

FOR PUBLICATION

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

CENTER FOR BIOLOGICAL
DIVERSITY, a non-profit
organization,

Plaintiff - Appellee,

v.

UNITED STATES
ENVIRONMENTAL PROTECTION
AGENCY; MICHAEL S. REGAN,
Administrator of the United States
Environmental Protection Agency,

Defendants - Appellants.

No. 23-2946

D.C. No.
4:22-cv-00138-
JCH

OPINION

Appeal from the United States District Court
for the District of Arizona
John Charles Hinderaker, District Judge, Presiding

Argued and Submitted April 7, 2025
San Francisco, California

Filed March 3, 2026

Before: Sidney R. Thomas, Richard A. Paez, and Eric D.
Miller, Circuit Judges.

Opinion by Judge Paez;
Dissent by Judge Miller

SUMMARY*

Environmental Law /Standing

The panel affirmed the district court’s summary judgment in favor of the Center for Biological Diversity (“CBD”) in its action against the U.S. Environmental Protection Agency (“EPA”) seeking to invalidate the EPA’s 2016 cadmium recommendations, and to compel the EPA to engage in a consultation under Endangered Species Act (“ESA”) § 7 before promulgating new recommendations under Clean Water Act (“CWA”) § 304.

Under § 303 of the CWA, States must promulgate water quality standards for all waters within their jurisdictions. Section 304(a) of the CWA requires the EPA to develop nationwide recommendations for States’ criteria. Under § 7 of the ESA, federal agencies must carry out consultations with the Fish and Wildlife Service and/or the National Marine Fisheries Service before taking agency action that may affect endangered species or their critical habitats.

The panel held that CBD had Article III standing to challenge EPA’s failure to consult with the Services under ESA § 7 before promulgating its CWA § 304(a) recommendations for cadmium. To establish standing, a

* This summary constitutes no part of the opinion of the court. It has been prepared by court staff for the convenience of the reader.

plaintiff must show that (1) it has suffered an injury in fact, (2) the injury is fairly traceable to the defendant's challenged action, and (3) it is likely, as opposed to merely speculative, that the injury will be redressed by a favorable decision.

First, CBD members established an injury in fact because the record contains ample evidence that less-stringent State water quality criteria harm listed species by increasing pollution, and that these harms impair CBD members' concrete interests in engaging in recreational and educational activities involving these species.

Second, the injury is traceable to an action by the EPA because consultation between EPA and the Services regarding the § 304(a) recommendations likely would have resulted in stricter water quality standards. Evidence of historical practice shows that many States will adopt EPA's § 304(a) recommendations, and State implementation is even more predictable given that several States have legislation or regulations requiring or incentivizing lawmakers to adopt the § 304(a) recommendations. The behavior of States is not unfettered, but controlled and predicted by EPA's § 304(a) recommendations.

Third, CBD's injury is redressable because consultation is likely to lead to stricter § 304(a) recommendations and at least one State is likely to adopt stricter water quality criteria in response to stricter § 304(a) recommendations, which would likely impact CBD members' interests in various listed species.

Turning to the merits, § 7 of the ESA requires agencies to consult with the Services before performing any "agency action" that "may affect" listed species or their critical habitats. In researching, developing, and publishing nationwide recommendations for aquatic pollutant levels,

which would foreseeably be adopted wholesale by many States, EPA carried out an “agency action” which “may affect” listed species, requiring consultation with the Services under § 7. Accordingly, the panel affirmed the district court’s summary judgment.

Dissenting, Judge Miller would reverse the district court’s judgment and remand with instructions to dismiss the case for lack of standing because CBD cannot establish traceability. To establish traceability, CBD must show that EPA exerts a “determinative or coerce effect” on a State’s decision to adopt the section 304 guidance levels. CBD cannot make that showing because EPA does not have a “determinative or coercive effect” on a State’s decision to propose criteria that incorporate EPA’s section 304 recommendations. It follows that CBD’s injury, which occurs only to the extent that States adopt the section 304 recommendation levels, is not fairly traceable to EPA.

COUNSEL

Claire E. Tonry (argued), Smith & Lowney PLLC, Seattle, Washington; Hannah M.M. Connor, Center for Biological Diversity, Washington, D.C.; for Plaintiff-Appellee.

Michelle Melton (argued) and Robert P. Stockman, Attorneys, Environment & Natural Resources Division, Appellate Section; Clifford E. Stevens Jr., Senior Trial Attorney; Kathrine E. Konschnik, Acting Assistant Attorney General; Todd Kim, Assistant Attorney General; United States Department of Justice, Washington, D.C.; Eleanor Garretson, Attorney Advisor, Office of General Counsel,

Environmental Protection Agency, Washington, D.C.; for Defendants-Appellants.

OPINION

PAEZ, Circuit Judge:

Under § 303 of the Clean Water Act (“CWA”), states, territories, and authorized tribes¹ (hereinafter, “States”) must promulgate water quality standards (“WQs”) for all waters within their jurisdictions. *See* 33 U.S.C. § 1313. WQs set maximum pollution levels, called “criteria,” for individual pollutants. *See id.* § 1313(c). Section 304(a) of the CWA also requires the Environmental Protection Agency (“EPA”) to develop nationwide recommendations for States’ criteria. *Id.* § 1314(a). Although these § 304(a) recommendations are nonbinding, States must either adopt them or explain the decision to depart from them, and criteria not based on the § 304(a) recommendations must be justified scientifically. *See* 40 C.F.R. §§ 131.20(a); 131.11(b)(1)(iii) (2016).² Under § 303 of the CWA, EPA must review State WQs to ensure compliance with that act. *See* 33 U.S.C. § 1313(c)(2)(A); 40 C.F.R. § 131.5. When a State’s WQs do not comply with the requirements of the CWA, EPA must promulgate WQs for the State directly. *Id.* § 1313(c)(3).

¹ *See* 40 C.F.R. § 131.3(j).

² We refer to the 2016 regulations, which differ slightly from the current version, because the plaintiff challenges an action undertaken by EPA in that year.

Under those circumstances, EPA often implements its § 304(a) recommendations in the noncompliant State.

Under § 7 of the Endangered Species Act (“ESA”), federal agencies must carry out consultations with the Fish and Wildlife Service (“FWS”) and/or the National Marine Fisheries Service (“NMFS”) (together, “the Services”) before taking any “agency action” that “may affect” endangered species or their critical habitats. 16 U.S.C. § 1536(a)(2); 50 C.F.R. § 402.14 (2016).

In 2016, EPA promulgated new § 304(a) recommendations for cadmium without consulting with the Services. In doing so, EPA asserted that § 7 of the ESA only requires it to consult with the Services before approving or disapproving each State’s WQSs under CWA § 303. The Center for Biological Diversity (“CBD”) filed the instant action to invalidate the 2016 cadmium recommendations and compel EPA to engage in § 7 consultation before promulgating new recommendations under CWA § 304. In granting summary judgment to CBD, the district court determined that EPA must comply with § 7 because EPA’s publication of § 304(a) recommendations is an “agency action” that “may affect” listed species or critical habitat. *See Ctr. for Biological Diversity v. U.S. Env’t Prot. Admin.*, No. CV-22-00138-TUC-JCH, 2023 WL 5333260, at *7, *11 (D. Ariz. Aug. 18, 2023). On appeal, EPA argues that CBD lacks standing to challenge EPA’s failure to consult before promulgating § 304(a) recommendations. Concerning the merits, EPA also argues that the promulgation of § 304(a) recommendations is not an “agency action” and that it has no effect on listed species or their critical habitat. We affirm.

I.

Because this case deals with the intersection of the CWA and the ESA, we briefly discuss the pertinent provisions of these two statutes. We then provide some background concerning the challenged 2016 § 304(a) recommendations for cadmium. Finally, we outline the relevant procedural history of this case before turning to the issues on appeal.

A.

The Clean Water Act aims “to restore and maintain the chemical, physical, and biological integrity of the Nation’s waters” by regulating and ultimately eliminating the discharge of pollutants. 33 U.S.C. § 1251(a). It sets forth Congress’s policy “to recognize, preserve, and protect the primary responsibilities and rights of States to prevent, reduce, and eliminate pollution.” *Id.* § 1251(b). EPA is responsible for administering the CWA, including those provisions related to establishing and reviewing water quality standards throughout the United States. *See id.* §§ 1251(d), 1313.

Section 303 of the CWA directs States to develop, adopt, and regularly review WQSs for all waters within their jurisdictions. *Id.* § 1313(a), (c); *see generally* 40 C.F.R. Part 131. WQSs include maximum pollution levels, called “criteria,” for individual pollutants in a State’s waterways.³ 33 U.S.C. § 1313(c)(2)(B). The CWA mandates use of these

³ WQSs consist of three components: (1) the designated uses of the water body; (2) water quality criteria identifying levels of pollutants adequate to protect the designated uses; and (3) an “anti-degradation policy” that protects existing uses and provides a mechanism for preventing water quality deterioration. *See* 33 U.S.C. § 1313(c), (d)(4)(B); *PUD No. 1 of Jefferson Cnty. v. Wash. Dep’t of Ecology*, 511 U.S. 700, 704-05 (1994); 40 C.F.R. § 130.3.

criteria for several regulatory purposes. Criteria are used to develop discharge limits in federal pollution permits, without which pollutant discharge from point sources is generally prohibited. *Id.* §§ 1311(a)–(b), 1341(a)(1), 1342(a)(1). In addition, States must use their water quality criteria to identify bodies of water that are “impaired” by high pollutant levels and to develop “total maximum daily loads” of pollutants for those bodies of water to protect wildlife. *Id.* § 1313(d).

Section 304 of the CWA directs EPA to “develop and publish” nationwide water quality criteria recommendations that “reflect[] the latest scientific knowledge” on the “identifiable effects” of pollutants on humans and aquatic species. *Id.* § 1314(a)(1). EPA has published and periodically updates § 304(a) recommendations for approximately sixty individual pollutants, covering acute pollution in marine and estuarine waters, acute pollution in fresh waters, chronic pollution in marine and estuarine waters, and chronic pollution in fresh waters. *See* U.S. Env’t Prot. Agency, National Recommended Water Quality Criteria - Aquatic Life Criteria Table (2025).⁴ To calculate these four recommended values, EPA uses an established, scientifically valid methodology that considers “all available information concerning toxicity to, and bioaccumulation by, aquatic organisms.” *See* U.S. Env’t Prot. Agency, Guidelines for Deriving Numerical National Water Quality Criteria for the Protection of Aquatic Organisms and Their Uses (2024).⁵

⁴ <https://www.epa.gov/wqc/national-recommended-water-quality-criteria-aquatic-life-criteria-table>.

⁵ <https://www.epa.gov/wqc/guidelines-deriving-numerical-national-water-quality-criteria-protection-aquatic-organisms-and>.

The CWA requires States to hold public hearings every three years for the purpose of reviewing their WQSs and making modifications if necessary. 33 U.S.C. § 1313(c)(1); 40 C.F.R. § 131.20. EPA's regulations provide that the "form" of a State's criteria should be numerical, although narrative criteria or criteria based on biomonitoring methods may be used "where numerical criteria cannot be established or to supplement numerical criteria." 40 C.F.R. § 131.11(b). In establishing numerical criteria, States are required to use values based on either EPA's § 304(a) recommendation, with or without modification for site-specific conditions, or "[o]ther scientifically defensible methods." *Id.* Moreover, during the triennial review process, States must revise their criteria to match any new or revised § 304(a) recommendations, or submit an explanation to EPA for the decision not to do so. *Id.* § 131.20(a). Importantly, while States must justify scientifically any proposed criteria other than the § 304(a) recommendation, *id.* § 131.11(b)(1)(iii), they need not justify scientifically their decision to retain existing criteria despite a new or revised § 304(a) recommendation, *id.* § 131.20(a).⁶ Rather, a State's

⁶ The relevant regulations make clear that a State need only provide additional scientific justification for new or revised proposed criteria that *departs* from the § 304(a) recommendations. *See* 40 C.F.R. § 131.20(a) ("[I]f a State does *not* adopt new or revised criteria for parameters for which EPA has published new or updated CWA section 304(a) criteria recommendations, *then* the State shall provide an explanation when it submits the results of its triennial review to the Regional Administrator consistent with CWA section 303(c)(1) and the requirements of paragraph (c) of this section.") (emphasis added); *see also id.* § 131.11(b)(1) ("In establishing criteria, States should: (1) Establish numerical values based on: (i) 304(a) Guidance; or (ii) 304(a) Guidance modified to reflect site-specific conditions; or (iii) Other scientifically defensible methods[.]"). Notably, the statutory construction of 40 C.F.R.

explanation for declining to adopt EPA’s revised § 304(a) recommendations may appeal to budget, priorities, or other economic concerns. Regardless of whether a State elects to revise its water quality criteria, it must submit “the results of the [triennial] review, any supporting analysis for the use attainability analysis, the methodologies used for site-specific criteria development, any general policies applicable to water quality standards and any revisions of the standards” to EPA for approval within thirty days of the final decision. *Id.* § 131.20(c).

EPA must approve any new and revised State WQSs before they can go into effect for use in CWA programs. 33 U.S.C. § 1313(c)(2)(A), (c)(3); 40 C.F.R. § 131.5. In approving a State’s proposed water quality criteria, EPA verifies that they “protect the designated water uses based on sound scientific rationale,” were revised or adopted pursuant to “applicable legal procedures,” and are consistent with the CWA and other applicable law. 40 C.F.R. § 131.5(a). If EPA determines that a State’s proposed criteria would *not* be consistent with the requirements of the CWA, then it must directly promulgate criteria for that State. 33 U.S.C. § 1313(c)(4).

EPA’s § 304(a) recommendations are not a safe harbor and are not presumed to be appropriate. Indeed, EPA has disapproved State water quality criteria that were at least as stringent as the relevant § 304(a) recommendations. *See* U.S. Env’t Prot. Agency, Email Concerning EPA’s Action on North Dakota’s Revised Chronic Aquatic Life Criterion for

§ 131.11(b)(1) necessarily implies that § 304(a) guidance is scientifically defensible.

Mercury 5–6 (July 15, 2022)⁷ (disapproving North Dakota’s 2022 water quality criterion for chronic mercury, which was based on the current § 304(a) value).

EPA also utilizes its § 304(a) recommendations for other regulatory purposes, including to establish cleanup requirements for contaminated sites under the Comprehensive Environmental Response, Compensation and Liability Act. *See* 42 U.S.C. § 9621(d)(2)(A); 40 C.F.R. § 300.430(e)(2)(i)(E).

B.

The Endangered Species Act provides a framework to conserve and protect the world’s flora and fauna by creating a list of endangered or threatened species and providing procedural and substantive protections for those species. *See* 16 U.S.C. §§ 1531–1544. The Services administer the ESA; the responsible Service is usually determined by species. *See* 50 C.F.R. § 402.01(b).

Section 4 of the ESA requires the Services to determine whether a given species qualifies for designation as endangered or threatened, and designate and periodically update critical habitat for those listed species. *See* 16 U.S.C. § 1533; 50 C.F.R. § 402.01(b).

Section 7 of the ESA requires federal agencies to ensure that “any action authorized, funded, or carried out by [the] agency” (“agency action”) is “not likely to jeopardize the continued existence of any endangered or threatened species” or adversely modify or destroy those species’ designated critical habitats. 16 U.S.C. § 1536(a)(2). Under

⁷ <https://www.epa.gov/system/files/documents/2024-05/actltr-16138-nd07152022.pdf>.

the applicable regulations, federal agencies must do so by reviewing their actions “at the earliest possible time” to determine whether they “may affect” a listed species or critical habitat. 50 C.F.R. § 402.14(a). If so, then the agency proposing the action (“action agency”) and the Service(s) must engage in a formal consultation. *Id.*; 16 U.S.C. § 1536(a)(4).

To initiate a formal consultation, the action agency must prepare certain materials for the consulting Service(s) to review, called a “biological assessment” or “biological evaluation.” *See* 16 U.S.C. § 1536(c); 50 C.F.R. § 402.14(c)(1); Memorandum of Agreement Between the Environmental Protection Agency, Fish and Wildlife Service and National Marine Fisheries Service Regarding Enhanced Coordination Under the Clean Water Act and Endangered Species Act, 66 Fed. Reg. 11202, 11210 (Feb. 22, 2001); Erin Ward & Pervaze Sheikh, Cong. Rsch. Serv., IF12423, Endangered Species Act (ESA) Section 7 Consultation 1 (2023).⁸ These materials include a detailed description of the project parameters and an analysis of the potential effects on listed species. Then, the Service(s) must prepare a “biological opinion” detailing whether the action will likely result in “jeopardy” to listed species. 16 U.S.C. § 1536(b)(3)–(4); 50 C.F.R. § 402.14(g)–(h). If so, the Service(s) must also include a list of reasonable and prudent alternatives to avoid jeopardy to listed species or adverse modification of designated critical habitat. *See* 16 U.S.C. § 1536(b)(3)–(4); 50 C.F.R. § 402.14(g)–(h).

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https://www.congress.gov/crs_external_products/IF/PDF/IF12423/IF12423.2.pdf.

Agencies may also avoid formal consultation by engaging in a voluntary informal consultation under 50 C.F.R. § 402.13. If, through informal consultation, the agency determines and the Service(s) concur that the action which “may affect” a listed species or critical habitat is “not likely to adversely affect” the species or habitat, then formal consultation is not required. *Id.*; *see id.* § 402.14(b)(1).

While either form of consultation is ongoing, the action agency must avoid making any “irreversible or irretrievable commitment of resources” that could foreclose implementation of any modifications or alternatives recommended by the consulting Service(s). 16 U.S.C. § 1536(d); 50 C.F.R. § 402.09.

C.

The parties do not dispute the material facts. While cadmium naturally occurs in surface waters at very low levels, most is introduced by anthropogenic activities including mining, manufacturing, and agriculture. No level of exposure to cadmium is beneficial for aquatic life or human health; cadmium is acutely toxic, although its toxicity varies based on water conditions and across species. Long-lived or migratory species are especially sensitive to cadmium, including sturgeon, sea turtles, salmonids, and freshwater mussels. Chronic cadmium exposure causes cancers, birth defects, and adverse effects on growth, reproduction, immune and endocrine functions, development, and behavior in aquatic species.

EPA first published § 304(a) recommendations for cadmium in 1980, with subsequent updates in 1985, 1995, and 2001. In 2016, EPA again revised its recommended criteria for cadmium based on around 100 new studies published since 2001 concerning the impact of cadmium on

aquatic life. The new studies included data for more than seventy-five new species. In total, data was available for nine species listed as endangered or threatened under the ESA.

Based on these studies, and after external peer review and a public comment period, EPA published updated § 304(a) recommendations for cadmium along with a lengthy report detailing its methodology. Of the four criteria recommendations for cadmium, only the freshwater chronic value became less stringent in 2016: the EPA tripled the recommended cadmium concentration compared to its 2001 recommendation. The other three became more stringent.

EPA did not consult with the Services before publishing its new § 304(a) recommendations for cadmium, asserting that it was only required to consult before deciding whether to approve each State's proposed WQSs under § 303. During notice and comment on the new cadmium recommendations, NMFS criticized EPA's "piecemeal" approach to consultation as incapable of fully capturing the implications of the WQSs for "broadly ranging species," "lead[ing] to an incomplete consideration" of effects. EPA acknowledged that nationwide consultation would "tend to produce" more stringent § 304(a) recommendations.

Every time EPA has directly promulgated cadmium criteria for a State, it has used its own § 304(a) recommendations to supplant the State's insufficient standards. *See, e.g.*, 40 C.F.R. § 131.38(b)(1) (implementing the 2001 § 304(a) recommendations for cadmium in California); Water Quality Standards; Establishment of Numeric Criteria for Priority Toxic Pollutants; States' Compliance—Revision of Metals Criteria, 60 Fed. Reg. 22229 (May 4, 1995) (interim final rule implementing the

1995 § 304(a) recommendations for cadmium in nine states, the District of Columbia, and Puerto Rico); Water Quality Standards; Establishment of Numeric Criteria for Priority Toxic Pollutants; States' Compliance, 57 Fed. Reg. 60848 (Dec. 22, 1992) (implementing the 1985 § 304(a) recommendations for cadmium in some states). In 2013, EPA disapproved Oregon's criteria for acute cadmium pollution in fresh water, even though it was based on EPA's 2001 § 304(a) recommendation. Aquatic Life Criteria for Copper and Cadmium in Oregon, 81 Fed. Reg. 22555, 22556–22557 (Apr. 18, 2016). In its place, however, EPA promulgated a new criterion for Oregon matching the § 304(a) recommendation for cadmium issued in 2016. Aquatic Life Criteria for Cadmium in Oregon, 82 Fed. Reg. 9166, 9168 (Feb. 3, 2017).

II.

In March 2022, CBD filed this action alleging that EPA violated § 7 of the ESA by failing to engage in nationwide consultation when it revised its 2016 § 304(a) recommendations for cadmium. CBD moved for summary judgment, seeking vacatur of EPA's chronic freshwater cadmium recommendation and remand of all four of the 2016 recommendations to EPA for consultation with the Services. EPA cross-moved for summary judgment, defending its failure to consult and arguing that CBD lacked standing. In August 2023, the district court granted in part CBD's motion for summary judgment, denied EPA's cross-motion for summary judgment, and granted the relief that CBD requested—vacating the chronic freshwater recommendation and remanding all four cadmium recommendations to EPA.

The district court rejected the government's argument that CBD lacked standing. The court concluded that CBD's members had established actual and imminent injury because EPA's failure to consult resulted in § 304(a) recommendations that insufficiently accounted for cumulative and interstate effects and would therefore tend to produce less stringent State cadmium criteria, threatening members' use of protected species. The court reasoned that consultation with the Services would have produced more stringent recommendations and that those recommendations likely would be adopted by States, establishing causation and redressability.

On the merits, the district court concluded that EPA's publication of § 304(a) recommendations is "agency action" under ESA § 7. In doing so, it invoked the test articulated in *Karuk Tribe of California v. U.S. Forest Service*, which considers (1) whether an agency affirmatively authorized, funded, or carried out the underlying activity, and (2) whether the agency had discretion to influence or modify the activity to benefit protected species.

The district court further determined that EPA's § 304(a) recommendations "may affect" listed species by influencing State criteria and thereby modulating pollution levels in the waters of those States. The court reasoned that because EPA's non-binding recommendations are "designed to influence state water-quality standards," and because EPA concedes that consultation "tends to produce" more stringent criteria, the "may affect" requirement of ESA § 7 was satisfied.

The district court remanded all four § 304(a) recommendations for cadmium to EPA and vacated the freshwater chronic recommendation. In reaching this

decision, the court determined that EPA's failure to consult was a serious violation of the ESA, that the risk to the environment of leaving the freshwater chronic recommendation in place was high, and that EPA was unlikely to adopt the same rule on remand. Upon vacatur of the 2016 chronic freshwater cadmium criterion, the more stringent 2001 criterion replaced it.

III.

We review de novo a district court's resolution of a summary judgment motion. *Karuk Tribe*, 681 F.3d at 1017. Summary judgment is appropriate when there is no genuine issue of material fact and the moving party is entitled to judgment as a matter of law. *Sierra Club v. Bosworth*, 510 F.3d 1016, 1022 (9th Cir. 2007). We review de novo "an agency's interpretation of a statute outside its administration," including EPA's interpretation of the ESA. *Karuk Tribe*, 681 F.3d at 1017.

IV.

CBD has standing to challenge EPA's failure to consult with the Services under ESA § 7 before promulgating its § 304(a) recommendations for cadmium.⁹ "To establish Article III standing, 'a plaintiff must show (1) it has suffered an 'injury in fact' that is (a) concrete and particularized and

⁹ Because CBD asserts an injury on behalf of its members, it must show that "(a) its members would otherwise have standing to sue in their own right; (b) the interests it seeks to protect are germane to the organization's purpose; and (c) neither the claim asserted nor the relief requested requires the participation of individual members in the lawsuit." *Nat. Res. Def. Council v. U.S. Env't Prot. Agency*, 38 F.4th 34, 54 n.16 (9th Cir. 2022). Because EPA does not contest prongs (b) and (c) and "we are satisfied that they are met here," our analysis focuses on (a). *Id.*

(b) actual or imminent, not conjectural or hypothetical; (2) the injury is fairly traceable to the challenged action of the defendant; and (3) it is likely, as opposed to merely speculative, that the injury will be redressed by a favorable decision.” *Ass’n of Irrigated Residents v. U.S. Env’t Prot. Agency*, 10 F.4th 937, 943 (9th Cir. 2021) (quoting *Friends of the Earth, Inc. v. Laidlaw Env’t Servs. (TOC), Inc.*, 528 U.S. 167, 180–81 (2000)). “[A]t the summary judgment stage, a plaintiff must offer evidence and specific facts demonstrating each element” of standing. *Ctr. for Biological Diversity v. Exp.-Imp. Bank of the U.S.*, 894 F.3d 1005, 1012 (9th Cir. 2018).

A.

“[A]lleged violations of Section 7(a)(2)’s consultation requirement constitute a procedural injury for standing purposes.” *Nat. Res. Def. Council v. Jewell*, 749 F.3d 776, 783 (9th Cir. 2014) (en banc) (quoting *Hunt v. Wash. State Apple Advert. Comm’n*, 432 U.S. 333, 343 (1977)). A “procedural right,” however, must also protect some “concrete interest” to create Article III standing. *Summers v. Earth Island Inst.*, 555 U.S. 488, 496 (2009). CBD’s members have established concrete, particularized, and actual or imminent injuries. The record contains ample evidence that less-stringent State water quality criteria harm listed species by increasing pollution, and that these harms impair CBD members’ concrete interests in those species.

CBD members routinely engage in educational and recreational activities for the purposes of observing, photographing, studying, and enjoying listed species such as Atlantic sturgeon, shortnose sturgeon, pallid sturgeon, green sturgeon, Chinook salmon, coho salmon, certain steelhead, Cumberlandian combshell mussels, Cumberland

moccasinshell mussels, orangefoot pimpleback pearly mussels, and hellbender salamanders.

As the record documents, elevated cadmium concentrations in our nation's waters cause long- and short-term harm to these and other species, thereby injuring CBD's members by diminishing their ability to pursue their recreational, educational, aesthetic, and scientific interests. Cadmium is acutely toxic and chronic exposure harms aquatic species' growth, reproduction, immune and endocrine functions, development, and behavior. State cadmium criteria directly affect cadmium levels in State waters by setting limits in pollutant discharge permits and determining "total maximum daily loads" for impaired bodies of water. *See* 33 U.S.C. §§ 1311(a)–(b), 1341(a)(1), 1342(a)(1), 1313(d).

EPA argues that CBD has not been injured because the methodology used to calculate the § 304(a) recommendations, which incorporated data from nine listed species and used "surrogate" species to account for others, was sufficient to protect listed species. CBD counters that the § 304(a) recommendations were produced using insufficient data and poor scientific methodology.

We affirm the district court's determination that CBD established that its members sustained or will sustain an injury in fact stemming from the 2016 § 304(a) recommendations for cadmium. As the record shows, NMFS found that those recommendations are likely to harm multiple listed species. In its public comments on the proposed recommendations, NMFS cautioned that only a comprehensive nationwide study could capture the full range of adverse effects; without accounting for nationwide effects, EPA's § 304(a) recommendations were likely to be

insufficiently protective of long-lived and migratory species. NMFS also expressed concerns with other aspects of EPA's methodology, including its use of data in adjusting for water hardness, which affects the toxicity of pollutants like cadmium.

In consultations on States' proposals to adopt criteria based on the 2016 § 304(a) recommendations, NMFS emphasized these concerns and elaborated on others, including limitations on the applicability of laboratory testing in field conditions and the absence of data concerning some of the most sensitive listed species. In these consultations, NMFS has repeatedly identified species likely to experience adverse effects. NMFS's concerns are especially weighty because the procedure that EPA bypassed—consultation—was intended to insert the Services' expertise on these precise questions to protect the precise interests at issue here. CBD has adequately established a procedural injury harming its interests in listed species.

B.

A litigant challenging the violation of a procedural right “can assert that right without meeting all the normal standards’ for traceability and redressability.” *Jewell*, 749 F.3d at 782 (quoting *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 572 n.7 (1992)). Such a plaintiff can instead establish standing by showing “(i) the agency violated certain procedural rules, (ii) those rules protect a concrete interest of the plaintiff, and (iii) it is ‘reasonably probable’ that the challenged action threatens that concrete interest.” *Navajo Nation v. Dep’t of the Interior*, 876 F.3d 1144, 1160 (9th Cir. 2017) (quoting *Citizens for Better Forestry v. U.S. Dep’t of Agric.*, 341 F.3d 961, 969–70 (9th Cir. 2003)). In short, “a

litigant who asserts a procedural violation under Section 7(a)(2) need only demonstrate that compliance with Section 7(a)(2) *could* protect his concrete interests.” *Jewell*, 749 F.3d at 783.

As discussed above, nationwide consultation is likely to produce more stringent § 304(a) recommendations by giving the Services the opportunity to study and present a biological opinion concerning interstate and cumulative effects on listed species and their habitats. As CBD argues, a nationwide study may better capture the interconnected nature of ecosystems and waterways, migration patterns, and the long lifespans of certain species. If EPA had complied with the ESA’s consultation requirement, its criteria for cadmium would have taken into account the Services’ serious concerns with EPA’s criteria. EPA itself acknowledges that nationwide consultation would “tend to produce” more stringent § 304(a) recommendations.

But the key issue is the causal link between the § 304(a) recommendations and the water quality criteria that States ultimately adopt. “Where an essential element of standing depends on the reaction of a third party to the requested government action or inaction, ‘it becomes the burden of the plaintiff to adduce facts showing that those choices have been or will be made.’” *WildEarth Guardians v. U.S. Forest Serv.*, 70 F.4th 1212, 1217 (9th Cir. 2023) (quoting *Exp.-Imp. Bank*, 894 F.3d at 1012).

Our court and the Supreme Court have identified several ways to make the causal showing required under these circumstances. The plaintiff may show that the defendant’s action had a “determinative or coercive effect upon the action” causing the injury. *Bennett v. Spear*, 520 U.S. 154, 169 (1997). Likewise, the plaintiff may show that “the

defendant had ‘clear regulatory authority over the third party who more directly caused the plaintiff’s injury’ or was ‘an integral participant in a third-party’s allegedly harmful action.’” *WildEarth*, 70 F.4th at 1217 (quoting *Exp.-Imp. Bank*, 894 F.3d at 1013). Litigants may also establish a causal link between a challenged government action and harm resulting from the independent conduct of third parties by “showing that third parties will likely react in predictable ways to” the challenged government action. *Dep’t of Commerce v. New York*, 588 U.S. 752, 768 (2019); see also *Murthy v. Missouri*, 603 U.S. 43, 57–58 (2024).

Just last year, the Supreme Court decided *Diamond Alternative Energy, LLC v. U.S. Environmental Protection Agency*, concerning fuel producers’ standing to challenge California regulations requiring automakers to limit greenhouse-gas emissions among new vehicles and manufacture a certain percentage of electric vehicles. 606 U.S. 100, 105–07 (2025). In deciding whether the fuel producers had Article III standing, the Supreme Court reiterated its emphasis on predictability, writing that “[c]ourts must distinguish the ‘predictable’ from the ‘speculative’ effects of government action or judicial relief on third parties” and “conclude that ‘third parties will likely react’ to the government regulation (or judicial relief) ‘in predictable ways’ that will likely cause (or redress) the plaintiff’s injury.” *Id.* at 112 (quoting *Food & Drug Admin. v. All. for Hippocratic Med.*, 602 U.S. 367, 383 (2024), and citing *Dep’t of Commerce*, 588 U.S. at 768). Because “[i]nvalidating the regulations likely (not certainly, but likely)” would have caused automakers to manufacture more vehicles that run on gasoline, the fuel producers had established redressability. *Id.* at 118.

Ultimately, while EPA's determinative or coercive regulatory control over the States may provide one strong basis for traceability, it is sufficient that the States' actions be a predictable consequence of EPA's § 304(a) recommendations.

CBD argues that a consultation between EPA and the Services regarding the § 304(a) recommendations likely would have resulted in stricter water quality standards because: (1) EPA has historically applied its § 304(a) recommendations when directly promulgating water quality standards for noncompliant States under 33 U.S.C. § 1313(c)(3)–(4); (2) the § 304(a) recommendations effectively set defaults which many States have adopted and from which they must justify departing under 40 C.F.R. §§ 131.11, 131.20(a); (3) a nationwide biological opinion would inform EPA's approvals or rejections of State water quality standard proposals under 40 C.F.R. § 131.5(b). We agree.

First, under 33 U.S.C. § 1313(c)(3)–(4), when States fail to adopt compliant criteria, EPA will directly promulgate the requisite water quality standards for the noncompliant State. When promulgating State standards for cadmium, EPA has always used its § 304(a) recommendations. For instance, in 2013, EPA disapproved Oregon's criteria for acute cadmium pollution in fresh waters and imposed on Oregon its most recent § 304(a) recommendation. Aquatic Life Criteria for Cadmium in Oregon, 82 Fed. Reg. at 9168. In doing so, it explained that “[t]he 2016 cadmium 304(a) criteria reflect the best available science.” *Id.* As EPA notes, the § 304(a) recommendations do not bind its decisions when directly promulgating water quality standards for States. But EPA's historical practice of using its own recommendations in this

context is particularly compelling evidence of traceability in this state-federal context.

Second, as the district court acknowledged, the § 304(a) recommendations are not in fact mere recommendations but effectively the default from which States must justify departing. In response, EPA argues that this justification need not be scientific but could be purely economic. This argument misreads the statute and regulations, which allow a State to provide a non-scientific reason when declining to adopt a new § 304(a) recommendation, 40 C.F.R. § 131.20(a), but nonetheless require that a State base any criterion it promulgates on the corresponding § 304(a) recommendation or justify any other criteria with a scientific explanation, *id.* § 131.11(b)(1) (requiring States to use the § 304(a) recommendation or “[o]ther scientifically defensible methods”). Moreover, as the district court noted, the process of generating criteria is costly and time intensive. *See* Water Quality Standards Regulatory Revisions, 80 Fed. Reg. 51020, 51028 (Aug. 21, 2015) (EPA noting that updating § 304(a) recommendations involves “invest[ing] significant resources”). While a § 304(a) recommendation is not necessarily a safe harbor, adopting it allows States to bypass much of the cost associated with scientific research and analysis. This incentive may explain why nearly every State has adopted some version of EPA’s § 304(a) recommendations for cadmium.

In fact, several States mandate adoption of EPA’s § 304(a) recommendations or impose additional hurdles to deter deviations from them. *See, e.g.*, 38 Me. Rev. Stat. Ann. tit. 38, § 420(2)(A) (requiring state to adopt EPA’s § 304(a) recommendations); N.M. Code R. § 20.6.4.13(F)(3) (imposing EPA’s § 304(a) recommendations automatically if the state does not adopt its own standards); Minn. R.

7050.0218. subp. 4(C) (establishing presumption that EPA’s § 304(a) recommendations will be adopted and imposing notice and hearing requirements before different criteria may be used in discharge permit limits).

Third, EPA’s failure to engage in the required consultation likely affects its downstream decisions to approve or reject proposed State criteria. As CBD argues, the consultation process would have provided EPA with a nationwide biological opinion, including scientific information suggesting that more protective State criteria are necessary to protect migratory and long-lived listed species. Armed with that information, EPA is likely to require more stringent criteria from the States.

Twenty-six states and several other jurisdictions had adopted the 2016 cadmium § 304(a) recommendation in whole or in part by the time that CBD filed this action in 2022. Notably, most States which had not adopted the 2016 recommendations had in effect cadmium criteria matching the § 304(a) recommendations issued by EPA in prior years. Thus, even if CBD’s injury depends to some extent on the independent discretion of States, the evidence shows that very few States have been willing to exercise their discretion to diverge from EPA’s § 304(a) recommendations.

CBD’s injury therefore easily satisfies this court and the Supreme Court’s various formulations of the traceability requirement where causation depends on decisions by third parties. Evidence of historical practice shows that many States will adopt EPA’s § 304(a) recommendations, rendering this result highly “predictable” under *Department of Commerce*, 588 U.S. at 768, and *Diamond Alternative*, 606 U.S. at 112, 117–18. And State implementation is even more predictable given that several States have legislation or

regulations requiring or incentivizing lawmakers to adopt the § 304(a) recommendations.

Similarly, the fact that forty-five out of fifty states have adopted some iteration of EPA’s § 304(a) recommendations for cadmium certainly suggests that § 304(a) recommendations are a “determinative” regulatory mechanism under *Bennett*, 520 U.S. at 169. And while the 2016 recommendations have not been “determinative” with respect to some States, CBD did not bring a state-level complaint. It challenged EPA’s failure to conduct a nationwide consultation on the grounds that nationwide harms would result, in part from widespread adoption by States of the 2016 recommendations.

Furthermore, EPA’s § 304(a) recommendations, which effectively establish a default and require a justification for departure, represent “clear regulatory authority” over the States and make EPA “an integral participant” in the water quality standard adoption process. *See Exp.-Imp. Bank*, 894 F.3d at 1013. The § 304(a) recommendations, which resulted from extensive study and analysis, are likely to influence EPA’s decisions to approve or reject States’ chosen criteria. Moreover, the record shows that EPA will directly implement the § 304(a) recommendations in States that are noncompliant. These are two additional means through which EPA is an “integral participant” in setting State criteria.

Our recent opinion in *Prutehi Litekyan: Save Ritidian v. U.S. Dep’t of Airforce* supports traceability here. 128 F.4th 1089 (9th Cir. 2025). There, we held that the plaintiffs had standing to allege a procedural injury stemming from the Air Force’s failure to conduct the environmental reviews and public engagement required by the National Environmental

Policy Act (NEPA) before detonating and burning waste munitions on a beach. *Id.* at 1099, 1106–07. Importantly, the fact that the waste disposal project could not go forward without a permit from the Guam EPA “d[id] not require a different result.” *Id.* at 1107. “So long as there is a reasonable probability that Guam EPA will approve the Air Force’s application[,] . . . enforcing that procedural right will reduce the likelihood of Prutehi Litekyan’s experiencing its asserted injury.” *Id.*

Guam EPA’s permitting requirement in *Pruethi Litekyan*, while not the same as the States’ decisions to adopt the § 304(a) criteria, is nevertheless analogous because an intervening agency must take one of two binary actions (to permit or not, to adopt or not) on the defendant federal agency’s proposal before the plaintiff could be harmed. And here, the large number of States which chose to adopt EPA’s 2016 § 304(a) recommendations for cadmium easily satisfies the “reasonable probability” of injury required by *Prutehi Litekyan* to establish traceability between CBD’s asserted injury and EPA’s challenged conduct. *Id.* at 1107.

EPA relies on several cases where we held that the plaintiff failed to establish traceability, but they are readily distinguishable. EPA’s strongest case, *WildEarth*, concerned the plaintiffs’ claim that the U.S. Forest Service’s grazing decisions would bring livestock into contact with wolves, leading to depredation, to which the Washington State Department of Fish & Wildlife would respond with “lethal removals” of the depredating wolves. *WildEarth*, 70 F.4th at 1214–15, 1217. In holding that the plaintiffs had not established traceability, we relied on the absence of any legal or regulatory framework connecting the Forest Service’s grazing decisions to the Washington Fish & Wildlife Department’s lethal removal decisions. *Id.* at 1217. Lethal

removals are not regulated by the Forest Service in any way, but are evaluated case by case by the Washington Fish & Wildlife Department, according to its own criteria and taking into account “considerations” which “do not include the Service’s actions.” *Id.* By contrast, States’ water quality standards are directly regulated by EPA, in large part through the § 304(a) recommendations, which are a key “consideration” in the process for adopting water quality standards. *Id.*

WildEarth held that standing did not exist “[b]ecause the injury ‘depends on the unfettered choices made by independent actors not before the courts and whose exercise of broad and legitimate discretion the courts cannot presume either to control or to predict.’” *Id.* at 1218 (quoting *ASARCO Inc. v. Kadish*, 490 U.S. 605, 615 (1989)). Here, the behavior of States is not unfettered, but controlled and certainly predicted by EPA’s § 304(a) recommendations. Moreover, EPA’s failure to consult with the Services—and the less-stringent § 304(a) criteria that resulted—predictably impacts its own decisions in implementing WQSs for States directly and in deciding whether to approve or reject States’ proposed WQSs. In the district court’s words, “EPA’s regulations may ‘only’ require States to justify any departure, but that requirement appears to have a powerful effect on what they actually do.” CBD has adequately established traceability.

C.

As discussed above, the normal causation and redressability requirements are relaxed for procedural rights claims. *Exp.-Imp. Bank*, 894 F.3d at 1012–13. Thus, a plaintiff “need only demonstrate that he has a procedural right that, if exercised, could protect his concrete interests

and that those interests fall within the zone of interests protected by the statute at issue.” *Id.* at 1013 (quoting *Cottonwood Env’t L. Ctr. v. U.S. Forest Serv.*, 789 F.3d 1075, 1083–84 (9th Cir. 2015)).

CBD’s asserted injury is redressable because consultation is likely to lead to stricter § 304(a) recommendations and at least one State is likely to adopt stricter water quality criteria in response to stricter § 304(a) recommendations, which would likely impact CBD’s members’ interests in various listed species. CBD has established Article III standing to challenge EPA’s failure to consult with the Services under ESA § 7.

V.

We turn to the merits of CBD’s claim. Section 7 of the ESA requires agencies to consult with the Services before performing any “agency action” that “may affect” listed species or their critical habitats. 16 U.S.C. § 1536(a)(2); 50 C.F.R. § 402.14(a). The terms “agency action” and “may affect” are defined broadly to ensure compliance with the ESA’s substantive protections. *Karuk Tribe*, 681 F.3d at 1021, 1027; *see also Pac. Rivers Council v. Thomas*, 30 F.3d 1050, 1055 (9th Cir. 1994). EPA’s publication of § 304(a) recommendations meets the definition of agency action and satisfies the relatively low “may affect” threshold to trigger mandatory consultation under § 7. *Karuk Tribe*, 681 F.3d at 1027.

A.

“Agency action” includes “all activities or programs of any kind authorized, funded, or carried out, in whole or in part, by Federal agencies.” 50 C.F.R. § 402.02; *see also* 16 U.S.C. § 1536(a)(2). “Examples include . . . actions directly

or indirectly causing modifications to the land, water, or air.” 50 C.F.R. § 402.02(d). Although we do not defer to agencies’ interpretation of their enabling statutes, the Services promulgated nearly identical regulatory language before Congress enacted the modern version of the ESA, and that language has remained consistent for over 45 years, so it offers strong evidence of the correct interpretation of the ESA. *See* Interagency Cooperation, 43 Fed. Reg. 870, 874 (Jan. 4, 1978); H. R. Rep. No. 95-1804, at 18 (1978) (Conf. Rep.); *Loper Bright Enters. v. Raimondo*, 603 U.S. 369, 394 (2024).

The promulgation of § 304(a) recommendations is a congressionally mandated activity that follows notice and comment procedures and requires “consultation with appropriate Federal and State agencies and other interested persons.” 33 U.S.C. § 1314(a). It is authorized, funded, and carried out by EPA. *See* 33 U.S.C. §§ 1251(d), 1314. Moreover, as CBD notes, EPA’s publication of § 304(a) recommendations is an activity that “directly or indirectly caus[es] modifications to . . . water” because EPA directly implements the criteria in its federal cleanup program, incentivizes States to adopt them as binding water quality criteria, and directly promulgates them in certain States and tribal lands.

EPA asserts that the phrase “authorized, funded, or carried out” creates a requirement that the alleged action involve “conduct with an impact in the physical world.” This interpretation is contrary to the text of the statute, its implementing regulations, and our precedents.

First, the statute and the regulations define “agency action” broadly, as “any action authorized, funded, or carried out by [a federal] agency.” 16 U.S.C. § 1536(a)(2); *see also*

50 C.F.R. § 402.02. By requiring “underlying conduct in the physical world,” EPA’s interpretation attempts to insert limiting language into the statute where there is none. As CBD argues, inserting a “physical world” limitation into the ESA would exempt major categories of agency actions from the consultation requirement, which flies in the face of Congress’s intent in using broad language and “affording endangered species the highest of priorities.” *Tenn. Valley Auth. v. Hill*, 437 U.S. 153, 194 (1978); *see also Karuk Tribe*, 681 F.3d at 1021.

Moreover, EPA’s interpretation contradicts Supreme Court precedent treating actions that had no component “in the physical world” as potential agency actions. In *National Association of Home Builders v. Defenders of Wildlife*, the Supreme Court treated EPA’s decision to transfer federal pollution permitting authority to a State’s water permitting program as an “agency action.” 551 U.S. 644, 668 (2007). Although the Court ultimately held that § 7 consultation was not required because the transfer decision was nondiscretionary, it nonetheless observed that the transfer decision was an “action authorized, funded, or carried out by a federal agency.” *Id.* Notably, EPA’s decision did not itself authorize, fund, or carry out any conduct in the physical world, but merely reduced its role in future pollution permitting. *Id.* at 650–51.

EPA relies on *Marbled Murrelet v. Babbitt*, in which we held that there was no “agency action” when FWS provided non-binding advice to two lumber companies in an ad hoc letter laying out conditions the companies could meet to avoid violating the ESA. 83 F.3d 1068, 1072 (9th Cir. 1996). But the reason for the outcome of that case was akin to *Home Builders*: there was no “agency action” because the agency “lack[ed] the discretion to influence the private action” to the

benefit of listed species. *Id.* at 1074 (quoting *Sierra Club v. Babbitt*, 65 F.3d 1502, 1509 (9th Cir. 1995)). Here, however, EPA concedes that its action satisfies that requirement. Moreover, issuing statutorily mandated § 304(a) recommendations which have nationwide consequences, including action-forcing mechanisms for every State, is altogether different than a one-off advice letter about a project that was not under the agency’s purview. *See id.* (noting that “there is no evidence that the [agency] had any power to enforce [the conditions laid out in its advice letter] other than its authority under section 9 of the ESA”).

Given the breadth of the statutory and regulatory language, Congress’s intent to strongly prioritize the protection of listed species, and the Supreme Court’s reasoning in *Home Builders*, the promulgation of § 304(a) recommendations is “agency action” “carried out” by EPA for the purposes of § 7 of the ESA.

B.

Like “agency action,” “may affect” determinations are analyzed broadly. As we have repeatedly explained, “‘may affect’ is a ‘relatively low’ threshold for triggering consultation,” such that “[a]ny possible effect, whether beneficial, benign, adverse or of an undetermined character, triggers the requirement.” *Karuk*, 681 F.3d at 1027 (quoting *California ex rel. Lockyer v. U.S. Dep’t of Agric.*, 575 F.3d 999, 1018–19 (9th Cir. 2009)). “An agency may avoid the consultation requirement only if it determines that its action will have ‘no effect’ on a listed species or critical habitat.” *Id.*¹⁰

¹⁰ EPA did not issue a formal “no effect” determination. We do not decide whether the statute or regulations required EPA to do so.

Although the applicable regulations did not define “may affect,” they defined “effects of the action” to include “the direct and indirect effects of an action on the species or critical habitat, together with the effects of other activities that are interrelated or interdependent with that action.” 50 C.F.R. § 402.02 (2016). “Indirect effects are those that are caused by the proposed action and are later in time, but still are reasonably certain to occur.” *Id.*

EPA argues that the regulatory language requiring “reasonabl[e] certain[ty]” of direct effects forecloses CBD from establishing that the § 304(a) recommendations “may affect” listed species. We note that the regulations’ “reasonabl[e] certain[ty]” requirement appears to be in some tension with our interpretation of 16 U.S.C. § 1536, as articulated by the *Karuk Tribe* en banc court. *Karuk Tribe* was explicit that “[a]ny possible effect . . . triggers the requirement” and that only if an agency “determines that its action will have ‘no effect’” is it exempt from consultation. 681 F.3d at 1027; *see Loper Bright*, 603 U.S. at 413 (holding that “courts need not and under the [Administrative Procedure Act] may not defer to an agency interpretation of the law simply because a statute is ambiguous”).

In any case, CBD has shown that in 2016, it was reasonably certain that § 304(a) recommendations would affect listed species. To meet this requirement, it needed only to show that it was foreseeable in 2016 that at least one State would implement § 304(a) recommendations in at least one body of water inhabited by at least one member of a listed species.

CBD has met this burden in several ways. First, most States had a demonstrated history of adopting EPA’s § 304(a) recommendations. Second, EPA had a

demonstrated history of implementing its § 304(a) recommendations in noncompliant States. *See, e.g.*, Water Quality Standards, 60 Fed. Reg. at 22229; 40 C.F.R. § 131.38(b)(1). Third, several States had legislation or regulations requiring or incentivizing state officials to adopt EPA’s § 304(a) recommendations. *See* Me. Rev. Stat. Ann. tit. 38, § 420(2)(A); Minn. R. 7050.0218, subp. 4(C).

Contrary to EPA’s assertion, it is irrelevant which States would adopt the cadmium § 304(a) recommendations; all that is needed to trigger § 7 consultation is “agency action” that “may affect” at least one member of a listed species. *See* 50 C.F.R. §§ 402.13–402.14. The publication of § 304(a) recommendations was therefore an “agency action” that “may affect” listed species and EPA violated the ESA by failing to consult with the Services.

Conclusion

The applicability of ESA § 7 consultation to EPA’s promulgation of § 304(a) recommendations appears to be an issue of first impression among the courts. EPA suggests that the outcome here will open the floodgates, requiring agencies to consult on every piece of nonbinding guidance they issue. Not so. The requirement that the agency activity “may affect” listed species plays an important limiting role. Moreover, some agency activities may be too insubstantial to be “carried out” in any meaningful sense. But in researching, developing, and publishing nationwide recommendations for aquatic pollutant levels, which would foreseeably be adopted wholesale by many States, EPA undeniably “carried out” an “agency action” which “may affect” listed species, requiring consultation with the Services under § 7.

AFFIRMED.

MILLER, Circuit Judge, dissenting:

This case involves nonbinding water quality guidance promulgated by the Environmental Protection Agency. The Center for Biological Diversity seeks to challenge that guidance, which it says caused States to adopt less protective water quality standards, resulting in harm to endangered species. But the publication of the guidance had no legally cognizable effect on state water quality standards, so any injury to CBD's interests is not traceable to that action. Although CBD may be able to challenge a State's decision to adopt a certain standard or EPA's decision to approve it, it lacks standing to challenge the nonbinding guidance at issue here.

I

The Clean Water Act makes States the “primary regulators” of water quality. *Puget Soundkeeper All. v. Port of Tacoma*, 104 F.4th 95, 104 (9th Cir. 2024) (quoting *Southern Cal. All. of Publicly Owned Treatment Works v. EPA*, 853 F.3d 1076, 1086 (9th Cir. 2017)). Section 303 of the Act requires States to adopt water quality standards (WQSs) for all waters within their jurisdiction. *See* 33 U.S.C. § 1313. “These state water quality standards provide ‘a supplementary basis . . . so that numerous point sources, despite individual compliance with effluent limitations, may be further regulated to prevent water quality from falling below acceptable levels.’” *PUD No. 1 of Jefferson Cnty. v. Washington Dep’t of Ecology*, 511 U.S. 700, 704 (1994) (quoting *EPA v. California ex rel. State Water Res. Control Bd.*, 426 U.S. 200, 205 n.12 (1976)). In developing their WQSs, States must identify the “designated uses” of waterways and define “criteria” that must be met for the waterways to support those uses. 33 U.S.C. § 1313(c)(2).

The criteria for toxic pollutants must be defined numerically as maximum pollution levels. *Id.* § 1313(c)(2)(B).

A State must review its WQSs every three years. 33 U.S.C. § 1313(c)(1). During that triennial review, the State need not update its criteria. If the State chooses to do so, the new criteria are subject to review by EPA. *Id.* § 1313(c)(2)(A). If EPA does not approve proposed WQSs, it must explain the changes the State must make, and, if the changes are not made within 90 days, it must promulgate WQSs itself. *Id.* § 1313(c)(3)–(4).

Section 304(a) of the Clean Water Act, entitled “Information and guidelines,” requires EPA to publish guidance “from time to time” on recommended maximum levels of various pollutants. 33 U.S.C. § 1314(a). If EPA has published new section 304 guidance for a particular pollutant, a State must consider that guidance, along with other “new information,” during its next triennial review. 40 C.F.R. § 131.20(a). But, as noted, the State need not update its WQSs during that review cycle, let alone adopt EPA’s recommended levels, and its decision to keep its existing criteria is not subject to EPA approval. The State must provide some reason why it opted to keep its existing criteria, but that reason can be based on economic or policy considerations. *See* Water Quality Standards Regulatory Revisions, 80 Fed. Reg. 51,020, 51,029 (Aug. 21, 2015) (“A state’s or authorized tribe’s explanation may be situation-specific and could involve consideration of priorities and resources.”).

If a State decides to update its criteria, it is free to propose whatever it deems appropriate, but EPA must review the proposed criteria to ensure that they are based on a “sound scientific rationale” and will “protect the

designated water uses.” 40 C.F.R. § 131.5(a)(2); *see id.* § 131.11(b)(1). Adopting the recommended level in EPA’s section 304 guidance is neither necessary nor sufficient for EPA approval.

This case involves EPA’s section 304 guidance for cadmium, a toxic metal that naturally occurs at low concentrations in surface waters but that can also be added to waterways by mining or industrial wastewater and agricultural runoff. EPA first published section 304 guidance for cadmium in 1980, with subsequent updates in 1985, 1995, and 2001. In 2016, EPA updated its section 304 guidance for cadmium, identifying new recommended maximum acute and chronic values for both freshwater and marine waters. Recommended Aquatic Life Ambient Water Quality Criteria for Cadmium—2016, 81 Fed. Reg. 19,176 (Apr. 4, 2016). The new guidance suggested lowering the maximum allowable level of cadmium for three of those categories but relaxing the chronic freshwater criterion. *Id.*

In 2022, CBD sued EPA, alleging that the agency had violated section 7 of the Endangered Species Act (ESA), which requires federal agencies to ensure that “any action authorized, funded, or carried out by [an] agency” is not likely to jeopardize an endangered or threatened species. 16 U.S.C. § 1536(a)(2). If an agency determines that an action “may affect” an endangered or threatened species or its critical habitat, it must consult with either the Fish and Wildlife Service or the National Marine Fisheries Service (the Services). *See* 50 C.F.R. § 402.14(a); 16 U.S.C. § 1536(a)(4). EPA did not consult with the Services before publishing its 2016 guidance. CBD claimed that EPA’s failure to consult resulted in a higher recommended chronic freshwater criterion for cadmium, thus causing harm to ESA-listed aquatic species.

The district court granted summary judgment to CBD. It determined that CBD had standing to challenge EPA’s 2016 guidance and that the promulgation of that guidance was an agency action under section 7 of the ESA, which meant that EPA was required to consult with the Services before publishing it.

II

This appeal turns on whether CBD has standing to challenge EPA’s section 304 guidance. To establish Article III standing, “a plaintiff must show (1) it has suffered an ‘injury in fact’ that is (a) concrete and particularized and (b) actual or imminent, not conjectural or hypothetical; (2) the injury is fairly traceable to the challenged action of the defendant; and (3) it is likely, as opposed to merely speculative, that the injury will be redressed by a favorable decision.” *Association of Irrigated Residents v. EPA*, 10 F.4th 937, 943 (9th Cir. 2021) (quoting *Friends of the Earth, Inc. v. Laidlaw Env’t Servs. (TOC), Inc.*, 528 U.S. 167, 180–81 (2000)). “[A]t the summary judgment stage, a plaintiff must offer evidence and specific facts demonstrating each element.” *Center for Biological Diversity v. Export-Import Bank of the U.S.*, 894 F.3d 1005, 1012 (9th Cir. 2018).

CBD has presented evidence that its members engage in recreational activities involving aquatic species such as salmon that may be harmed by elevated levels of cadmium in water. Based on that evidence, CBD can show that it faces an injury in fact. But to establish standing, it must also show that the injury is traceable to an action by EPA. (Of course, it must also show redressability, but because its failure to show traceability is independently fatal to its claim, I focus on that element of standing.)

CBD cannot establish traceability. Its theory of traceability relies on the following chain of inferences: If EPA had consulted with the Services, it would have produced stricter section 304 guidance; if EPA had published that stricter guidance, States would have decided to update their WQSs and would have proposed adopting the levels in the new, stricter guidance; if States had made such proposals, EPA would have approved them; and if the new, legally enforceable WQSs had become effective, there would be less cadmium in water and less harm to CBD's members' species of interest.

I agree that the first link in that chain of inferences is sound. Alleged violations of the ESA's consultation requirement "constitute a procedural injury for standing purposes." *Natural Res. Def. Council v. Jewell*, 749 F.3d 776, 783 (9th Cir. 2014) (en banc). And we have held that when a plaintiff alleges a procedural injury, "the causation and redressability requirements are relaxed." *Whitewater Draw Nat. Res. Conservation Dist. v. Mayorkas*, 5 F.4th 997, 1013 (9th Cir. 2021) (quoting *Western Watersheds Project v. Kraayenbrink*, 632 F.3d 472, 485 (9th Cir. 2011)). "But the causation and redressability requirements are 'relaxed' for procedural claims only in the sense that a plaintiff 'need not establish the likelihood that *the agency* would render a different decision after going through the proper procedural steps.'" *WildEarth Guardians v. United States Forest Serv.*, 70 F.4th 1212, 1216 (9th Cir. 2023) (emphasis added) (quoting *Export-Import Bank*, 894 F.3d at 1012). In other words, CBD need not prove that EPA would have published more stringent cadmium criteria had it consulted with the Services.

That CBD has claimed a procedural injury, however, does not relax its burden to establish the remainder of its

causal chain—in particular, that there is a causal link between EPA’s publication of guidance and States’ proposal of WQSs that incorporate that guidance. That is because “[t]he relaxation of redressability standards for procedural injuries . . . applies only to the Agency’s actions, not to third parties not before the court.” *WildEarth Guardians*, 70 F.4th at 1217 (omission in original) (quoting *Food & Water Watch v. USDA*, 1 F.4th 1112, 1116 n.2 (D.C. Cir. 2021)).

The States—the key actors in CBD’s chain of causation—are third parties not before the court. And a plaintiff ordinarily cannot establish causation when its injury “depends on the unfettered choices made by independent actors not before the courts and whose exercise of broad and legitimate discretion the courts cannot presume either to control or to predict.” *ASARCO Inc. v. Kadish*, 490 U.S. 605, 615 (1989). Instead, when an “essential element of standing depends on the reaction of a third party to the requested government action or inaction, it becomes the burden of the plaintiff to adduce facts showing that those choices have been or will be made.” *WildEarth Guardians*, 70 F.4th at 1217 (internal quotation marks omitted) (quoting *Export-Import Bank*, 894 F.3d at 1012).

“A plaintiff can do so by showing that the defendant’s action exerts a ‘determinative or coercive effect’ on the third-party conduct that directly causes the injury.” *WildEarth Guardians*, 70 F.4th at 1217 (quoting *Bennett v. Spear*, 520 U.S. 154, 169 (1997)). “More specifically, the defendant’s action could have such an effect if the defendant had ‘clear regulatory authority over the third party who more directly caused the plaintiff’s injury’ or was ‘an integral participant in a third-party’s allegedly harmful action.’” *Id.* (quoting *Export-Import Bank*, 894 F.3d at 1013).

To establish traceability, then, CBD must show that EPA exerts a “determinative or coerce effect” on a State’s decision to adopt the section 304 guidance levels. *Bennett*, 520 U.S. at 169. CBD cannot make that showing.

After EPA publishes new section 304 recommendations, States are not required to update their WQSs in their next triennial review, let alone adopt EPA’s new section 304 recommendations. *See* 40 C.F.R. § 131.20. Although States must *consider* EPA’s new section 304 guidance during their next triennial review, they can decline to update their existing WQSs and need only provide EPA with some reason why they retained their existing criteria. *See* 40 C.F.R. § 131.20(a); 80 Fed. Reg. 51,020, 51,029 (Aug. 21, 2015). As EPA points out, “[a] state’s response to EPA’s § 304 recommendations can be the equivalent of ‘thanks for sharing.’”

Notably, many States have not updated their cadmium criteria in decades. Arkansas, Hawaii, and Louisiana, for example, have not updated their cadmium criteria since around 1985, even though EPA has published new cadmium guidance three times since then, and Michigan, New York, and Ohio have not updated their cadmium criteria since 1996, despite two new section 304 recommendations since that time. States’ responses to EPA’s 2016 guidance further prove the point. CBD brought this action roughly six years after the 2016 guidance was published, at which time more than 20 States had not fully adopted the guidance levels.

Even if a State chooses to update its WQSs, it need not adopt EPA’s section 304 guidance, and EPA must approve the State’s new WQSs so long as they are based on a “sound scientific rationale” and will “protect the designated water uses.” 40 C.F.R. § 131.5(a)(2). Before 1980, EPA applied a

presumption in favor of its section 304 recommendations, but it has formally rescinded that policy. Water Quality Criteria Documents, 45 Fed. Reg. 79,318, 79,319–20 (Nov. 28, 1980). Instead, the agency has made clear that “[w]hile States are free to draw on EPA’s 304(a) criteria as support for State criteria, they are equally free to use any other criteria for which they have sound scientific support.” Water Quality Standards Regulation, 48 Fed. Reg. 51,400, 51,411 (Nov. 8, 1983).

True to its word, EPA has approved water quality criteria that are less stringent than its section 304 guidance levels. In the 1990s, for example, Maryland and Virginia adopted dioxin criteria that were less stringent than EPA’s recommended criteria. *Natural Res. Def. Council v. EPA*, 16 F.3d 1395, 1399 (4th Cir. 1993). EPA approved those States’ criteria because it agreed that they were “scientifically defensible, protective of human health, and in full compliance with the [Clean Water Act].” *Id.* More recently, in 2022, North Carolina adopted, and EPA approved, criteria for cadmium (in non-trout-bearing waters) that diverged from EPA’s 2016 section 304 recommendations.

Conversely, the section 304 guidance is not a safe harbor, and EPA has disapproved state WQSs that incorporated its section 304 guidance. For example, in 2022, EPA disapproved North Dakota’s criteria for chronic mercury even though North Dakota had adopted EPA’s section 304 guidance for mercury. *See* U.S. Env’t Prot. Agency, EPA’s Action on North Dakota’s Revised Chronic Aquatic Life Criterion for Mercury 5–6 (July 15, 2022), <https://www.epa.gov/system/files/documents/2024-05/actltr-16138-nd07152022.pdf>. And in 2013, EPA disapproved Oregon’s criteria for acute freshwater cadmium, even though Oregon had adopted EPA’s then-

current section 304 guidance. *See* Aquatic Life Criteria for Copper and Cadmium in Oregon, 81 Fed. Reg. 22,555, 22,556–57 (Apr. 18, 2016).

Putting all this together, EPA does not have a “determinative or coercive effect” on a State’s decision to propose criteria that incorporate EPA’s section 304 recommendations. *Bennett*, 520 U.S. at 169. Though EPA has “clear regulatory authority” over a State’s WQSs when it decides to approve or disapprove a State’s proposed criteria, it does not wield that authority to force its section 304 guidance levels on States, nor does it rubber-stamp a State’s WQSs that adopt its section 304 guidance. *Export-Import Bank*, 894 F.3d at 1013. In the same vein, though EPA may be an “integral participant” when it decides whether to approve a State’s WQSs, it does not use its role in that process to require States to adopt its section 304 guidance. *Id.* It follows that CBD’s injury, which occurs only to the extent that States adopt the section 304 recommendation levels, is not fairly traceable to EPA.

III

In reaching a contrary conclusion, the court today emphasizes that States’ actions in setting WQSs are “a predictable consequence of EPA’s § 304(a) recommendations.” Because many States have historically opted to adopt EPA’s section 304 guidance—and some States have laws encouraging or requiring the adoption of that guidance—the court reasons that any harm that arises from the States’ WQSs must be traceable to that guidance.

But we have never held that downstream injuries are traceable to government recommendations just because the third-party actors responsible for those injuries find the government’s nonbinding guidance persuasive. It is not

surprising that many States have historically adopted EPA’s section 304 recommendations: The EPA office responsible for creating the guidance is staffed by expert biologists, toxicologists, and statisticians, and the reports it produces are required to “accurately reflect[] the latest scientific knowledge” about the effects of certain pollutants on aquatic life. 33 U.S.C. § 1314(a)(1). EPA’s nonbinding recommendations do not become “determinative or coercive,” *Bennett*, 520 U.S. at 169, just because a State “decides that [EPA] sometimes has a point,” *Children’s Health Def. v. Meta Platforms, Inc.*, 112 F.4th 742, 757 (9th Cir. 2024).

Our precedent also makes clear that “predictable consequences” are not enough to make third-party actions traceable to the government for standing purposes. In *WildEarth Guardians*, for example, the Washington State Department of Fish and Wildlife had a policy that permitted it to kill gray wolves that attacked livestock. 70 F.4th at 1214. The plaintiffs alleged that the Forest Service’s decision to allow more grazing would lead to more wolf attacks on livestock and thus lead the Department to kill more gray wolves. *Id.* at 1214–15. It was undisputed that the Forest Service’s decision would predicably lead to the killing of more wolves, but we nevertheless held that the plaintiffs lacked standing to challenge that decision because the Forest Service did not regulate or participate in the killing, so its determinations about grazing did not have a “‘determinative or coercive effect’ on the harmful conduct of the Department of Fish and Wildlife.” *Id.* at 1218 (quoting *Bennett*, 520 U.S. at 169). *WildEarth Guardians* makes clear that when harm is caused by a third party, the government must have taken a more active role—akin to authorizing, commanding, or cajoling that third party, *see id.* at 1217—

for the harm to be traceable to the government. As already explained, EPA’s publication of nonbinding section 304 guidance does not rise to that level.

None of the cases the court cites suggests a different conclusion. *Diamond Alternative Energy, LLC v. EPA* involved a challenge to “determinative or coercive” government action: EPA’s approval of California’s regulations requiring car makers to produce more electric vehicles and fewer gas-powered vehicles. 606 U.S. 100, 106–07 (2025). Unlike the action challenged here, the EPA approval in that case directly authorized California to require car makers to change their behavior in a way that predictably inflicted an injury on fuel producers, who would sell less fuel because of the EPA-approved mandatory shift toward electric cars. *Id.* at 113–14. It is entirely consistent with *WildEarth Guardians*, then, that the Supreme Court determined that the fuel producers had standing.

Our decision in *Prutehi Litekyan: Save Ritidian v. United States Department of the Air Force* is similarly inapposite. 128 F.4th 1089 (9th Cir. 2025). There, we held that a nonprofit dedicated to protecting natural and cultural resources had standing to challenge the Air Force’s failure to conduct an environmental review before submitting an application to the Guam EPA for permission to detonate munitions on a beach. *Id.* at 1099, 1104–07. Crucially, the injury-causing action (detonating munitions) was to be taken directly by the government, not by a third party.

Finally, the court misreads *Department of Commerce v. New York* in relying on it for the categorical proposition that a plaintiff can establish traceability whenever “third parties will likely react in predictable ways” to the challenged government action. 588 U.S. 752, 768 (2019). In that case,

the plaintiff States alleged that adding a citizenship question to the census would cause their noncitizen residents to respond at lower rates, leading to an undercount of their population and potentially causing each State to “los[e] a seat in Congress or qualify[] for less federal funding.” *Id.* at 767. Even though the government’s decision to add a citizenship question did not directly command or coerce noncitizens into not responding to the census, the Supreme Court held that the States had standing because it was “satisfied that, in these circumstances, [the States] have met their burden of showing that third parties will likely react in predictable ways to the citizenship question.” *Id.* at 768.

But the Court did not announce, as a general rule, that predictability alone is enough for traceability. Such a rule would be a significant—and entirely unexplained—departure from the “determinative or coercive” standard articulated in *Bennett*, a case that *Department of Commerce* cited with approval. 588 U.S. at 768. Instead, *Department of Commerce* suggests that there may be unusual situations in which actions taken by a third party acting out fear of coercive government action (there, possible deportation), may be considered effectively determined by the challenged government action. “[I]n these circumstances,” the Court held, traceability may be established. *Id.*

That principle does not support finding traceability here. Although some noncitizens in *Department of Commerce* understandably feared deportation, CBD has not attempted to show that any State similarly fears that EPA will misuse its authority and disapprove scientifically sound criteria—or take any other punitive action—merely because a State chooses not to adopt EPA’s section 304 recommendations. Rather, the record shows only that States, while exercising their sovereign prerogative to set their own environmental

policies, tend to find EPA's recommendations persuasive and choose to adopt them. That is insufficient to establish traceability.

* * *

Because CBD's injury is not traceable to any action of EPA, I would reverse the judgment of the district court and remand with instructions to dismiss this case for lack of standing.