UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

INSTITUTE FOR FISHERIES RESOURCES, et al., Plaintiffs, v. SYLVIA MATHEWS BURWELL, et al., Defendants.	Case No. 16-cv-01574-VC **ORDER GRANTING MOTION TO DISMISS** Re: Dkt. No. 50

Under the Endangered Species Act and its implementing regulations, when a government agency is contemplating a particular action, it must consider whether that action could affect a species listed as threatened or endangered. 50 C.F.R. § 402.14(a). If the "action agency" determines that its proposed action will have "no effect" on a listed species, it has no obligation to consult with the Fish and Wildlife Service (which administers the Endangered Species Act with respect to terrestrial and freshwater species) or the National Marine Fisheries Service (which administers the Act with respect to marine species). *Pac. Rivers Council v. Thomas*, 30 F.3d 1050, 1054 (9th Cir. 1994). Conversely, if the agency determines that its actions "may affect" a listed species or critical habitat, it must consult with the relevant expert agency. Consultation will typically take one of two forms. First, the action agency and the expert agency might conduct "informal consultation," which is "an optional process that includes all discussions, correspondence, etc., between the Service and the Federal agency . . . designed to assist the Federal agency in determining whether" a more formal process is necessary. 50 C.F.R. § 402.13(a). "If during informal consultation it is determined by the Federal agency . . . that the action is not likely to adversely affect listed species or critical habitat," and the expert agency

issues a "written concurrence" in that conclusion, this ends the obligation to consult any further. *Id.* Otherwise, the agencies must typically engage in a more rigorous "formal consultation" to determine the impact of the proposed action on the species. *Id.* § 402.14(a).

This case involves the FDA's approval of a company's proposal to create a kind of genetically modified salmon. That approval process does not fit neatly into the regulatory scheme described above. The FDA initially determined that its contemplated approval of the genetically modified salmon "may affect" a listed species (a population of wild salmon), which triggered the requirement to consult with the Fish and Wildlife Service (because the wild salmon spend part of their lives in freshwater) and the National Marine Fisheries Service (because the wild salmon spend part of their lives at sea). But, according to the allegations in this lawsuit, while the FDA was communicating informally with these agencies, the Fish and Wildlife Service suggested that the FDA change its initial determination. Specifically, the Fish and Wildlife Service suggested that the FDA retract its "may effect" determination and conclude instead that approval of the genetically modified salmon would have "no effect" on the species. The FDA accepted this suggestion and concluded that approval of the genetically modified salmon would have no effect on the species. After reaching this new conclusion, the FDA sent letters to both the Fish and Wildlife Service and the National Marine Fisheries Service in which it shared its new "no effect" determination and asked the Services to respond. The Fish and Wildlife Service wrote back, stating: "your 'no effect' determination seems well supported." The National Marine Fisheries Service sent a letter acknowledging the FDA's "no effect" determination, without expressing any view on the merits of that determination.

The plaintiffs have sued the federal government to challenge the federal government's approval of the genetically modified salmon. They assert thirteen claims under several different statutes. Two of those claims are relevant here. Claim ten is brought against the FDA under the Endangered Species Act, and it challenges the FDA's determination, as the "action agency," that approval of the genetically modified salmon would have "no effect" on the endangered salmon. Claim eleven is brought against the Fish and Wildlife Service under the Administrative

Procedure Act (based on an alleged underlying violation of the Endangered Species Act), and it challenges the letter the Service sent to the FDA saying "your 'no effect' letter seems well supported."

The government agrees that the plaintiffs may pursue the tenth claim, but it moves to dismiss the eleventh claim on the ground that the Fish and Wildlife Service's letter was not "final agency action" within the meaning of 5 U.S.C. § 704. This motion is granted, and dismissal of the eleventh claim is with prejudice. As explained below, although the plaintiffs may turn out to be correct that the FDA's mid-stream "no effect" determination did not actually terminate its legal duty to consult with the expert agencies, that argument is properly pursued in connection with the tenth claim against the FDA, not the eleventh claim against the Fish and Wildlife Service.

As discussed at the outset, the relevant regulation says that an action agency has a duty to consult "if" a "may affect" determination "is made." 50 C.F.R. § 402.14(a). The regulation does not (at least explicitly) state that a subsequent "no effect" determination by the action agency absolves the agency of the requirement to complete consultation that was triggered by the initial "may effect" determination. Indeed, the regulation lists three ways for consultation to be terminated – none of which involves the action agency's decision to change a "may affect" determination to a "no effect" determination. *Id.* § 402.14(l)(1)-(3). Thus, one potential reading of the regulation is that, although an action agency can avoid the need for consultation by making a "no effect" determination at the outset, the action agency cannot end its duty to consult by changing a "may affect" determination to a "no effect" determination mid-stream. In other words, it may be that once there was enough uncertainty to have caused the action agency to conclude that its proposed action may indeed affect a listed species, the agency may not proceed with the proposed action until it completes consultation with the expert agency. As a practical matter, this would mean that even if the action agency wishes it had never made a "may effect" determination in the first place, once it does so it must either: (i) engage in "formal consultation" with the expert agency; or (ii) obtain "written concurrence" from the expert agency "that the

proposed action is not likely to adversely affect any listed species or critical habitat." *Id.* § 402.14(b)(1).

But there is no need to decide, in the context of the motion to dismiss the plaintiffs' eleventh claim against the Fish and Wildlife Service, whether the regulations preclude an action agency from terminating its consultation obligation by taking back its initial determination that its proposed action "may effect" the listed species. Whether or not it was allowed to do so as a legal matter, as a practical matter the FDA's "no effect" determination ended the consultation that is contemplated by the regulations. To qualify as informal consultation, inter-agency dialogue must be "designed to assist the [action] agency in determining whether formal consultation or a conference is required." *Id.* § 402.13(a). Here, the FDA had already made a "no effect" determination, and necessarily concluded as a result that consultation would not be required. The FDA then sought advisory opinions from the National Marine Fisheries Service and the Fish and Wildlife Service, and the agencies responded in different ways, with the former declining to give advice and the latter stating that "your 'no effect' determination seems well supported." But neither response was final agency action, because they were "purely advisory" and lacked "direct and appreciable legal consequences." *Bennett v. Spear*, 520 U.S. 154, 178 (1997). And because the Fish and Wildlife Service's response was not final agency action, the plaintiffs may not challenge it under the Administrative Procedure Act.

It's unclear why the Fish and Wildlife Service would want to dissuade an action agency from its conclusion that a proposed action "may affect" a species, as occurred here. Perhaps the Service (or someone in the Service) concluded that the FDA was being overcautious in its "may affect" determination, and wanted to find a way to avoid the Service's obligation to complete consultation. But even in situations where the Service, through informal consultation with the action agency, determines that the action agency never ought to have initiated consultation in the first place, the regulation seems to give the Service the ability to dispose of the matter promptly and efficiently – namely, by providing a "written concurrence" that "that the proposed action is not likely to adversely affect any listed species or critical habitat." *Id.* § 402.14(b)(1). This

eliminates the need for "formal consultation" and allows the action agency to go on its way. In this case, by instead suggesting informally that the FDA change its "may effect" determination to a "no effect" determination, the Service prompted the FDA to act in a way that may have violated the applicable regulations. In other words, it's possible the Fish and Wildlife Service got the FDA into some trouble. But that is a question to be answered at summary judgment in connection with the tenth claim, where the plaintiffs may argue that the FDA's "no effect" determination was arbitrary and capricious, FAC ¶ 236, and that the regulations prohibited the FDA from acting without "completing [the] consultation" it had begun through its "may affect" determination, FAC ¶ 237. And of course, the government will have the opportunity to propose an alternative reading of the regulation.[1]

IT IS SO ORDERED.

Dated: August 30, 2016

VINCE CHHABRIA
United States District Judge

[1] At oral argument, counsel for the government asserted that the plaintiffs should not be permitted to submit evidence outside the FDA's administrative record for purposes of the plaintiffs' Endangered Species Act claim against the FDA. Although the government is free to make that argument if it wishes, it should be aware that the Ninth Circuit has held that courts "may consider evidence outside the administrative record for the limited purposes of reviewing" claims arising directly under the Endangered Species Act. *W. Watersheds Project v. Kraayenbrink*, 632 F.3d 472, 497 (9th Cir. 2011).