditional fisheries.

199. For these reasons, the plain language of NEPA, the CEQ regulations implementing NEPA, the FDA regulations implementing NEPA, and well-established precedent all require FDA to prepare an EIS before deciding whether to approve the AquaBounty application. 42 U.S.C. § 4332(2)(C); 40 C.F.R. §§ 1508.27; 1502.3; 21 C.F.R. § 25.42(b).

200. In 2011, Plaintiffs CFS, FoE, and FWW formally petitioned FDA to refrain from taking any final action on the AquaBounty application until FDA had completed an EIS. FDA denied the petition on the same day it issued the GE salmon approval.

201. By issuing an inadequate EA and FONSI instead of preparing an EIS and by denying several of the Plaintiffs' petition seeking an EIS, FDA has acted in a manner that is arbitrary, capricious, an abuse of discretion, not in accordance with law, and without observance of procedures required by law, in violation of NEPA, 42 U.S.C. § 4332, and the APA. 5 U.S.C. §§ 701-706.

202. The actions and inactions of the Defendants described in this Cause of Action are causing injuries to the Plaintiffs, for which they have no adequate remedy at law.

SEVENTH CLAIM FOR RELIEF
VIOLATION OF NEPA AND APA:
IMPROPER RELIANCE ON MITIGATION

203. Plaintiffs re-allege, as if fully set forth, each and every allegation set forth in paragraphs 1 through 202 of this Complaint.

204. NEPA requires agencies to disclose and analyze measures to mitigate the impacts of proposed actions. 40 C.F.R. §§ 1502.14(f); 1502.16(h). Here, FDA relies on AquaBounty's containment plan for the Prince Edward Island and Panama facilities to mitigate environmental risks associated with the escape of AquaBounty's GE salmon, but the agency has not actually established that these mitigation measures will effectively mitigate all potential significant risks, nor has it ensured compliance with the described mitigation measures through monitoring or other means.

205. Reliance on AquaBounty's purportedly sufficient mitigation measures is not a substitute for FDA compliance with NEPA's mandate to examine potential significant environmental impacts. An agency cannot rely on mitigation measures to avoid performing a detailed analysis of the environmental impacts of an action. *See, e.g., Northern Plains Resource Council v. Surface Transp. Bd.*, 668 F.3d 1067, 1085-86 (9th Cir. 2001). Here, FDA has improperly relied on AquaBounty's containment measures, and failed to analyze the potential impacts should/when any or all of those measures fail. Although it is standard scientific practice, FDA has not conducted a quantitative failure mode analysis to test the reliability of AquaBounty's various biological, geographical, and physical measures. Nor did FDA consider or analyze any alternative mitigation measures.

206. Mitigation must also be enforceable, including the on-going duty of the agency to monitor and ensure compliance. Yet FDA's FONSI depends in part on its reliance on containment and other mitigation measures developed by, and solely under the control of, AquaBounty. FDA has not explained how it will monitor continued compliance with the containment measures at either facility described in AquaBounty's application, or any other

facility that may foreseeably produce AquaBounty's GE salmon. This is particularly vital given AquaBounty's plans to expand production to various other sites around the world.

207. Courts examine mitigation measures to see whether such measures keep impacts below the EIS threshold, which sets a "low standard" for whether a project "may have a significant effect." *See, e.g.*, *Klamath Siskiyou Wildlands Center v. Boody*, 468 F.3d 549, 562 (9th Cir. 2006). FDA cannot use uncertain, unanalyzed, and unenforced mitigation to evade meeting the low EIS threshold and preparing an EIS.

208. FDA's reliance on mitigation provided by, and subject to the sole control of, AquaBounty was arbitrary, capricious, an abuse of discretion, not in accordance with law, and without observance of procedures required by law, in violation of NEPA, 42 U.S.C. § 4332, its implementing regulations, and the APA. 5 U.S.C. §§ 701-706.

209. The actions and inactions of the Defendants described in this Cause of Action are causing injuries to the Plaintiffs, for which they have no adequate remedy at law.

EIGHTH CLAIM FOR RELIEF
VIOLATION OF NEPA AND APA:
FAILURE TO COMPLY WITH NEPA FOR ITS GE ANIMAL PROGRAM

210. Plaintiffs re-allege, as if fully set forth, each and every allegation set forth in paragraphs 1 through 209 of this Complaint.

211. Under NEPA, all federal agencies must prepare an EIS on "every recommendation and report on proposals for legislation and other major federal actions significantly affecting the quality of the human environment." 42 U.S.C. § 4332(2)(C).

212. The definition of "major federal action" includes "adoption of programs, such as a group of concerted action to implement a specific policy or plan." 40 C.F.R. § 1508.18(b)(3). Agency polices are also "major federal action[s]." *Id.* §§ 1508.18, 1508.18(a) ("'Major federal action' includes … new or revised … policies"); 46 Fed. Reg. 18,026, 18,038 (Mar. 23, 1981) ("When are EISs required on policies, plans or programs? An EIS must be prepared if an agency proposes to implement a specific policy.").

213. NEPA regulations require agencies to prepare a programmatic EIS "for broad Federal actions such as the adoption of new agency programs or regulations." 40 C.F.R.

§ 1502.4(b). An agency "program" or "proposal" that exists in fact but is not necessarily declared by the agency still requires a programmatic EIS. *Id.* § 1508.23 (defining "proposal" to include that a "proposal may exist in fact as well as by agency declaration that one exists"). Such programmatic EISs should be undertaken "before the program has reached a stage of investment or commitment to implementation likely to determine subsequent development or restrict later alternatives." *Id.* § 1502.4(c)(3).

214. FDA has purported to create the regulatory framework for GE animal approvals under the FFDCA's new animal drug provisions in its 2009 GE Animal Guidance. FDA recently revised and reissued the GE Animal Guidance in June 2015. The GE Animal Guidance is a major federal action significantly affecting the human environment. FDA has not completed any NEPA analysis on the effects of the GE Animal Guidance framework.

215. FDA approved the first GE animal for human consumption pursuant to the GE Animal Guidance, the AquaBounty GE salmon, in November 2015. FDA's approval of the AquaBounty application marks the first GE animal commercially approved for human consumption commercial approval within this new, highly significant, and unprecedented program.

216. An EIS is particularly crucial here, when FDA is acting and purporting to establish and apply a new framework regarding novel GE organisms. FDA's continuing failure to prepare a programmatic EIS (or any other NEPA analysis) for its GE animal approval program, as purportedly established by its GE Animal Guidance, and as now concretely applied in its GE salmon approval, violates NEPA.

217. FDA's decision to create the GE animal program and then begin specific approvals without analyzing any of the impacts of its unprecedented program was arbitrary, capricious, an abuse of discretion, not in accordance with law, and without observance of procedures required by law, in violation of NEPA, 42 U.S.C. § 4332, its implementing regulations, and the APA. 5 U.S.C. §§ 701-706.

218. The actions and inactions of the Defendants described in this Cause of Action are causing injuries to the Plaintiffs, for which they have no adequate remedy at law.

NINTH CLAIM FOR RELIEF
VIOLATION OF THE FDA AMENDMENTS ACT AND APA:
FAILURE TO CONSULT WITH NOAA TO ANALYZE ALL RISKS PRESENTED BY THE GE SALMON

219. Plaintiffs re-allege, as if fully set forth, each and every allegation set forth in paragraphs 1 through 218 of this Complaint.

220. Section 1007 of the Federal Food and Drug Act Amendments of 2007 requires that FDA consult with NMFS to produce a report on any environmental risks associated with GE seafood products, including impacts on wild fish stocks. 21 U.S.C. § 2106.

221. FDA has not consulted with NOAA and produced the report, as Congress required. In response to comments on FDA's draft EA, FDA stated that any report associated with all GE seafood products would be impracticable because GE salmon is the only seafood product for which FDA has information concerning environmental risks. FDA thus concluded that the final EA and FONSI prepared in association with AquaBounty's application constitute the report required by Section 1007 of the FDA Amendments Act.

222. The final EA and FONSI do not meet the requirements of the FDA Amendments Act because they were not prepared in consultation with NMFS, as required by the statute. Further, the EA and FONSI do not adequately describe all the environmental risks associated with GE salmon or GE seafood products, as described above. FDA has thus failed to comply with Section 1007 of the FDA Amendments Act and must produce a report in consultation with NMFS.

223. FDA's decision that its EA and FONSI, prepared pursuant to NEPA, also fulfill its mandatory and independent duty to consult and issue a report under the FDA Amendments Act was arbitrary, capricious and contrary to law, in violation of the APA, 5 U.S.C. § 706(2).

224. FDA's failure to consult and produce the required report in the nine years since Congress required it, and in the interim, still approve the AquaBounty GE salmon without consulting and producing the required report also constitutes a "failure to act" pursuant to 5 U.S.C. § 551(13) and agency action unlawfully withheld and unreasonably delayed pursuant to 5 U.S.C. § 706(1), in violation of the APA.

225. The actions and inactions of the Defendants described in this Cause of Action are causing injuries to the Plaintiffs, for which they have no adequate remedy at law.

TENTH CLAIM FOR RELIEF
VIOLATION OF ESA:
FAILURE TO CONSULT REGARDING APPROVAL OF NEW ANIMAL DRUG APPLICATION FOR GE SALMON

226. Plaintiffs re-allege, as if fully set forth, each and every allegation set forth in paragraphs 1 through 225 of this Complaint.

227. Section 7(a)(2) of the ESA prohibits agency actions that jeopardize the survival of listed species or that destroy or adversely modify their critical habitat. 16 U.S.C. § 1536(a)(2). To assist in complying with this duty, federal agencies, like FDA, must consult with NMFS and FWS whenever they take an action that "may affect" a listed species or the species' critical habitat. *Id.*; 50 C.F.R. § 402.14(a).

228. The ESA and its implementing regulations broadly define agency action. 50 C.F.R. §§ 402.02; 402.03. FDA's approval of AquaBounty's new animal drug application constitutes "agency action" under ESA section 7(a)(2). *Id*.

229. Under the ESA, agency actions that "may affect" a listed species or critical habitat may not proceed unless and until the federal agency first ensures, through completion of the consultation process, that the action is not likely to cause jeopardy or adverse modification of critical habitat. 16 U.S.C. § 1536(a), (d); 50 C.F.R. §§ 402.14; 402.13. The threshold for a "may affect" determination and the required ESA section 7(a)(2) consultation is low. *See* 51 Fed. Reg. 19,926, 19,949 (June 3, 1986) ("Any possible effect, whether beneficial, benign, adverse or of an undetermined character, triggers the formal consultation requirement.").

230. As detailed above and as highlighted by fisheries biologists at both FWS and NMFS, the activities permitted by FDA's approval of the new animal drug application—including the breeding, transportation, and husbandry of GE salmon at the Prince Edward Island and Panama facilities and the reasonably foreseeable production of GE salmon production at other facilities—"may affect" listed species and their critical habitat by, *inter alia*, risking release of GE salmon that may: compete with listed wild salmon populations that inhabit or migrate in

areas near the facilities for food, space, and mates; cause genetic introgression and reduction in fitness by breeding with listed wild salmon; and spread disease to wild populations. These impacts satisfy the low threshold that the ESA, its implementing regulations, and the Services' Consultation Handbook set for a "may affect" determination.

231. FDA's determination that its action has "no effect" on listed salmon species fails to consider these impacts, improperly assumes that untested and unproven mitigation measures can address these impacts, and is not based on the best scientific and commercial data available about the risks posed by commercial production of GE salmon. FDA also based its determination on a limited definition of the scope of its action to include only effects directly associated with the production of GE salmon on Prince Edward Island and in Panama, ignoring AquaBounty's stated plans to expand its operations to additional facilities, both domestically and abroad. FDA likewise limited its analysis because it did not consider impacts to other threatened or endangered species aside from Atlantic salmon, including effects on listed Pacific salmon and other salmonids, like steelhead and trout.

232. FDA has violated the ESA by approving the new animal drug application for GE salmon without first completing consultation with NMFS and FWS regarding an action that "may affect" listed species and/or their critical habitat. FDA's failure to consult with the Services to insure that its action is not likely to jeopardize endangered or threatened species or adversely modify critical habitat violates the ESA, 16 U.S.C. § 1536(a)(2), its implementing regulations; and the APA, 5 U.S.C. §§ 701-706.

ELEVENTH CLAIM FOR RELIEF
VIOLATION OF ESA AND APA:
FWS'S DETERMINATION THAT CONSULATION WAS NOT REQUIRED IS ARBITRARY AND CONTRARY TO LAW

233. Plaintiffs re-allege, as if fully set forth, each and every allegation set forth in paragraphs 1 through 232 of this Complaint.

234. The ESA's implementing regulations allow an agency to pursue an optional informal consultation process for actions that "may affect" listed species. 50 C.F.R. § 402.13. If during that process the Services concur in writing with the agency's conclusion that an action is

"not likely to adversely affect" listed species, the consultation process is complete. *Id.* § 402.14(b)(1). If an agency concludes that its action has "no effect" on listed species—and thus that it need not engage in any consultation with the Services—it may not seek a written concurrence from the Services. The action agency is solely responsible for its compliance with the mandates of Section 7. 16 U.S.C. § 1536(a)(2).

235. By at least 2009, FDA initiated consultation with the Services regarding AquaBounty's new animal drug application. In August 2010, FDA sent the Services letters concluding that its approval of AquaBounty's application "may affect" but was "not likely to adversely affect" endangered Atlantic salmon populations.

236. In October 2010, based on input from FWS, FDA changed its previous conclusions. FDA informed FWS and NMFS that it had determined its approval of AquaBounty's new animal drug application would instead have "no effect" on listed species and terminated the consultation process.

237. On December 16, 2010, FWS sent a letter to FDA acknowledging the agency's "no effect" determination and purporting to concur in that determination.

238. Nothing in the ESA, its implementing regulations, or the Services' Consultation Handbook allows FWS to concur in an action agency's "no effect" determination. FWS lacks the authority to make any such determination under the ESA and its implementing regulations. 16 U.S.C. § 1536(a).

239. FWS's purported concurrence and complicity in FDA's "no effect" determination for an action that "may affect" listed species violates the ESA, 16 U.S.C. § 1536(a)(2), its implementing regulations, and the APA, 5 U.S.C. §§ 701-706.

TWELFTH CLAIM FOR RELIEF
VIOLATION OF THE FFDCA AND APA:
FAILURE TO ENSURE ENVIRONMENTAL SAFETY OF GE ANIMALS AND GE SALMON

240. Plaintiffs re-allege, as if fully set forth, each and every allegation set forth in paragraphs 1 through 239 of this Complaint.

241. FDA's new animal drug authority is directly tied to whether the drug is "safe and effective" for its intended use. 21 U.S.C. § 360b(b)(1). Under the FFDCA and FDA regulations, the review and approval of new animal drug applications is focused on the "safety and effectiveness" of the new animal drug. *See, e.g.*, 21 U.S.C. §§ 360b(a)(1); (b)(1)(H); (d)(1)-(2); (i); 21 C.F.R. §§ 514.1(b)(8); 514.105. FDA can only approve a new animal drug application for a drug that is "safe" under the prescribed or recommended conditions of the application. 21 U.S.C. § 360b(d). FDA's approval of GE salmon violated the FFDCA and was arbitrary and capricious because it failed to rationally consider all the factors relevant to ensuring that the GE salmon drug approval was safe for, *inter alia*, the environment.

242. The FFDCA does not limit the factors that FDA considers when evaluating whether a drug is safe and effective during review and approval of a new animal drug application and when exercising its ongoing enforcement authority over those applications. *See, e.g.*, 21 U.S.C. § 360b(d)(2). In its GE Animal Guidance and, as applied in its GE salmon approval, FDA has expressly interpreted the FFDCA to include environmental risks as a relevant factor when evaluating the safety and effectiveness of a drug.

243. Despite FDA's acknowledgment that it must consider environmental safety as part of its "safety and effectiveness" evaluation, the GE Animal Guidance fails to rationally explain what factors FDA will consider relevant to this determination and how FDA will weigh or consider such factors when it evaluates whether an application is "safe and effective" in its approvals and decisionmaking.

244. FDA does not detail or explain, for example, how it will assess and determine the environmental or ecological risks posed by GE animals, how or whether it will require adoption of measures or methods necessary to ensure that GE animals will not escape confinement, introduce or spread diseases, or otherwise contaminate wild populations or ecosystems. FDA

does not detail or explain what requirements, measures, or methods are necessary to mitigate or remediate any accidental release of GE animals into the environment or how it will require and enforce the adoption of such measures to ensure the continued safety of approved GE animals. Nor does FDA detail how it will weigh and combine these or other relevant factors in its decision that a new animal drug is "safe" for the environment. FDA's GE Animal Guidance was developed without full consideration of these and other factors relevant to environmental risk and fails to rationally explain how FDA will substantively consider environmental risk as part of its review and approval of new animal drug applications.

245. When purportedly applying this guidance to its review and approval of AquaBounty's GE salmon new animal drug application, FDA failed to ensure that AquaBounty's GE salmon was "safe and effective" under the FFDCA because it failed to adequately consider or evaluate all of the factors and evidence relevant to environmental safety. As described above, FDA's environmental safety evaluation of AquaBounty's GE salmon was legally flawed and scientifically inadequate, for at least the following reasons: (1) it failed to adequately assess the risks of escape or release of AquaBounty's GE salmon, and failed to encompass or meaningfully review the environmental and interrelated risks associated with such escape or release and; (2) it failed to consider the best scientific evidence available regarding the environmental risks of AquaBounty's GE salmon. As a result, FDA's conclusion that AquaBounty's GE salmon was "safe" was arbitrary and not based on a rational assessment of the factors relevant to environmental risks.

246. FDA's failure to consider and rationally explain how it will consider the factors relevant to environmental safety in its GE Animal Guidance is arbitrary and capricious, an abuse of discretion, and not in accordance with law, in violation of the APA, 5 U.S.C. §§ 701-706, and the FFDCA, 21 U.S.C. §§ 301-399(f).

247. In purportedly applying the GE Animal Guidance in its approval of the new animal drug application for GE salmon, FDA similarly failed to consider the factors relevant to the environmental safety of GE salmon and/or to rationally explain its conclusion that GE salmon is safe for the environment. FDA's conclusion that AquaBounty's GE salmon is "safe"

is arbitrary, capricious, an abuse of discretion, and not in accordance with law, in violation of the APA, 5 U.S.C. §§ 701-706, and the FFDCA, 21 U.S.C. §§ 301-399(f).

248. The actions and inactions of the Defendants described in this Cause of Action are causing injuries to the Plaintiffs, for which they have no adequate remedy at law.

THIRTEENTH CLAIM FOR RELIEF
VIOLATION OF APA, FDA MODERNIZATION ACT OF 1997:
THE 2009 AND 2015 GE ANIMAL GUIDANCE

249. Plaintiffs re-allege, as if fully set forth, each and every allegation set forth in paragraphs 1 through 248 of this Complaint.

250. Through the adoption of the GE Animal Guidance, and through the agency's subsequent revisions to that document, FDA has created a new program and regulatory framework for review and approval of GE animals under its new animal drug authority.

251. Under the APA, a "rule" is "the whole or a part of an agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy." 5 U.S.C. § 551(4). Rules generally must be promulgated with public notice, an opportunity for comment, consideration of and response to those comments, and must be codified in the Code of Federal Regulations. *Id.* § 553; 44 U.S.C. § 1510.

252. Under the Food and Drug Administration Modernization Act of 1997 (Modernization Act), FDA may issue guidance documents in certain limited circumstances, but must ensure that such guidance documents "shall not create or confer any rights for or on any person" and are not binding. 21 U.S.C. § 371(h)(1)(A)-(B).

253. FDA announced its decision to regulate GE animals under the new animal drug provisions of the FFCDA in its GE Animal Guidance, purportedly in accordance with the procedures in the Modernization Act. FDA did not publically notice its decision to apply the new animal drug provisions to GE Animals or the framework it developed for doing so as a regulation, the public did not comment on this decision as a binding regulation, and it is not codified in the Code of Federal Regulations.

254. The GE Animal Guidance is a de facto amendment to FDA's existing regulations for new animal drugs, which do not specifically extend or provide a framework for the approval

of GE animals, to include the review and approval of GE animals. 21 U.S.C. § 321(g)(1) (definition of "drug") and § 321(v) ("new animal drug"). The GE Animal Guidance does not qualify as "guidance" under the Modernization Act, and should have been promulgated as a rule, because it confers legal rights to entities seeking approval of GE animals and binds FDA to accept and review those applications.

255. According to FDA's practice and statements, development and adoption of the GE Animal Guidance was necessary before the agency could review and approve new animal drug applications for GE animals, including GE salmon. Prior to its promulgation, FDA could reject an application for approval of a GE animal (and its lineage) under the new animal drug provisions because GE animals were not considered "drugs." No regulatory pathway for GE animals existed and no GE animals were approved. After the Guidance, FDA now must accept and process such new animal drug applications, as evidenced by its approval, after the issuance of the Guidance, of new animal drug applications for GE Salmon, GE goats, GE chickens, and GE rabbits.[2]

256. While FDA did offer notice and comment on the GE Animal Guidance, its failure to offer such notice and comment in the APA formal rulemaking context deprived stakeholders, including Plaintiffs, of the formality and finality in FDA's determination and interpretation of its authority.

257. FDA's failure to promulgate its framework for regulating GE animals under the new animal drug provisions of the FFDCA as a rulemaking violates the Modernization Act and its implementing regulations, 21 U.S.C. § 371(h); 21 C.F.R. § 10.115; the APA, 5 U.S.C. §§ 553; 706(2)(A), (D); and the Federal Register Act, 44 U.S.C. § 1510.

258. The actions and inactions of the Defendants described in this Cause of Action are causing injuries to the Plaintiffs, for which they have no adequate remedy at law.

---

[2] FDA, *Genetically Engineered Animals*, http://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/GeneticEngineering/GeneticallyEngineeredAnimals/default.htm; FDA, *FDA approves first drug to treat a rare enzyme disorder in pediatric and adult patients*, http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm476013.htm; FDA, *FDA approves new product to treat rare genetic disease*, http://www.fda.gov/newsevents/newsroom/pressannouncements/ucm405526.htm.

PRAYERS FOR RELIEF

WHEREFORE, the Plaintiffs respectfully request that the Court:

1. Adjudge and declare that the FDA decision to approve the AquaBounty GE salmon and the GE Animal Guidance are not authorized by the FFDCA, and are instead *ultra vires* agency action, in violation of the FFDCA and the APA;

2. Issue an injunction requiring FDA to withdraw its assertion of jurisdiction over GE animals, and prohibiting FDA from asserting jurisdiction over, or initiating any rulemaking or enforcement proceedings based on any illegal assertion of jurisdiction over the manufacture, labeling, or marketing of GE animals;

3. Adjudge and declare that the FDA decision to approve the AquaBounty application, as well as the EA and FONSI issued by the FDA in connection with that approval, are in violation of the FFDCA, NEPA, the ESA and the APA;

4. Adjudge and declare that the FDA violated NEPA by failing to prepare a programmatic EIS or any other NEPA analysis for its development and adoption of the GE Animal Guidance, which establishes a policy and a de facto program for GE animal regulation by FDA that requires NEPA compliance;

5. Adjudge and declare that the FDA's failure to produce a report in consultation with NMFS studying all possible risks of the production of GE seafood, including GE salmon, is in violation of the FDA Amendments Act and the APA;

6. Adjudge and declare that the FDA GE Animal Guidance, on its face and as applied to GE salmon, is arbitrary and capricious in violation of the FFDCA, and the APA;

7. Declare that FDA is in violation of section 7(a)(2) of the ESA, 16 U.S.C. § 1536(a)(2), by failing to complete consultation necessary to ensure that its GE salmon approval is not likely to jeopardize the continued existence of listed species or destroy or adversely modify their critical habitat;

8. Declare that FWS is in violation of the ESA and in excess of its statutory authority by purporting to concur in FDA's conclusion that its approval of GE salmon would have "no effect" on listed species in violation of section 7(a)(2) of the ESA, 16 U.S.C. § 1536(a)(2);

9. Vacate the FDA decision to approve the AquaBounty application, enjoin the agency from taking any action pursuant to that decision, and order that the FDA comply with all requirements of NEPA, the ESA, and the APA, including preparing an EIS and engaging in consultation with the Services, in the event that the agency conducts a new review of that application;

10. Vacate the GE Animal Guidance and order FDA to undertake formal rulemaking procedures if the agency is to attempt to apply the FFDCA to GE animals, and order the FDA to first undertake an EIS on that program;

11. Award the Plaintiffs their fees, costs, expenses, and disbursements, including reasonable attorneys' fees, associated with this litigation under the Equal Access to Justice Act, 28 U.S.C. § 2412 and the Endangered Species Act, 16 U.S.C.§ 1540; and

12. Grant such further and additional relief as this Court deems just and proper.

Respectfully submitted this 30th day of March, 2016 in San Francisco, California.

/s/ Adam Keats

Adam Keats (CSB No. 191157)
George Kimbrell (*Pro Hac Vice pending*)
Center for Food Safety
303 Sacramento Street, 2nd Floor
San Francisco, CA 94111
T: (415) 826-2270 / F: (415) 826-0507
Emails: akeats@centerforfoodsafety.org
gkimbrell@centerforfoodsafety.org

Stephen D. Mashuda (*Pro Hac Vice pending*)
Earthjustice
705 Second Avenue, Suite 203
Seattle, WA 98104
T: (206) 343-7340 / F: (206) 343-1526
Email: smashuda@earthjustice.org

Brettny Hardy (*Pro Hac Vice pending*)
Earthjustice
50 California St, Suite 500
San Francisco, CA 94111
T: (415) 217-2142
Email: bhardy@earthjustice.org

Counsel for Plaintiffs