

PUBLISHED

**UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT**

DOW AGROSCIENCES LLC;
MAKHTESHIM AGAN OF NORTH
AMERICA, INC.; CHEMINOVA, INC.
USA,

Plaintiffs-Appellants,

v.

NATIONAL MARINE FISHERIES
SERVICE; ERIC C. SCHWAAB,

Defendants-Appellees.

No. 09-1968

Appeal from the United States District Court
for the District of Maryland, at Greenbelt.
Alexander Williams, Jr., District Judge.
(8:09-cv-00824-AW)

Argued: October 27, 2010

Decided: March 2, 2011

Before NIEMEYER, SHEDD, and AGEE, Circuit Judges.

Reversed and remanded by published opinion. Judge Niemeyer wrote the opinion, in which Judge Shedd and Judge Agee joined.

COUNSEL

ARGUED: Christopher Landau, KIRKLAND & ELLIS, LLP, Washington, D.C., for Appellants. Robert Parke Stockman, UNITED STATES DEPARTMENT OF JUSTICE, Washington, D.C., for Appellees. **ON BRIEF:** David B. Weinberg, Eric Andreas, WILEY REIN LLP, Washington, D.C.; David Menotti, Warren U. Lehrenbaum, PILLSBURY WINTHROP SHAW PITTMAN LLP, Washington, D.C.; Michael D. Shumsky, KIRKLAND & ELLIS, LLP, Washington, D.C., for Appellants. Ignacia S. Moreno, Assistant Attorney General, Andrew C. Mergen, Michael T. Gray, Meredith L. Flax, Pamela B. Lawrence, Environmental & Natural Resources Division, UNITED STATES DEPARTMENT OF JUSTICE, Washington, D.C., for Appellees.

OPINION

NIEMEYER, Circuit Judge:

The question presented by this appeal is whether a "biological opinion" issued by the National Marine Fisheries Service to the Environmental Protection Agency (EPA) pursuant to the Fisheries Service's consulting role under the Endangered Species Act is subject to judicial review in the district court under the Administrative Procedure Act (APA), 5 U.S.C. § 704. The Fisheries Service, which provided the biological opinion to the EPA as part of the EPA's process of reregistering for sale and use the insecticides chlorpyrifos, diazinon, and malathion, concluded that the insecticides will destroy or harm Pacific salmonids and their habitat.

Pesticide manufacturers who hold the registrations for those insecticides commenced this action to challenge the biological opinion. The district court dismissed the action, concluding that the biological opinion is not reviewable under the

APA because the EPA has not yet acted on the biological opinion and when it does issue a final order on whether to reregister the insecticides, the order, including the biological opinion, will be subject to judicial review in a court of appeals, as authorized in the Federal Insecticide, Fungicide, and Pesticide Act (FIFRA), 7 U.S.C. § 136n.

In this appeal from the district court's dismissal order, we conclude that, under *Bennett v. Spear*, 520 U.S. 154 (1997), the Fisheries Service's biological opinion is a final agency action and that deferring judicial review of the biological opinion until the EPA acts on reregistration of the insecticides would not provide the manufacturers adequate review of the biological opinion. Accordingly, we conclude that the Fisheries Service's biological opinion is judicially reviewable under § 704 of the APA. We reverse and remand for further proceedings in the district court.

I

The issue whether the Fisheries Service's biological opinion is reviewable in court under § 704 of the APA or is only reviewable in a court of appeals after the EPA issues an order on the reregistration of the three insecticides at issue, as authorized by FIFRA, 7 U.S.C. § 136n, can better be resolved with an understanding of the interaction of two statutory schemes—the Endangered Species Act of 1973 (ESA) and FIFRA. If FIFRA provides adequate judicial review of a biological opinion issued by the Fisheries Service to the EPA, then judicial review under the APA is unavailable. *See* 5 U.S.C. § 704 (authorizing judicial review if there is "no other adequate remedy in a court").

A

Congress enacted the ESA "to conserve endangered species and threatened species," 16 U.S.C. § 1531(c)(1), and to that end the ESA requires each federal agency in carrying out its

functions to "insure" that its 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 habitat" deemed critical to such species, *id.* § 1536(a)(2). The Act requires that the Secretary of the Interior publish a list of those species that the Secretary determines to be endangered or threatened. *Id.* § 1533(c)(1). The Act also makes it unlawful for any person to "take" any endangered species, meaning to "harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, or collect" the species. *Id.* § 1538(a)(1)(B); *id.* § 1532(19).

When a federal agency's action is likely to jeopardize the existence of any endangered species, the agency is required to consult or confer with the Secretary of the Interior to engage in a process under which the Secretary provides an opinion evaluating the agency's actions under the ESA. *Id.* § 1536(a). Consultation and conferral with the Secretary require that the agency, called the "acting agency," interact with either the National Marine Fisheries Service or the U.S. Fish and Wildlife Service as "the consulting agency," depending on the species or habitat involved. 50 C.F.R. §§ 402.01, 402.14. The consulting agency is then required to review all relevant information, to make evaluations of the acting agency's proposed actions and the effects of its actions on the species or its habitat, and to issue a "biological opinion" ("BiOp") as to whether the agency's proposed action "is likely to jeopardize the continued existence of listed species or result in the destruction or adverse modification of critical habitat." 50 C.F.R. § 402.14(g)(4), (h). The consulting agency's issuance of a BiOp terminates the formal consultation between the acting agency and the consulting agency. 50 C.F.R. § 402.14(i).

The acting agency may then take under advisement the consulting agency's recommendations, as stated in the BiOp, and decide how to proceed. If the acting agency chooses to comply with the terms and conditions of the BiOp, the acting agency and its employees become exempt from prosecution

for any violation of the ESA, thus providing a "safe harbor." 16 U.S.C. § 1536(o)(2). The safe harbor also protects applicants for registration of pesticides or holders of those registrations. The acting agency may also choose not to comply with the BiOp. But in any event, the acting agency is not free to alter either the BiOp, which is the final decision of another agency, or the safe harbor created by the BiOp. *See Bennett*, 520 U.S. at 169-70.

B

The acting agency in this case is the EPA in its capacity as the Administrator of FIFRA.

FIFRA provides that "no person in any State may distribute or sell to any person any pesticide that is not registered [with the EPA] under this subchapter." 7 U.S.C. § 136a(a). The EPA is required to register a pesticide if it determines that

- (A) [the pesticide's] composition is such as to warrant the proposed claims for it;
- (B) its labeling and other material required to be submitted comply with the requirements of this subchapter;
- (C) it will perform its intended function without unreasonable adverse effects on the environment; and
- (D) when used in accordance with widespread and commonly recognized practice it will not generally cause unreasonable adverse effects on the environment.

Id. § 136a(c)(5). And FIFRA prohibits manufacturers from selling or distributing a registered pesticide in a manner inconsistent with the registration. *Id.* § 136j.

To ensure that registrations are up to date, 1988 amendments to FIFRA require the EPA to reregister any pesticide that was first registered before November 1, 1984. 7 U.S.C. § 136a-1(a). In the reregistration process, the EPA examines data to determine whether registered pesticides still meet FIFRA's requirements, including the requirements that the pesticide perform without "unreasonable adverse effects" on the environment. If a registrant fails to conform to the reregistration process or no longer meets the requisite criteria, the EPA may deny reregistration and cancel the registration. *Id.* §§ 136a-1, 136d. Thus, whenever the EPA determines that a pesticide or its labeling does not comply with the provisions of FIFRA or "when used in accordance with widespread and commonly recognized practice, [the pesticide] generally causes unreasonable adverse effects on the environment," the EPA can cancel the pesticide's registration. *Id.* § 136d(b).

FIFRA provides for judicial review of the EPA's pesticide registration decisions. 7 U.S.C. § 136n. If the EPA issues an order following a public hearing, its order is reviewable exclusively in the courts of appeals. If, however, the EPA has not issued an order following a hearing, its inaction is reviewable in the United States district courts. *Id.*

II

Chlorpyrifos was first registered in 1965; diazinon, in 1956; and malathion, in 1956. Accordingly, under FIFRA's 1988 amendments requiring the reregistration of pesticides registered before November 1, 1984, these insecticides became subject to reregistration by the EPA.

In January 2001, several environmental groups filed a suit against the EPA in the Western District of Washington, alleging that the EPA was violating the ESA by failing to consult with the Secretary of the Interior with respect to the EPA's reregistration and continuing approval of 54 active ingredients in pesticides, including the three insecticides involved in this

case. The district court agreed with the plaintiffs and ordered the EPA to initiate consultation with the National Marine Fisheries Service in connection with the pesticide ingredients. *Wash. Toxics Coalition v. EPA*, Civ. No. 01-132, 2002 WL 34213031 (W.D. Wash. July 2, 2002). Accordingly, in December 2004, the EPA initiated formal consultation with the Fisheries Service on 37 active pesticide ingredients, including chlorpyrifos, diazinon, and malathion, having concluded that they "may affect" listed Pacific salmonid species and their habitats.

When the Fisheries Service failed for several years to issue its BiOps pursuant to the EPA's formal consultation, an environmental group filed suit in the Western District of Washington to require the Fisheries Service to issue its BiOps, as required by the ESA. *See Northwest Coalition for Alternatives to Pesticides v. Nat'l Marine Fisheries Serv.*, Civ. No. 07-1791 (W.D. Wash. filed Nov. 5, 2007). The Fisheries Service settled the suit on July 30, 2008, by agreeing to issue its first BiOp within 90 days. One day after the settlement agreement, the Fisheries Service issued a draft of its first BiOp, which addressed the effects of chlorpyrifos, diazinon, and malathion. The draft concluded that these insecticides would jeopardize critical habitat and prey for "evolutionarily significant units" of 28 Pacific salmonid species that are listed as endangered or threatened. Shortly after issuing the draft BiOp, the Fisheries Service opened an online docket to enable persons to comment on the draft until September 15, 2008. On November 18, 2008, it issued its final BiOp on the three insecticides.

The final BiOp concluded that chlorpyrifos, diazinon, and malathion would jeopardize numerous salmonid species and adversely affect critical habitat for them. Specifically, it found that the exposure to these pesticides will kill salmonids and, even at low exposure levels, will reduce salmonid growth, reduce the availability of prey, and impair salmonids' swimming and olfactory senses. In short, the Fisheries Service's BiOp concluded that reregistration of the insecticides would

jeopardize the survival of 27 of 28 listed salmonid species and adversely affect the critical habitat of 25 of the 26 species for which critical habitat had been designated. The BiOp, however, recommended a "reasonable and prudent alternative" to the current registrations by (1) requiring setbacks for the application of insecticides that would be 500 feet away from salmonid habitats for ground applications and 1,000 feet for aerial application; (2) limiting application in high wind; (3) requiring a 20-foot strip of vegetation near surface waters connected to salmonid habitats; (4) requiring regular reports concerning fish mortality; and (5) limiting application when soil moisture is, or is likely to become, high. The BiOp also issued an "Incidental Take Statement" requiring that the EPA implement a Fisheries Service approved effectiveness monitoring plan.

Upon the Fisheries Service's issuance of the final BiOp, the formal consultation between the EPA and the Fisheries Service ended. *See* 50 C.F.R. § 402.14(1).

The EPA has yet to release its decision on the reregistration of chlorpyrifos, diazinon, and malathion. But it has advised the Fisheries Service by letter that it intends to implement only some of the Fisheries Service's proposed label changes and to adopt its own buffer requirements, which the EPA stated would accomplish the Fisheries Service's goals. *See* Letter from Richard P. Keigwin, Jr., Director, Special Review and Reregistration Division, U.S. EPA, to James H. Lecky, Director, Office of Protected Resources, Nat'l Marine Fisheries Service (Sept. 10, 2009), *available at* <http://www.epa.gov/oppfead1/endanger/litstatus/wtc/>.

Dow AgroSciences LLC, Makhteshim Agan of North America, Inc., and Cheminova, Inc. USA, manufacturers of pesticides and holders of registrations for chlorpyrifos, diazinon, and malathion (collectively, "Pesticide Manufacturers"), commenced this action in the district court against the National Marine Fisheries Service under § 704 of the APA to

obtain judicial review of the Fisheries Service's final BiOp governing chlorpyrifos, diazinon, and malathion. In their complaint, the Pesticide Manufacturers allege that the Fisheries Service did not comply with the ESA's mandate that its BiOp be based on the "best scientific and commercial data available," 16 U.S.C. § 1536(a)(2). They allege that the Fisheries Service ignored superior scientific studies submitted by them and supported by the EPA. Additionally, they allege that the Fisheries Service accelerated the timeline for issuing the final BiOp, causing the agency not to address material comments submitted in response to the draft BiOp.

On the motion of the Fisheries Service, the district court dismissed the action for lack of jurisdiction. *Dow Agro-Sciences LLC v. National Marine Fisheries Service*, 638 F. Supp. 2d 508 (D. Md. 2009). The court concluded

In the case before this Court the Biological Opinion was prepared during an EPA licensing proceeding under FIFRA. If the EPA relies on the Biological Opinion and seeks to cancel Plaintiffs' pesticide registrations, EPA will have to issue an order under FIFRA. Any such order could only be challenged in a federal court of appeals.

* * *

As the federal courts of appeals have exclusive jurisdiction over FIFRA orders, the Court finds that it does not have jurisdiction over matters that could directly affect the exclusive jurisdiction.

Id. at 513. From the entry of that July 29, 2009 order, the Pesticide Manufacturers timely filed this appeal.

III

The Pesticide Manufacturers contend that the Fisheries Service's BiOp was a final agency action, as the term is used in

the APA, that is subject to judicial review in the district court. *See* 5 U.S.C. § 704. They argue that the BiOp was the "consummation of the [Fisheries Service's] decisionmaking process" and has "direct and appreciable legal consequences," *Bennett v. Spear*, 520 U.S. 154, 177-78 (1997) (internal quotation marks omitted).

The National Marine Fisheries Service contends that even if the BiOp is a final agency action, it would be reviewable in a district court under the APA only if there were "no other adequate remedy in a court." 5 U.S.C. § 704. The Fisheries Service claims that in this case "there will be adequate review of the BiOp by the court of appeals on review of any decision by the EPA to cancel or alter the registrations as provided by FIFRA's special statutory jurisdictional provision," 7 U.S.C. § 136n. It maintains, accordingly, that judicial review now in the district court is not authorized by the APA.

Section 704 of the APA provides that "final agency action for which there is no other adequate remedy in a court [is] subject to judicial review." 5 U.S.C. § 704 (emphasis added). Thus we must determine (1) whether a BiOp is a final agency action, and (2) whether there is another adequate remedy in a court for review of the BiOp.

On the first question, the Supreme Court has held that a BiOp is a final agency action. First, it "mark[s] the 'consummation' of the agency's decisionmaking process"—the Fisheries Service's work as a consulting, specialist agency. *Bennett*, 520 U.S. at 178 (quoting *Chicago & Southern Air Lines, Inc. v. Waterman S.S. Corp.*, 333 U.S. 103, 113 (1948)). Second, it determines "rights or obligations" or is an action from which "legal consequences will flow." *Id.* (quoting *Port of Boston Marine Terminal Ass'n v. Rederiaktiebolaget Transatlantic*, 400 U.S. 62, 71 (1970)). Specifically addressing the legal consequences of a BiOp, the Court stated:

[The action agency] runs a substantial risk if its (inexpert) reasons turn out to be wrong. A Biological

Opinion of the sort rendered here alters the legal regime to which the action agency is subject. . . . [T]he Biological Opinion's Incidental Take Statement constitutes a permit authorizing the action agency to "take" the endangered or threatened species so long as it respects the Service's "terms and conditions." The action agency is technically free to disregard the Biological Opinion and proceed with its proposed action, but it does so at its own peril (and that of its employees) for "any person" who knowingly "takes" an endangered or threatened species is subject to substantial civil and criminal penalties, including imprisonment.

520 U.S. at 169-70; *see also id.* at 178 ("[T]he Biological Opinion and accompanying Incidental Take Statement alter the legal regime to which the action agency is subject, authorizing it to take the endangered species if (but only if) it complies with the prescribed conditions"). Applying *Bennett*, we conclude that the Fisheries Service's BiOp was a final agency action.

On the second question, whether there is another adequate remedy in a court for review of the BiOp, FIFRA does provide for judicial review in the court of appeals of "any order issued *by the Administrator* [the EPA] following a public hearing." 7 U.S.C. § 136n(b) (emphasis added). But because a BiOp is not an "order issued by the Administrator [the EPA]," the plain language does not provide *statutory* support for an argument that a BiOp issued *by the Fisheries Service* can be subject to judicial review as part of the FIFRA Administrator's decision.

Nonetheless, an exclusive judicial review provision applies to "all issues inhering in the controversy." *City of Tacoma v. Taxpayers of Tacoma*, 357 U.S. 320, 336 (1958). Thus, if a challenge to the BiOp inheres in the challenge to a final EPA order under FIFRA, it would be reviewable under FIFRA's

judicial review provisions. We conclude, however, that a challenge to the adequacy of the Fisheries Service's BiOp is not an issue inherent in the EPA's eventual order on the reregistration of the three insecticides under FIFRA. There are several reasons that support this conclusion.

First, the BiOp has immediate and independent legal consequences that cannot be changed on later review of the EPA's action on reregistration, even if the EPA relies on the BiOp. The EPA's reregistration of pesticides involves a broad array of different issues relating to whether the pesticides perform as claimed, their labeling, and their effect on the environment. *See* 7 U.S.C. § 136a(c)(5). Even though the EPA must also consider a BiOp, it cannot change it or modify it. *See Bennett*, 520 U.S. at 169-70. The BiOp is the final action of the Fisheries Service that determines whether the use of certain pesticides will jeopardize an endangered or threatened species or adversely affect their habitats. To issue a BiOp, the Fisheries Service develops its own record and makes its own findings.

In this case, the Fisheries Service concluded that the use of chlorpyrifos, diazinon, and malathion "is likely to jeopardize the continued existence" of Pacific salmonids and "is likely to destroy or adversely modify" their habitats. The Fisheries Service conditioned any further use of chlorpyrifos, diazinon, and malathion on modifications in their use that were significant. The conditions require that the insecticides not be applied in specified areas near salmonid habitats and that they not be applied anywhere when certain weather factors exist. The conditions also require that any person applying the insecticides report "all incidents of fish mortality that occur within four days of application."

Most importantly, the BiOp creates a safe harbor *for all persons*. *See* 16 U.S.C. § 1536(o)(2). If a person, including a government employee, knowingly "takes" an endangered or threatened species, that person is subject to civil and criminal

penalties. If, however, a person "takes" a protected species while complying with the BiOp's terms, that person is insulated from liability. Thus, as the Supreme Court has noted, while a BiOp does not create a legally binding prohibition, "[i]n reality [the BiOp] has a powerful coercive effect." *Bennett*, 520 U.S. at 169. As the Court explained, the action agency would "very rarely choose" to act contrary to the Fisheries Service's recommendation, and if it did so, it would do so "at its own peril (and that of its employees)," because in doing so it would lose statutory immunity and expose itself to the civil and criminal penalties, including imprisonment. *Id.* at 170. As the Court pointed out, "The [Fisheries] Service itself is, to put it mildly, keenly aware of the virtually determinative affect of its biological opinions." *Id.*

In this way, therefore, any continued use of chlorpyrifos, diazinon, and malathion is subject to the Fisheries Service's BiOp, which "alters the legal regime to which the action agency [and the Pesticide Manufacturers] is subject," *Bennett*, 520 U.S. at 169, and the safe harbor from liability under the ESA is finally and exclusively defined by the BiOp, not by the EPA's final reregistration decision under FIFRA.

Second, if the EPA were to choose not to rely on the Fisheries Service's BiOp, then the BiOp would not be subject to any review in a judicial proceeding challenging the FIFRA reregistration order. Yet, the BiOp would still exist, having significant legal consequences, as we have noted, because it makes final findings and defines the safe harbor from civil and criminal liability. Thus, after the EPA's reregistration decision, the Pesticide Manufacturers would still be governed in part by the BiOp. If the Pesticide Manufacturers took an action that complied with the EPA's reregistration decision, but did not comply with all of the terms of the BiOp, they would not be protected by the BiOp's safe harbor. In such a situation, the Pesticide Manufacturers would still be subject to the legal consequences for "taking" a protected species as

defined by the ESA. Only the BiOp protects persons from liability.

Third, when a court of appeals reviews the EPA's *reliance on a BiOp* issued by the Fisheries Service, the court's review would not be the same as if the district court were to review the BiOp itself directly under the APA. When a court of appeals reviews the EPA's reliance on a BiOp, it would determine only whether *the EPA's reliance* was arbitrary and capricious. But only by direct judicial review by the district court under the APA could the BiOp's findings and conclusions themselves be challenged. *See City of Tacoma v. FERC*, 460 F.3d 53, 75 (D.C. Cir. 2006) ("[W]hen we are reviewing the decision of an action agency to rely on a BiOp, the focus of our review is quite different than when we are reviewing a BiOp directly. In the former case, the critical question is whether the action agency's reliance was arbitrary and capricious, not whether the BiOp itself is somehow flawed"). As the court in *City of Tacoma* explained, while the remedy flowing from the EPA's inappropriate reliance could result in reversal of the EPA's reregistration, because the EPA had no authority or requirement to address the adequacy of the BiOp itself, there could never be a basis for the reviewing court to vacate the BiOp. The BiOp would remain as the final action of the Fisheries Service which would persist in shaping the legal regime under which both the action agency and the Pesticide Manufacturers thereafter function. As the Supreme Court observed, the Fisheries Service's BiOp would remain "virtually determinative." *See Bennett*, 520 U.S. at 170.

Fourth, if the EPA were to choose to follow the Fisheries Service's BiOp, any challenge to the EPA's reliance on the BiOp on judicial review could not itself cause the EPA to alter the BiOp. The EPA does not have that authority, and the Fisheries Service would not be a party to the proceeding. The only issue that could be reviewed would be the reasonableness of *the EPA's reliance* on the BiOp. Even if a court were to find that the EPA's reliance was arbitrary and capricious

because of an unreasonable or unsupportable BiOp, the remedy would relate only to reregistration; the BiOp's final findings and definition of the safe harbor would continue to be in effect as final agency action, *see* 50 C.F.R. § 401.14(1), and its legal consequences could still not be altered, regardless of the EPA's reregistration order. *See Bennett*, 520 U.S. at 169-70.

Fifth, the plain language of FIFRA's judicial review provisions does not contain "clear and convincing evidence" that Congress intended FIFRA's judicial review provisions to govern review of a BiOp issued by a different agency—the Fisheries Service, which is within the Department of Commerce. *See Abbott Labs. v. Gardner*, 387 U.S. 136, 141 (1967) (requiring "clear and convincing evidence" that Congress intended to restrict judicial review). Because there is a strong presumption that Congress intends to allow for judicial review of final agency actions, *see Bowen v. Michigan Academy of Family Physicians*, 476 U.S. 667, 670 (1986), BiOps therefore should be subject to judicial review under the APA. Not only does FIFRA's language not provide clearly for judicial review of BiOps, but also any review under FIFRA would be restricted to the EPA's reliance on the BiOps and then only to those portions on which the EPA relies.

In sum, the BiOp in this case was the final agency action of the Fisheries Service, which has ongoing legal consequences, and it could not be altered, modified, or changed by the EPA during its registration process under FIFRA. In some circumstances, the BiOp might not even be considered by the EPA, leaving review under the APA as the only avenue for judicial review. And if the EPA followed the BiOp, only the EPA's action in relying on the BiOp, not the adequacy of the BiOp itself, could be reviewed. In these circumstances, a challenge to an EPA order on registration does not provide an adequate judicial review of the BiOp.

The circumstances of this case and the statutory roles of the agencies involved distinguish this case from those in which

agency actions have been found to inhere in final agency actions. For example, in *Telecommunications Research & Action Ctr. v. FCC*, 750 F.2d 70, 75 (D.C. Cir. 1984), the D.C. Circuit held that resolution of or challenge to an agency's unreasonable delay in making a decision inhered in that agency's final action because the nonfinal nature of the delay indicated that the process in reaching a decision was a part of decisionmaking and could not be reviewed independently. See also *Taxpayers of Tacoma*, 357 U.S. at 336 (characterizing "all objections to the order, to the license it directs to be issued, and to the legal competence of the licensee to execute its terms" as issues inhering in an order). By contrast, a Fisheries Service's BiOp and the EPA's final order under FIFRA are two distinct final agency actions. While the BiOp might become part of the EPA's ruling, the EPA proceeding could not reopen and modify the BiOp, especially when the Fisheries Service would not be a party to the proceeding.

The Fisheries Service relies on *City of Tacoma v. FERC*, 460 F.3d 53 (D.C. Cir. 2006), to argue that a BiOp is subject to exclusive judicial review under the provision provided for EPA orders in administering FIFRA. In *City of Tacoma*, the D.C. Circuit reviewed a challenge to a FERC licensing process in which the plaintiff alleged that FERC relied on flawed BiOps in its decisionmaking. The D.C. Circuit allowed review of the BiOps in the course of review of FERC's action, even though the proceeding was challenging only FERC's final action in relying on the BiOps. *Id.* at 76. While we do not determine here whether to follow this decision, any precedential value it might provide is limited to a discussion of whether a court of appeals could expand the permissive scope of review when reviewing an acting agency's action to include review of the BiOp itself. But a ruling providing for such an expansion of judicial review does not *preclude* judicial review of a BiOp under the APA in other procedural circumstances.

The procedural posture in this case is different from that in *City of Tacoma*, where reliance on the BiOp was challenged

in connection with the acting agency's final order. In the procedural posture presented here, where judicial review of a BiOp itself is sought prior to the acting agency's final action, courts have allowed for judicial review of the BiOp, as we do here. *See Miccosukee Tribe v. United States*, 566 F.3d 1257, 1264 (11th Cir. 2009); *Ctr. for Biological Diversity v. U.S. Fish & Wildlife Serv.*, 450 F.3d 930, 940-41 (9th Cir. 2006). Indeed, even the D.C. Circuit has recognized judicial review under the circumstances presented here. *See Rancho Viejo, LLC v. Norton*, 323 F.3d 1062, 1066 n.1 (D.C. Cir. 2003).

For all of the foregoing reasons, we hold the district court had jurisdiction over the Pesticide Manufacturer's complaint and it therefore erred in dismissing this action for lack of jurisdiction.

IV

The National Marine Fisheries Service also contends that plaintiffs' claims are not ripe for decision because resolution of them may prove unnecessary once the plaintiffs have exhausted their administrative remedies before the EPA under FIFRA.

In resolving the Fisheries Service's ripeness argument, we assess two factors: (1) the fitness of the issue for judicial decision and (2) the hardship to the parties of withholding court consideration. *Abbott Labs.*, 387 U.S. at 149. In determining whether an issue is fit for judicial decision, we consider the agency's interest in "crystallizing its policy before that policy is subject to review" and the court's interest in "avoiding unnecessary adjudication and in deciding issues in a concrete setting." *Reg'l Mgmt. Corp. v. Legal Servs. Corp.*, 186 F.3d 457, 465 (4th Cir. 1999).

The Fisheries Service's argument here is based on its view that the BiOp could become insignificant. As it argues in its brief, the

EPA is not required to adopt the reasonable and prudent alternative provided in the BiOp, and EPA may decide to take actions that are acceptable to the Registrants by either declining to modify the FIFRA registrations or adopting less stringent restrictions—in which case the dispute may never materialize. Alternatively, if EPA decides to take a FIFRA action to which the registrants object, FIFRA provides the Registrants an opportunity to demand an administrative hearing. The result of the FIFRA administrative hearing may satisfy the Registrants without the need for court intervention.

As we have noted, the Fisheries Service's BiOp represents the culmination of its decisionmaking process. Under the agency's regulations, the Fisheries Service's role in consulting with the EPA "is terminated with the issuance of the biological opinion." 50 C.F.R. § 402.14(l). Accordingly, there is no reason to conclude that the Fisheries Service would crystallize its policy at some later time. *See Reg'l Mgmt. Corp.*, 186 F.3d at 465. Moreover, because the BiOp will stand as final agency action even after the EPA's registration decision is issued, its effect will never be insignificant. As the Supreme Court noted in *Bennett*, a BiOp alters the legal landscape by allowing persons to comply with the BiOp and avoid ESA sanctions. *Bennett*, 520 U.S. at 169-70. Thus, it cannot be said that the BiOp could become insignificant depending on how the EPA rules. Indeed, the Pesticide Manufacturers may suffer hardship simply by delay of judicial review. The BiOp creates a safe harbor, which, if set incorrectly, can burden the plaintiffs by narrowing the scope of behavior protected from ESA prosecution.

Accordingly, we conclude that a challenge to the BiOp is ripe for judicial review at this time.

For the reasons given, we reverse the district court's order dismissing this case and remand for further proceedings.

REVERSED AND REMANDED