No. 12-35976

IN THE UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

Native Village of Point Hope; Alaska Community Action on Toxics; Northern Alaska Environmental Center,

Plaintiffs-Appellants,

-v.-

United States Environmental Protection Agency,

Defendant-Appellee,

and

Teck Alaska Incorporated; Nana Regional Corporation,

Intervenor Defendants-Appellees.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF ALASKA (HON. TIMOTHY M. BURGESS)

FEDERAL DEFENDANT-APPELLEE'S ANSWERING BRIEF

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GLOSSARY

APA	Administrative Procedure Act
CWA	Clean Water Act
EPA	U.S. Environmental Protection Agency
ER	Excerpts of Record
NPDES	National Pollutant Discharge Elimination System
SER	Supplemental Excerpts of Record
TDS	Total Dissolved Solids

JURISDICTIONAL STATEMENT

The U.S. Environmental Protection Agency ("EPA") agrees with the jurisdictional statement in the opening brief filed by Appellants, referred to collectively as "Point Hope."

STATEMENT OF THE ISSUE

Whether EPA's approval of Alaska's site-specific water quality criterion for total dissolved solids ("TDS") in the Main Stem of Red Dog Creek during Arctic grayling spawning season was arbitrary or capricious where EPA based its approval on a comprehensive review of existing scientific evidence and, consistent with a recent study's recommendation, an additional study into the impacts of TDS exposure on fertilization success in Arctic grayling.

STATEMENT OF THE CASE

This case concerns EPA's approval under the Clean Water Act ("CWA") of Alaska's proposed limit on the concentration of TDS in the Main Stem of Red Dog Creek, a water body about 50 miles inland from the Chukchi Sea in a remote corner of northwest Alaska. The limit at issue in this case, known as a site-specific water quality criterion, applies during the spawning season of a particular type of fish in the salmonid family, Arctic grayling. A different site-specific criterion, which Alaska adopted and EPA approved in 2003, applies to Red Dog Creek throughout the rest of the year and is not challenged in this case. In general, Alaska's site-specific criteria limit the amount of TDS that Red Dog Mine, which is located in the headwaters of Red Dog Creek, may discharge into Red Dog Creek pursuant to a permit issued under the CWA.

In evaluating the site-specific criterion at issue, EPA first reviewed the available scientific evidence on TDS toxicity in aquatic life. Then, consistent with the recommendation of a recent study, EPA ordered an additional study into the effects of TDS exposure on the fertilization success of Arctic grayling. The results of that study showed that exposure to increasing concentrations of TDS did not significantly affect fertilization success in Arctic grayling. EPA therefore determined that Alaska's criterion was scientifically defensible and would protect Arctic grayling during spawning. After EPA approved the criterion, Point Hope brought suit under the Administrative Procedure Act ("APA"), and the district court granted summary judgment to EPA.

On appeal, Point Hope does not contend that TDS concentrations at the levels permitted by Alaska's site-specific criterion will negatively impact the fertilization success of Arctic grayling. Point Hope's sole argument instead is that EPA erred by not ordering even further study of the delayed effects of TDS exposure during fertilization. However, based on a reasonable interpretation of the scientific evidence before it, EPA did not deem such additional studies necessary to conclude that the criterion would protect Arctic grayling during spawning. Because the expert scientific agency charged with administering the CWA examined the relevant information, sufficiently explained its reasoning, and reached a reasonable decision supported by the administrative record, this Court should affirm the district court's judgment in favor of EPA.

STATUTORY BACKGROUND

The CWA was enacted "to restore and maintain the chemical, physical, and biological integrity of the Nation's waters." 33 U.S.C. § 1251(a). The Act prohibits the "discharge of any pollutant," defined as "any addition of any pollutant to navigable waters from any point source,"[1] except "as in compliance with" specified provisions of the Act. *Id.* §§ 1311(a), 1362(12)(A). Most point source dischargers must obtain and adhere to the terms of National Pollutant Discharge Elimination System ("NPDES") permits. *Id.* § 1342.[2] NPDES permits contain effluent limitations, *id.* § 1311(b), which specify the quantities, rates, or concentrations of pollutants that the permit holder may discharge, *id.* § 1362(11).

The CWA also directs the States, with EPA approval and oversight, to establish "water quality standards" for intrastate waters. *Id.* § 1313(a)–(c). Water quality standards "establish the desired condition of a waterway" and ensure that numerous point sources, despite individual compliance with effluent limitations, do not cause water quality to fall below acceptable levels. *Arkansas v. Oklahoma*, 503 U.S. 91, 101 (1992). In establishing water quality standards, States first designate the beneficial uses for waterways in the State, such as water supply, fish propagation, or navigation. 33 U.S.C. § 1313(c)(2)(A);

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[1] A "point source" is "any discernible, confined and discrete conveyance . . . from which pollutants are or may be discharged." *Id.* § 1362(14).

[2] NPDES permits are issued by EPA or, in certain jurisdictions, by state agencies authorized to administer the NPDES program subject to EPA review. 33 U.S.C. § 1342(a)–(d).

40 C.F.R. § 131.10. States then adopt water quality criteria, which specify the amount of a constituent, expressed in either numeric or narrative form, that a water body may contain without impairing its designated beneficial uses. 40 C.F.R. §§ 131.3(b), 131.11. Water quality criteria typically apply on a statewide basis for all waters with a given designated use, but States may adopt site-specific criteria for a particular water body or segment. *See id.* § 131.11(b)(1)(ii). Once such water quality standards have been adopted, the effluent limitations in NPDES permits are calculated to ensure that the authorized discharges will attain and maintain the standards applicable to the receiving water. *See Arkansas*, 503 U.S. at 101.

Under the framework established by the CWA, States have the "primary responsibility" for preventing water pollution, 33 U.S.C. § 1251(b), including by establishing water quality standards, *id.* §§ 1313(a), 1313(c). Specifically, States are required to adopt water quality standards, review them at least once every three years, and modify them, as appropriate. *Id.* §§ 1313(a)(3)(A), 1313(c)(1). Any new or modified standards that a State adopts must be submitted to EPA, which then must determine whether the standard is consistent with the

Act. *Id.* §§ 1313(c)(2)(A), 1313(c)(3); *see also* 40 C.F.R. § 131.11(a)(1) (water quality criteria "must be based on sound scientific rationale and must contain sufficient parameters or constituents to protect the designated use"). Upon EPA's approval, the State's standards become effective. 33 U.S.C. § 1313(c)(3).

If EPA concludes that a State's water quality standard does not comply with the CWA, it must notify the State of any changes necessary to gain approval; if the State does not adopt those changes, then EPA must promulgate an appropriate standard on the State's behalf. 33 U.S.C. § 1313(c)(3), (4).

STATEMENT OF FACTS

I. RED DOG CREEK AND RED DOG MINE.

The Red Dog Creek system is located in a remote area of northwest Alaska approximately 50 miles inland from the mouth of the Wulik River, which flows into the Chukchi Sea. (ER 212.)[3] Water from Red Dog Creek reaches the Chukchi Sea by flowing into a larger creek that eventually empties into the Wulik River. (ER 132–34.) The Native

[3] ER refers to the Excerpts of Record filed by Appellants. SER refers to the Supplemental Excerpts of Record filed jointly by EPA and Intervenor Defendants-Appellees.

Village of Point Hope, an Inupiat Eskimo community and federally recognized tribe, lies 50 miles northwest of the mouth of the Wulik River, on a barrier island along the coast of the Chukchi Sea. (ER 34.)

The Red Dog Creek system is composed of the Main Stem and two major tributaries, the North and Middle Forks, as well as a third tributary, the South Fork. (ER 132.) The Middle Fork flows through a surface ore deposit before joining the North Fork to form the Main Stem of Red Dog Creek. (ER 132, 135.) Due to the high concentrations of metals caused by the ore deposit, fish have not been observed to use the Middle Fork, including before mining began. (ER 135, 140.)

Red Dog Mine, which mines zinc and lead, is located within portions of the headwaters of Red Dog Creek. A dam near the mouth of the South Fork of Red Dog Creek forms an impoundment to store wastewater and tailings from the mine's operations. (ER 132.) To maintain the water level in the tailings impoundment at safe levels, the mine operator, Teck Alaska, obtained a NPDES permit to discharge treated wastewater into the Middle Fork. (ER 124, 126.) Those discharges occur when surface waters are not frozen, typically from mid-May through mid-October. (ER 132.)

Before discharging wastewater, Teck treats the wastewater to reduce metals and other substances to concentrations allowed by the NPDES permit. One of the substances limited by the NPDES permit is TDS, which generally refers to any minerals, salts, or metals dissolved in water. (ER 242.) The main components of the TDS in the mine's wastewater are calcium and sulfate. (ER 135, 152.) Teck uses lime to remove toxic metals, such as zinc, lead, and cadmium, from the wastewater and replace them with calcium and sulfate. (ER 135, 152.) Lower concentrations of calcium and sulfate occur naturally in fresh water. (ER 135.) The Mine's treatment process thus lowers the concentration of toxic metals but increases the overall concentration of TDS in the wastewater and, consequently, in the Middle Fork and Main Stem of Red Dog Creek. (ER 135, 137–38, 152.)

In recent years, use of the Main Stem of Red Dog Creek by Arctic grayling appears to be increasing. (ER 139.) Arctic grayling currently spawn in portions of the Main Stem during a six to eleven day period in late May to early June, depending upon water temperatures. (ER 139.) Fry hatch two to three weeks later, in late June, and migrate downstream to the Wulik River in late August or September. (ER 139.)

II. ALASKA'S ADOPTION AND EPA'S APPROVAL OF SITE-SPECIFIC CRITERIA FOR TDS IN THE MAIN STEM OF RED DOG CREEK.

The State of Alaska, acting through its Department of Environmental Conservation, has designated fish growth and propagation as a beneficial use of Red Dog Creek. (ER 214.) Alaska's statewide water quality criterion limits TDS concentrations to between 500 and 1,000 mg/L in water bodies used by aquatic life. (ER 126, 214.) In 2001, however, Teck requested that Alaska promulgate a site-specific water quality criterion for TDS in the Main Stem of Red Dog Creek. Teck proposed that TDS concentrations in the Main Stem be limited to 1,500 mg/L, except during the Arctic grayling spawning season, when Teck proposed that the limit would be 500 mg/L. (ER 246.) In deciding whether to adopt the proposed criterion, Alaska considered water quality and aquatic life monitoring data at the site, the results of laboratory studies and existing scientific literature concerning TDS toxicity in aquatic species, and public comments. Alaska concluded that the scientific evidence reasonably demonstrated that the proposed site-specific criterion would fully protect aquatic life in the Main Stem of Red Dog Creek and therefore adopted the criterion subject to EPA's review and approval. (ER 241–42, 246–57.)

In 2003, EPA reviewed Alaska's site-specific criterion and considered three lines of evidence: (1) laboratory toxicity studies using EPA-developed protocols that examined the effect of simulated Red Dog Mine TDS concentrations on various life stages of fish and macroinvertebrates; (2) a literature review that summarized and evaluated the results from 28 studies concerning the effects of TDS on aquatic life; and (3) field surveys of aquatic life found in the Red Dog Creek system since the Mine began operations in 1989. (ER 215–18.) After examining that evidence, EPA concluded that limiting TDS concentrations in the Main Stem of Red Dog Creek to 1,500 mg/L would be protective of Arctic grayling throughout all life stages other than spawning. (ER 218.) On July 16, 2003, EPA approved Alaska's site-specific criterion for times outside the Arctic grayling spawning season, and Point Hope did not challenge EPA's decision.[4]

EPA declined, however, to take action on Alaska's TDS criterion for the Arctic grayling spawning season due to the results of a 2003 study conducted by Michael S. Stekoll and others. According to EPA, the Stekoll study provided "clear evidence" that TDS in a composition

[4] The time for any challenge to EPA's 2003 decision has now expired. 28 U.S.C. § 2401(a).

similar to that of Red Dog Mine effluent has impacts on "fertilization success" in some salmonids, but that the effects "vary widely from species to species" so that EPA could not extrapolate the results of one species to another. (ER 100; *see also* ER 216 (summarizing Stekoll's results).) The Stekoll study recommended that subsequent research concentrate on "short term bioassays at critical stages, such as fertilization or hatch." (ER 355.) EPA therefore required a further study to determine the effects of TDS exposure on fertilization success in Arctic grayling.

Teck's environmental consultants conducted the required study, with EPA and State input into the testing protocols and study design. (ER 103–04, 177.) Using fish from area waters and following most of the same protocols used by Stekoll, the researchers attempted to fertilize Arctic grayling eggs in solutions with varying concentrations of TDS and examined their fertilization success rate. (ER 185–86.) After certain problems that occurred in the first year of testing were corrected (ER 105, 116–17, 197–99), the second year of testing produced "very consistent data indicating no effects on fertilization success up to the highest TDS concentration tested," which was 2,782 mg/L (ER 199). The researchers ultimately concluded that the "weight of the evidence" from the study "strongly suggests that TDS is having no significant effect on Arctic grayling fertilization success." (ER 200–01.)

In light of the results from the study, Teck submitted a revised request to establish a 1,500 mg/L limit on TDS in the Main Stem of Red Dog Creek during Arctic grayling spawning season. (ER 115.) Alaska reviewed the follow-up study results, along with the other scientific evidence that it had previously reviewed at the time of the original request, and concluded that the proposed site-specific criterion would fully protect Arctic grayling. (ER 113.) Alaska therefore adopted the proposed criterion and submitted its decision to EPA for review and approval.

EPA agreed that the follow-up study provided an "acceptable basis" for setting the water quality criterion because the laboratory methods, quantity of data, and data analysis were appropriate. (ER 105.) EPA noted the "consistency of the results" from the second year of study, which "demonstrate[d] no effect on reproduction at TDS concentrations in excess of" 2,782 mg/L. (ER 106.) EPA approved the criterion because the State had a "scientifically defensible" basis to conclude that it would protect the designated uses of the Main Stem of Red Dog Creek. (ER 101.)

III. THE DISTRICT COURT'S DECISION.

The district court granted EPA's motion for summary judgment and upheld the challenged water quality criterion. (ER 27.) Before the district court, Point Hope argued that EPA's approval of the criterion was arbitrary and capricious because it allegedly "failed to consider the long-term or chronic impacts" of exposing Arctic grayling to TDS during fertlization. (ER 15.)[5] The district court correctly rejected that argument, holding that EPA had reasonably focused the follow-up study on "fertilization success," rather than the delayed effects of TDS exposure during fertilization. As the district court explained, EPA concluded that the scientific evidence supported Alaska's criterion, except that the Stekoll study raised a concern about the impact of TDS exposure on "fertilization success" in other salmonids. (ER 15.) The district court also found it significant that the Stekoll study specifically recommended further "short term" studies at the fertilization stage, rather than the longer-term investigation advocated by Point Hope. (ER

[5] Point Hope raised a number of other arguments before the district court that it has abandoned on appeal.

15–16.) The district court thus concluded that EPA did not ignore an "important" aspect of the problem and upheld EPA's approval of the criterion. (ER 16.)

STANDARD OF REVIEW

This Court reviews the district court's grant of summary judgment de novo. *See Wild Fish Conservancy v. Salazar*, 628 F.3d 513, 521 (9th Cir. 2010). This Court must affirm unless it finds that EPA's decision was "arbitrary, capricious, an abuse of discretion," or otherwise contrary to the CWA. *Id.* (quoting 5 U.S.C. § 706(2)(A)). Review under that standard is narrow and the Court may not substitute its judgment for that of the agency. A court does not sit as a "panel of scientists" that "chooses among scientific studies" and "orders the agency to explain every possible scientific uncertainty." *Lands Council v. McNair*, 537 F.3d 981, 987–88 (9th Cir. 2008) (en banc). To the contrary, a court generally must be "at its most deferential" when reviewing scientific judgments and technical analyses within the agency's expertise. *N. Plains Res. Council, Inc. v. Surface Transp. Bd.*, 668 F.3d 1067, 1075 (9th Cir. 2011); *see also Balt. Gas & Elec. Co. v. Natural Res. Def. Council, Inc.*, 462 U.S. 87, 103 (1983) ("[A] reviewing court must generally be at its most deferential" when an agency is "making predictions, within its area of special expertise, at the frontiers of science.").

"The [agency's] action . . . need only be a reasonable, not the best or most reasonable, decision." *River Runners for Wilderness v. Martin*, 593 F.3d 1064, 1070 (9th Cir. 2010). Agency factual conclusions must be supported only by "substantial evidence," which is "such relevant evidence as a reasonable mind might accept as adequate to support a conclusion." *Envtl. Def. Ctr., Inc. v. EPA*, 344 F.3d 832, 872 & n.56 (9th Cir. 2003) (citing *Dickinson v. Zurko*, 527 U.S. 150, 164 (1999)).[6] "Even when an agency explains its decision with less than ideal clarity, a reviewing court will not upset the decision on that account if the agency's path may reasonably be discerned." *Alaska Dep't of Envtl. Conservation v. EPA*, 540 U.S. 461, 496 (2004) (internal quotation marks omitted). The Court ultimately must affirm the agency if it "considered the relevant factors and articulated a rational connection

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[6] "Substantial evidence" means merely enough evidence "to justify, if the trial were to a jury, a refusal to direct a verdict when the conclusion sought to be drawn from it is one of fact for the jury." *NLRB v. Columbian Enameling & Stamping Co.*, 306 U.S. 292, 300 (1939). The standard is more deferential even than the "clearly erroneous" standard for appellate review of trial court findings. *Zurko*, 527 U.S. at 162, 164.

between the facts found and the choices made." *Pac. Coast Fedn. of Fishermen's Ass'ns v. Blank*, 693 F.3d 1084, 1091 (9th Cir. 2012) (citation omitted).

SUMMARY OF ARGUMENT[7]

EPA considered the available scientific evidence and, consistent with Stekoll's recommendation, ordered an additional "short term" study into the effects of TDS on fertilization success in Arctic grayling. Because the weight of the scientific evidence showed that TDS concentrations of 1,500 mg/L would be protective of Arctic grayling spawning, EPA reasonably concluded that Alaska's adoption of the site-specific criterion was scientifically defensible and would protect the designated uses of the Main Stem of Red Dog Creek.

Point Hope's argument that EPA also had to order an additional study into the delayed effects of TDS exposure during fertilization

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[7] We did not contest Point Hope's standing in district court. In our view, the Native Village of Point Hope satisfies the requirements for Article III standing based on the declaration of Franklin Sage. (ER 31–32.) Because the Village has standing to raise each of the arguments presented in the opening brief, the court need not inquire into the standing of the other plaintiffs. *Planned Parenthood of Idaho, Inc. v. Wasden*, 376 F.3d 908, 918 (9th Cir. 2004) ("Where the legal issues on appeal are fairly raised by one plaintiff who had standing to bring the suit, the court need not consider the standing of the other plaintiffs.") (internal quotation marks and alteration omitted).

should be rejected. Neither the APA nor the CWA requires EPA to resolve every scientific uncertainty by conducting new studies before concluding that a proposed water quality criterion will protect designated uses. Here, EPA exercised its discretion to require an additional study on fertilization success in Arctic grayling because Stekoll's research had demonstrated that TDS exposure impacted fertilization success in some salmonids. Contrary to Point Hope's assertion, EPA did not interpret the Stekoll study to have shown that TDS exposure during fertilization caused increased mortality rates at later stages of development. Because EPA's interpretation of Stekoll's study is reasonable, this Court should defer to EPA's judgment that the scientific evidence in the record did not warrant conducting the type of long-term Arctic grayling tests that Point Hope demands.

EPA did not act arbitrarily or capriciously in approving Alaska's criterion and the judgment of the district court should be affirmed.

ARGUMENT

I. DUE TO EVIDENCE OF TDS'S EFFECT ON FERTILIZATION SUCCESS IN SOME SALMONIDS, EPA PROPERLY EXERCISED ITS DISCRETION TO ORDER A FURTHER STUDY ON THAT SPECIFIC EFFECT IN ARCTIC GRAYLING.

Contrary to the impression created by Point Hope's opening brief, EPA's role here was not to develop its own preferred criterion for TDS in the Main Stem of Red Dog Creek. The CWA delegates that duty in the first instance to the State of Alaska. *See* 33 U.S.C. §§ 1313(c)(1), 1313(c)(2)(A); *see also* 33 U.S.C. § 1251(b) (recognizing the "primary responsibilities and rights of States to prevent, reduce, and eliminate pollution"of waters within their borders). EPA's role was to ensure that Alaska had a "sound scientific rationale" to conclude that its site-specific water quality criterion would protect the designated uses of the Main Stem of Red Dog Creek, including the propagation of aquatic life. 40 C.F.R. § 131.11(a)(1); *see also Natural Res. Def. Council v. U.S. EPA*, 16 F.3d 1395, 1399, 1402 (4th Cir. 1993) (EPA performs a "reviewing capacity" to ensure that the underlying criteria are "scientifically defensible and are protective of designated uses").

To fulfill that duty, EPA reviewed the available scientific evidence concerning the effects of TDS on aquatic life, as well as field surveys of aquatic life in the Red Dog Creek system, and concluded that Alaska's criterion for times outside the spawning season would protect Arctic grayling. (ER 211, 215–18.) Because the Stekoll study provided "clear evidence" that TDS exposure impacted "fertilization success" in some salmonids, and because that result could not necessarily be extrapolated to Arctic grayling, EPA followed Stekoll's recommendation and ordered an additional "short term" test on fertilization success in Arctic grayling. (ER 100, 355.) Given the results of that follow-up study, including the fact that the second-year data consistently showed no effect on fertilization success at TDS concentrations of 2,782 mg/L, EPA reasonably concluded that Alaska's 1,500 mg/L limit on TDS during the Arctic grayling spawning season was "scientifically defensible" and would be protective of Arctic grayling. (ER 101.)

Point Hope does not dispute that the follow-up study showed that the proposed criterion would not significantly impact fertilization success in Arctic grayling. Rather, Point Hope's exclusive argument on appeal is that EPA also had to "obtain" information about the "long-term and delayed impacts" to Arctic grayling from TDS exposure during fertilization before EPA could approve Alaska's criterion. (Opening Br.

22.) In other words, Point Hope contends that EPA had to order even more studies before it could approve Alaska's criterion.

Point Hope's argument lacks merit. "EPA typically has wide latitude in determining the extent of data-gathering necessary to solve a problem." *Sierra Club v. U.S. EPA*, 167 F.3d 658, 662 (D.C. Cir. 1999); *see also Hercules, Inc. v. EPA*, 598 F.2d 91, 115 (D.C. Cir. 1978) ("Choice among scientific test data is precisely the type of judgment that must be made by EPA, not [the] court."). EPA is not required to resolve or explain "every possible scientific uncertainty" in its decision. *Lands Council*, 537 F.3d at 988. If it were, it is difficult to imagine when EPA would be able to approve water quality criteria, for the science on any given pollutant's potential effects is rarely conclusive. *See Dioxin/Organochlorine Ctr. v. Clarke*, 57 F.3d 1517, 1523 (9th Cir. 1995) (upholding EPA-promulgated "total maximum daily load" that was based on "inconclusive and diverse scientific data regarding the toxicity of dioxin"); *Natural Res. Def. Council v. EPA*, 529 F.3d 1077, 1086 (D.C. Cir. 2008) (rejecting argument that "EPA could have used *better* data in conducting its risk analysis" because the sole question was "whether EPA has acted reasonably, not whether it has acted flawlessly").

Nor must EPA fill every gap in existing scientific knowledge before reaching a decision. "In areas implicating technical expertise and judgment, courts do not require 'perfect studies' or data." *Envtl. Def. Ctr., Inc. v. EPA*, 344 F.3d 832, 869 (9th Cir. 2003) (quoting *Sierra Club*, 167 F.3d at 662); *see also Natural Res. Def. Council v. Muszynski*, 268 F.3d 91, 101 (2d Cir. 2001) ("EPA's hands are not tied just because it must act based on scientific knowledge that is incomplete or disputed."). The CWA directs EPA to base its water quality criteria guidelines[8] on "the latest scientific knowledge," not the results of conclusive scientific studies ordered by EPA. 33 U.S.C. § 1314(a); 40 C.F.R. § 131.3(c). And although the CWA authorizes EPA to request additional information,

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[8] Consistent with the CWA, 33 U.S.C. § 1314(a), EPA has developed guidelines to assist the States in establishing water quality criteria by specifying, for some pollutants, the maximum concentrations that EPA believes would still protect aquatic life and human health. *See* EPA Water Quality Standards Handbook Introduction and § 3.1 (Statutory Addendum at 6–8). EPA calls those guidelines "Section 304(a) Guidance." 40 C.F.R. § 131.3(c). States may rely on Section 304(a) Guidance in adopting water quality criteria, or they may use "[o]ther scientifically defensible methods." 40 C.F.R. 131.11(b)(1)(iii). Because there is no such guidance on TDS for aquatic life protection, Alaska had to develop its criterion using scientifically defensible methods.

including further scientific studies, in fulfilling its duties, *see* 33 U.S.C. § 1318(a), EPA has ample discretion to decide whether and how to exercise that authority. *Cf. Natural Res. Def. Council v. U.S. EPA*, 863 F.2d 1420, 1434 (9th Cir. 1988) (EPA has "wide discretion" under 33 U.S.C. § 1318(a)). EPA properly exercised that discretion here by requiring a follow-up study into a specific effect on Arctic grayling—the effect of TDS exposure on fertilization success—because Stekoll had demonstrated that effect in other salmonids. (ER 100.)

Point Hope observes that when EPA issues water quality criteria guidelines, EPA considers "both the acute and chronic impacts of exposure to a pollutant" to protect against "unacceptable long-term and short-term effects" on aquatic life. (Opening Br. 21–22 (citing ER 450–54, 456–57).) *See also* EPA Water Quality Standards Handbook §§ 3.3, 3.5.1 (Statutory Addendum at 9–10) (providing that state-promulgated "[a]quatic life criteria should protect against both short-term (acute) and long-term (chronic) effects"). Those guidance documents, however, do not indicate that EPA must always have data on the delayed effects of acute exposure to a pollutant at a particular life stage, such as fertilization.

According to EPA's guidance, "acute" means "a stimulus severe enough to rapidly induce an effect," and "chronic" means "a stimulus that lingers or continues for a relatively long period of time, often one tenth of the life span or more." EPA Water Quality Standards Handbook, Glossary (Statutory Addendum at 4–5). Thus, the guidance merely indicates that proposed criteria should account for the effects of both short-term and long-term exposure to a pollutant. Those documents do not mean that data on the delayed effects of acute exposure is necessary in every case.

As explained above, in its unchallenged 2003 decision, EPA reviewed the existing scientific information on TDS's toxicity to aquatic species and concluded that limiting long-term TDS exposure to concentrations of 1,500 mg/L would be protective of Arctic grayling during all life stages except spawning. (ER 215–18.) However, because the core finding of the Stekoll study was that TDS exposure during fertilization impacted fertilization success in some salmonids, EPA followed Stekoll's recommendation and properly exercised its discretion to require an additional study of TDS's impacts on fertilization success in Arctic grayling. (ER 100, 355.) As explained in the next section, EPA did not interpret the Stekoll study to have found that TDS exposure during fertilization increased later mortality rates in other salmonids. EPA's decision not to order further study into that effect on Arctic grayling therefore was not arbitrary or capricious.

II. EPA'S INTERPRETATION OF THE STEKOLL STUDY, AND CONSEQUENT DECISION TO FOCUS THE FOLLOW-UP STUDY ON FERTILIZATION SUCCESS RATHER THAN DELAYED EFFECTS, WAS REASONABLE AND DESERVES DEFERENCE FROM THE COURT.

Point Hope's central argument on appeal is that EPA erred in not ordering long-term testing with Arctic grayling because the Stekoll study allegedly proved that "later, delayed impacts, including mortality, were also caused by TDS exposure during fertilization." (Opening Br. 20.) That argument, however, is based on a misinterpretation of the Stekoll study not shared by EPA. As explained below, EPA's decision was based on its reasonable interpretation of the Stekoll study's conclusion, which was that increasing concentrations of TDS caused decreased "fertilization success" in some salmonids. (ER 100, 216.) Because EPA's interpretation of the Stekoll study was reasonable, this court should defer to EPA's scientific judgment that long-term testing on the delayed effects of TDS exposure during fertilization in Arctic grayling was unwarranted.

A. The Court Should Defer to EPA's Interpretation of the Stekoll Study so Long as It Is Reasonable.

It is neither Point Hope's nor the court's role to interpret the results of the Stekoll study in the first instance. Rather, this Court must "'defer to the agency's interpretation of equivocal evidence, so long as it is reasonable.'" *Central Ariz. Water Conservation Dist. v. United States EPA*, 990 F.2d 1531, 1540 (9th Cir. 1993) (quoting *NRDC, Inc. v. EPA*, 902 F.2d 962, 968 (D.C. Cir. 1990)); *see also id.* at 1545 ("Because Congress delegated to EPA the power to regulate on the borders of the unknown, this court will not interfere with the agency's reasonable interpretations of equivocal evidence." (internal quotation marks omitted); *Marsh v. Oregon Natural Res. Council*, 490 U.S. 360, 377 (1989) ("Because analysis of the relevant documents requires a high level of technical expertise, we must defer to the informed discretion of the responsible federal agencies." (internal quotation marks omitted)); *Animal Legal Defense Fund, Inc. v. Glickman*, 204 F.3d 229, 235 (D.C. Cir. 2000) ("Courts are most deferential to agency readings of scientific evidence.").

EPA interpreted Stekoll's study to have "conclude[d] that total dissolved solids (TDS) with a composition similar to that of Red Dog

Mine effluent, reduces fertilization success in six species of salmonids at varying concentrations." (ER 216.) As explained in more detail below, that interpretation of Stekoll's results is amply supported by his recommendation to follow up with "short term" tests at the fertilization stage and his consistent finding that fertilization rates decreased with increasing concentrations of TDS. (ER 271, 275–76, 289–90, 355; SER 284.) It was only because the Stekoll study strongly demonstrated an effect on "fertilization success" in some other salmonids that EPA deemed it necessary to order an extra study on that effect in Arctic grayling. (ER 100.)

Although Stekoll did observe some trends in his data suggesting a connection between TDS exposure and later mortality rates, in EPA's scientific judgment Stekoll's results did not warrant a long-term study on the delayed effects of TDS exposure during fertilization in Arctic grayling. (*See* ER 435 (stating that Stekoll's interim report showed only that there "may" be adverse affects to the "long-term survival of salmon eggs when they are exposed to calcium-dominated TDS during the fertilization stage").) This court "defer[s] to an agency decision not to invest the resources necessary to conduct the perfect study." *Envtl. Def.*

Ctr., Inc. v. EPA, 344 F.3d 832, 872 (9th Cir. 2003) (citing *Am. Iron & Steel Inst. v. EPA*, 115 F.3d 979, 1004 (D.C.Cir.1997)).

Given the equivocal evidence concerning delayed effects from TDS exposure during fertilization, EPA's judgment that the science did not warrant the type of long-term testing with Arctic grayling demanded by Point Hope should be upheld. *See, e.g.*, *Natural Res. Def. Council*, 16 F.3d at 1404 (upholding EPA approval of state water quality criterion despite contrary study because EPA maintained that the study's "results [were] inconclusive" and the court was "not in a position to second-guess [that] technical decision by administrative experts"); *Public Citizen Health Research Group v. Tyson*, 796 F.2d 1479, 1504 (D.C. Cir. 1986) (upholding agency's decision because evidence cited by plaintiff "[did] not amount to a scientific certainty binding on the agency").

B. EPA's Interpretation of Stekoll's Study Was Reasonable and Therefore Deserves Deference.

1. Stekoll's Recommendation to Conduct Additional "Short Term" Tests at the Fertilization Stage.

As the district court correctly observed (ER 13–14), Stekoll recommended further "short term" tests at critical stages, such as "fertilization or hatch," which is precisely the type of study that EPA ordered here. (ER 355.) Although Stekoll did suggest that "long-term" assays could be conducted, he recommended such studies only "if deemed necessary" to protect "critical populations." (ER 355.) Stekoll therefore recognized that long-term testing is not always warranted and left it to subsequent decision makers, such as EPA, to exercise their scientific judgment. Stekoll's own recommendation for further study therefore supports EPA's exercise of its discretion to require a short-term test on fertilization success in Arctic grayling.

Indeed, Stekoll himself conducted subsequent short-term testing on Arctic grayling's exposure to TDS in Red Dog Creek and focused exclusively on fertilization success, not later mortality rates. (SER 283–90.) Stekoll explained that his previous work had shown that TDS exposure caused significant reductions in "fertilization success" and he had thus recommended that his acute "fertilization test" be used in follow up studies. (SER 284.)[9] Because the results of Stekoll's Arctic

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[9] Stekoll also stated that he observed lower rates of survival in juvenile salmonids "chronically" exposed to TDS "from the fertilization stage to the fry stage." (SER 292.) However, as explained in Subsection II.B.3 below, Stekoll's chronic assays show only that lower rates of survival occurred from exposure to TDS throughout multiple life stages—not from TDS exposure <u>during fertilization</u>, as Point Hope contends. (Opening Br. 20.)

grayling tests were inconclusive, he recommended that Arctic grayling "be tested again under more controlled conditions." (SER 291.) The follow-up study required by EPA served that purpose. Stekoll's own subsequent characterization of his work and recommendation for further study therefore also support EPA's decision to focus the follow-up test on fertilization success, rather than delayed effects from TDS exposure during fertilization.

2. Stekoll's Acute Assays.

Stekoll conducted two types of tests as part of his original research: acute and chronic. The acute assays exposed several species of salmon eggs, not including Arctic grayling, to TDS during fertilization and for a short period thereafter. Stekoll stated that out of his results for those tests, "[o]nly reduced rates of fertilization with increasing concentration of TDS were significant." (ER 271; *see also* ER 275 (summarizing 1999 data and explaining that "[m]ost of the effect was from lack of fertilization"), 276 (same for 2000 data).) The central finding from Stekoll's acute assays was a "significant trend of increasing numbers of unfertilized eggs with increasing TDS concentration exposure," and the sensitivity of that effect varied widely among the tested species. (ER 289–90.) It was that “clear” finding that prompted EPA to require additional studies of the effects of TDS on fertilization success in Arctic grayling before EPA would approve Alaska’s criterion. (ER 100.)

Stekoll’s results with respect to later mortalities of fertilized eggs were not clear. Point Hope focuses on Stekoll’s statement, based on his 1999 acute data, that “[e]ggs in our experiment that were fertilized in TDS had more problems afterwards” in terms of later mortality rates. (ER 284; *see also* ER 275 (summarizing 1999 data).) However, Stekoll was not able to replicate that result using the same experimental design in 2000. (ER 276 (summarizing 2000 data); *compare* ER 279 (BY99 graphs showing linear trends in short-term and long-term mortality) *with* ER 282 (BY00 graphs showing no trends in short-term or long-term mortality).) Thus, although Stekoll cautioned that data from one of his acute tests indicated a relationship between TDS exposure during fertilization and later mortalities, that was not the conclusion of his research. Rather, the core finding of Stekoll’s acute research was a consistent, statistically significant correlation between increasing concentrations of TDS and decreased fertilization success in some salmonids (which did not include Arctic grayling). (ER 271, 275–76, 289–90.)

3. Stekoll's Chronic Assays.

Stekoll's chronic assays examined the impacts of exposing Coho salmon to TDS throughout fertilization, incubation, hatch, and growth to the fry stage. (ER 306–07, 315–17.) Stekoll reported that such chronic exposure to TDS at concentrations of 2,500 mg/L significantly increased post-hatch mortality levels. (ER 326–27, 334.) However, because TDS exposure in the chronic assays lasted throughout several life stages, Stekoll's result absolutely does not support Point Hope's assertion that later mortalities were "caused by TDS exposure during fertilization." (Opening Br. 20 (emphasis supplied).)[10] Rather, at most, it showed that long-term exposure to TDS throughout several life stages increased later mortality rates. Importantly, EPA's 2003 decision already considered the effects of long-term TDS exposure and EPA

[10] Point Hope attempts to draw that same unwarranted conclusion from a statement in a literature review that TDS "in the range of 750 mg/L *significantly reduces fertilization and hatching rates*" in other salmonids and extends the time it takes for them to develop into later stages. (Opening Br. 20 (quoting ER 367) (emphasis supplied by Point Hope).) But fertilization and hatch are different life stages, *see* ER 139, and the statement on which Point Hope relies does not indicate when or for how long the fish were exposed to TDS.

concluded that limiting TDS exposure to concentrations of 1,500 mg/L would be protective of Arctic grayling throughout all life stages other than spawning. (ER 211, 215–18.) Point Hope does not and cannot challenge that decision here.

Only one of the "chronic" tests in Stekoll's study exposed eggs to TDS exclusively during fertilization. (ER 336–37 (discussing Treatment Scheme C in Brood Year 2012).) In that test, there was no significant effect of TDS exposure on "post-hatch mortality" (ER 346 & figure 3.13), but there were a significant number of "eggs that were never fertilized or embryos that died before hatching," which Stekoll termed "pre-hatch mortality" (ER 345 & figure 3.12). The data does not show whether the number of fertilized eggs that died before hatch was significant on its own, or if most of the effect was from lack of fertilization, as was the case with the acute assays (ER 275–76). Accordingly, this test also does not support Point Hope's assertion that TDS exposure during fertilization caused increased mortalities at later stages of development. (Opening Br. 20.)

Finally, Point Hope observes that in summarizing the results of all of his chronic assays, Stekoll stated that "[h]igher TDS concentrations at fertilization were related to higher pre-hatch mortality rates." (Opening Br. 9–10 (quoting ER 354).) However, as previously discussed, it was not unusual for Stekoll to include unfertilized eggs in his "pre-hatch mortality" results. (ER 345.) Stekoll's statement therefore does not necessarily mean that exposure to TDS during fertilization caused later mortalities, as opposed to decreased fertilization success.

EPA interpreted Stekoll's study to have concluded that TDS exposure impacted fertilization success in other salmonids (ER 100, 216), not that TDS exposure during fertilization caused later mortality, as Point Hope contends (Opening Br. 20). EPA's interpretation is reasonable because it is supported by Stekoll's acute and chronic assay data, as well as his own recommendation for further study and later characterization of his results. The Court therefore should defer to EPA's interpretation of the scientific evidence and EPA's scientific judgment that the follow-up study should focus on fertilization success in Arctic grayling, not the delayed effects of TDS exposure during fertilization.

* * *

In sum, the district court correctly held that EPA did not fail to address an "important" aspect of the problem by not ordering a long-term study of the delayed effects of TDS exposure during fertilization in Arctic grayling. (ER 16.) Unlike decreased fertilization success, EPA did not interpret the Stekoll study to have shown that TDS exposure during fertilization caused later mortality in other salmonids. Because EPA's interpretation of the Stekoll study is reasonable, the Court should defer to EPA's judgment that the scientific evidence did not warrant the type of long-term tests with Arctic grayling that Point Hope demands.

Significantly, EPA followed the precise recommendation of the Stekoll study by requiring an additional "short term" test on the effect of TDS at the "fertilization" stage. (ER 355.) Point Hope does not dispute that the results of that study showed that exposure to TDS concentrations of 1,500 mg/L would not significantly impact fertilization success in Arctic grayling. (ER 106.) And EPA had already concluded from its previous review of the existing science that limiting long-term TDS exposure to concentrations of 1,500 mg/L would be protective of Arctic grayling.

EPA "considered the relevant factors and articulated a rational connection between the facts found and the choices made." *Pac. Coast Fedn.*, 693 F.3d at 1091. Accordingly, the Court should defer to EPA's scientific expertise and uphold its decision that Alaska's TDS criterion for the Arctic grayling spawning season was "scientifically defensible" and would protect the designated uses of the Main Stem of Red Dog Creek. (ER 101.)

CONCLUSION

For the foregoing reasons, the district court's judgment in favor of EPA should be affirmed.

Respectfully submitted,

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STATEMENT OF RELATED CASES

Counsel for EPA is unaware of any case that is related to this appeal within the meaning of Ninth Circuit Rule 28-2.6.

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CERTIFICATE OF COMPLIANCE WITH TYPE VOLUME LIMITATION

This brief complies with the type volume limitation set forth in Rule 32(a)(7)(B) of the Federal Rules of Appellate Procedure. Excepting the portions described in Rule 32(a)(7)(B)(iii), the brief contains 6,855 words.

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STATUTORY AND REGULATORY ADDENDUM

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* This document is publically available and can be accessed at http://water.epa.gov/scitech/swguidance/standards/handbook/ (last visited May 28, 2013).

United States
Environmental Protection
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Office of Water
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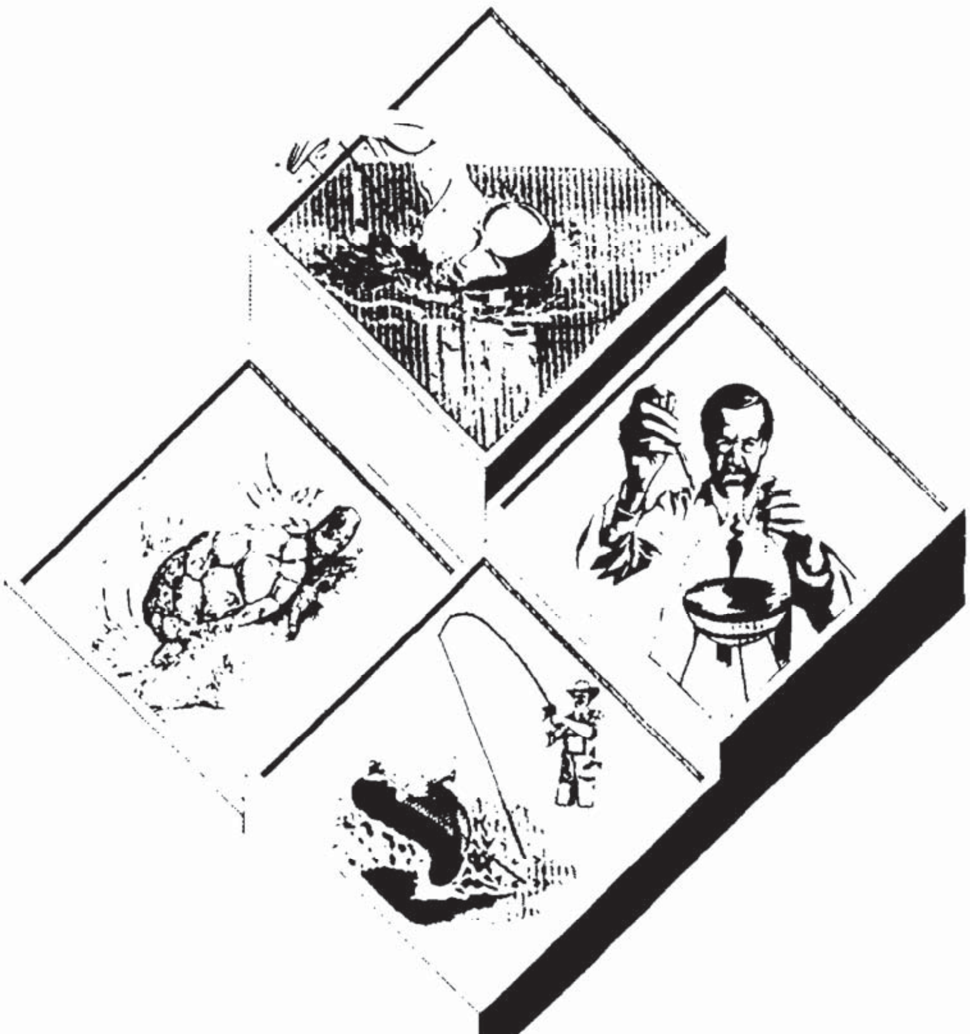
Water Quality Standards Handbook:

Second Edition



"... to restore and maintain the chemical, physical, and biological integrity of the Nation's waters."

Section 101(a) of the Clean Water Act

Contains Update #1
August 1994

SA 01

WATER QUALITY STANDARDS

HANDBOOK

SECOND EDITION

Water Quality Standards Branch
Office of Science and Technology
U.S. Environmental Protection Agency
Washington, DC 20460

September 1993

Contains update #1
August 1994

GLOSSARY

WATER QUALITY STANDARDS HANDBOOK

SECOND EDITION

GLOSSARY

The "Act" refers to the Clean Water Act (Public Law 92-500, as amended (33 USC 1251, et seq.) (40 CFR 131.3.)

"Acute" refers to a stimulus severe enough to rapidly induce an effect; in aquatic toxicity tests, an effect observed in 96- hours or less is typically considered acute. When referring to aquatic toxicology or human health, an acute affect is not always measured in terms of lethality (USEPA, 1991a.)

"Acute-chronic ratio" (ACR) is the ratio of the acute toxicity of an effluent or a toxicant to its chronic toxicity. It is used as a factor for estimating chronic toxicity on the basis of acute toxicity data, or for estimating acute toxicity on the basis of chronic toxicity data (USEPA, 1991a.)

"Acutely toxic conditions" are those acutely toxic to aquatic organisms following their short-term exposure within an affected area (USEPA, 1991a.)

"Additivity" is the characteristic property of a mixture of toxicants that exhibits a total toxic effect equal to the arithmetic sum of the effects of the individual toxicants (USEPA, 1991a.)

"Ambient toxicity" is measured by a toxicity test on a sample collected from a water body (USEPA, 1991a.)

"Antagonism" is the characteristic property of a mixture of toxicants that exhibits a less-than-additive total toxic effect (USEPA, 1991a.)

"Aquatic community" is an association of interacting populations of aquatic organisms in a given water body or habitat (USEPA, 1990; USEPA, 1991a.)

"Averaging period" is the period of time over which the receiving water concentration is averaged for comparison with criteria concentrations. This specification limits the duration of concentrations above the criteria (USEPA, 1991a.)

"Bioaccumulation" is the process by which a compound is taken up by an aquatic organism, both from water and through food (USEPA, 1991a.)

"Bioaccumulation factor" (BAF) is the ratio of a substance's concentration in tissue versus its concentration in ambient water, in situations where the organism and the food chain are exposed (USEPA, 1991a.)

"Bioassay" is a test used to evaluate the relative potency of a chemical or a mixture of chemicals by comparing its effect on a living organism with the effect of a standard preparation on the same type of organism. Bioassays are frequently used in the pharmaceutical industry to evaluate the potency of vitamins and drugs (USEPA, 1991a.)

"Bioavailability" is a measure of the physicochemical access that a toxicant has to the biological processes of an organism. The less the bioavailability of a toxicant, the less its toxic effect on an organism (USEPA, 1991a.)

"Bioconcentration" is the process by which a compound is absorbed from water through gills or epithelial tissues and is concentrated in the body (USEPA, 1991a.)

"Bioconcentration factor" (BCF) is the ratio of a substance's concentration in tissue versus its concentration in water, in situations where the food chain is not exposed or contaminated. For non-metabolized substances, it represents equilibrium partitioning between water and organisms (USEPA, 1991a.)

"Biological criteria" are narrative expressions or numeric values of the biological characteristics of aquatic communities based on appropriate reference conditions. As such, biological criteria serve as an index of aquatic community health. It is also known as **biocriteria** (USEPA, 1991a.)

"Biological integrity" is the condition of the aquatic community inhabiting unimpaired water bodies of a specified habitat as measured by community structure and function (USEPA, 1991a.)

"Biological monitoring" describes the use of living organisms in water quality surveillance to indicate compliance with water quality standards or effluent limits and to document water quality trends. Methods of biological monitoring may include, but are not limited to, toxicity testing (such as ambient toxicity testing or whole-effluent toxicity testing) and biological surveys. It is also known as **biomonitoring** (USEPA, 1991a.)

"Biological survey or biosurvey" is collecting, processing, and analyzing a representative portion of the resident aquatic community to determine its structural and/or functional characteristics (USEPA. 1991a.)

"Biomagnification" is the process by which the concentration of a compound increases in species occupying successive trophic levels (USEPA, 1991a.)

"Cancer potency slope factor" (q_1*) is an indication of a chemical's human cancer-causing potential derived using animal studies or epidemiological data on human exposure; based on extrapolation of high-dose levels over short periods of time to low-dose levels and a lifetime exposure period through the use of a linear model (USEPA, 1991a.)

"Chronic" defines a stimulus that lingers or continues for a relatively long period of time, often one-tenth of the life span or more. Chronic should be considered a relative term depending on the life span of an organism. The measurement of a chronic effect can be reduced growth, reduced reproduction, etc., in addition to lethality (USEPA, 1991a.)

"Community component" is a general term that may pertain to the biotic guild (fish, invertebrates, algae), the taxonomic category (order, family, genus, species), the feeding strategy (herbivore, omnivore, predator), or the organizational level (individual, population, assemblage) of a biological entity within the aquatic community (USEPA, 1991a.)

Water Quality Handbook - Chapter 3: Water Quality Criteria (40 CFR 131.11)

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You will need Adobe Reader to view some of the files on this page. See EPA's PDF page to learn more.

The term "water quality criteria" has two different definitions under the Clean Water Act (CWA). Under section 304(a), EPA publishes water quality criteria that consist of scientific information regarding concentrations of specific chemicals or levels of parameters in water that protect aquatic life and human health (see section 3.1 of this Handbook). The States may use these contents as the basis for developing enforceable water quality standards. Water quality criteria are also elements of State water quality standards adopted under section 303(c) of the CWA (see sections 3.2 through 3.6 of this Handbook). States are required to adopt water quality criteria that will protect the designated use(s) of a water body. These criteria must be based on sound scientific rationale and must contain sufficient parameters or constituents to protect the designated use.

3.1 EPA Section 304(a) Guidance

Updated Information

National Recommended Water Quality Criteria

EPA and a predecessor agency have produced a series of scientific water quality criteria guidance documents. Early Federal efforts were the "Green Book" (FWPCA,

1968) and the "Red Book" (USEPA, 1976). EPA also sponsored a contract effort that resulted in the "Blue Book" (NAS/NAE, 1973). These early efforts were premised on the use of literature reviews and the collective scientific judgment of Agency and advisory panels. However, when faced with the need to develop criteria for human health as well as aquatic life, the Agency determined that new procedures were necessary. Continued reliance solely on existing scientific literature was deemed inadequate because essential information was not available for many pollutants. EPA scientists developed formal methodologies for establishing scientifically defensible criteria. These were subjected to review by the Agency's Science Advisory Board of outside experts and the public. This effort culminated on November 28, 1980, when the Agency published criteria development guidelines for aquatic life and for human health, along with criteria for 64 toxic pollutants (USEPA, 1980a,b). Since that initial publication, the aquatic life methodology was amended (Appendix H), and additional criteria were proposed for public comment and finalized as Agency criteria guidance. EPA summarized the available criteria information in the "Gold Book" (USEPA, 1986a), which is updated from time to time. However, the individual criteria documents (see Appendix I), as updated, are the official guidance documents.

EPA's criteria documents provide a comprehensive toxicological evaluation of each chemical. For toxic pollutants, the documents tabulate the relevant acute and chronic toxicity information for aquatic life and derive the criteria maximum concentrations (acute criteria) and criteria continuous concentrations (chronic criteria) that the Agency recommends to protect aquatic life resources. The methodologies for these processes are described in Appendices H and J and outlined in sections 3.1.2 and 3.1.3 of this Handbook.

—3.1.1 State Use of EPA Criteria Documents

EPA's water quality criteria documents are available to assist States in:

- adopting water quality standards that include appropriate numeric water quality criteria;
- interpreting existing water quality standards that include narrative "no toxics in toxic amounts" criteria;
- making listing decisions under section 304(1) of the CWA;
- writing water quality-based NPDES permits and individual control strategies; and
- providing certification under section 401 of the CWA for any Federal permit or license (*e.g.*, EPA-issued NPDES permits, CWA section 404 permits, or Federal Energy Regulatory Commission licenses).

In these situations, States have primary authority to determine the appropriate level to protect human health or welfare (in accordance with section 303(c)(2) of the CWA) for each water body. However, under the Clean Water Act, EPA must also review and approve State water quality standards; section 304(1) listing decisions and draft and final State-issued individual control strategies; and in States where EPA writes NPDES permits, EPA must develop appropriate water quality-based permit limitations. The States and EPA therefore have a strong interest in assuring that the decisions are legally defensible, are based on the best information available, and are subject to full and meaningful public comment and participation. It is very important that each decision be supported by an adequate record. Such a record is critical to meaningful comment, EPA's review of the State's decision, and any subsequent administrative or judicial review.

Any human health criterion for a toxicant is based on at least three interrelated considerations:

- cancer potency or systemic toxicity,
- exposure, and
- risk characterization.

- Current National Recommended Criteria – This compilation of national recommended water quality criteria is presented as a summary table containing recommended water quality criteria for the protection of aquatic life and human health in surface water for approximately 150 pollutants.
- Water Quality Standards and Criteria Strategy (2003) – This website describes milestones for high priority strategic actions that were established in 2003, including issuing implementation guidance for bacteria criteria, developing pathogen and sediment criteria, and developing a selection process for producing new or revised chemical criteria.

Federal Rules involving Water Quality Criteria

- Final Water Quality Standards for the State of Florida's Lakes and Flowing Waters (2010) – This action established numeric nutrient criteria for Florida's inland waters.
- Bacteria Rule for Coastal and Great Lakes Waters (2004) – This rule established more protective health-based federal bacteria standards for those states and territories bordering Great Lakes or ocean waters that have not yet adopted standards in accordance with the BEACH Act of 2000.
- Water Quality Standards for Puerto Rico (2004) – Promulgated primary contact Recreation Uses and associated water quality criteria for six water bodies.
- Establishment of Numeric Criteria for Priority Pollutants for the State of California (2000) – EPA promulgated this rule to fill a gap in California water quality standards that was created in 1994 when a State court overturned the State's water quality control plans containing water quality criteria for priority toxic pollutants. Between 1994 and 2000 the State of California lacked numeric water quality

States may make their own judgments on each of these factors within reasonable scientific bounds, but documentation to support their judgments, when different from EPA's recommendation, must be clear and in the public record. If a State relies on EPA's section 304(a) criteria document (or other EPA documents), the State may reference and rely on the data in these documents and need not create duplicative or new material for inclusion in their records. However, where site-specific issues arise or the State decides to adopt an approach to any one of these three factors that differs from the approach in EPA's criteria document, the State must explain its reasons in a manner sufficient for a reviewer to determine that the approach chosen is based on sound scientific rationale (40 CFR 131.11 (b)).

—3.1.2 Criteria for Aquatic Life Protection

The development of national numerical water quality criteria for the protection of aquatic organisms is a complex process that uses information from many areas of aquatic toxicology. (See Appendix H (PDF) (18 pp, 1.5MB) for a detailed discussion of this process.) After a decision is made that a national criterion is needed for a particular material, all available information concerning toxicity to, and bioaccumulation by. aquatic organisms is collected and reviewed for acceptability. If enough acceptable data for 48- to 96-hour toxicity tests on aquatic plants and animals are available, they are used to derive the acute criterion. If sufficient data on the ratio of acute to chronic toxicity concentrations are available, they are used to derive the chronic or long-term exposure criteria. If justified, one or both of the criteria may be related to other water quality characteristics, such as pH, temperature, or hardness. Separate criteria are developed for fresh and salt waters.

Updated Information

- Aquatic Life Criteria - This website provides basic information on 304(a) recommended criteria for the protection of aquatic life. This page also provides updates on criteria development.
- Aquatic Life: Contaminants of Emerging Concern (2008) - This white paper details technical issues and recommendations for deriving ambient water quality criteria for aquatic life for contaminants of emerging concern.
- Water Quality Models and Tools - This website provides access to a number of specialized models and tools for water quality managers, including those related to criteria.

The Water Quality Standards Regulation allows States to develop numerical criteria or modify EPA's recommended criteria to account for site-specific or other scientifically defensible factors. Guidance on modifying national criteria is found in sections 3.6 and 3.7. When a criterion must be developed for a chemical for which a national criterion has not been established, the regulatory authority should refer to the EPA guidelines (Appendix H) (PDF) (18 pp, 1.5MB).

criteria required by the Clean Water Act for many priority toxic pollutants, necessitating this action by EPA.

- Beaches Environmental Assessment and Coastal Health Act (BEACH Act) of 2000 - The BEACH Act established uniform criteria for testing, monitoring, and notifying public users of possible coastal recreation water problems.
- Advanced Notice of Proposed Rulemaking for Water Quality Standards (1998) | Print Version (PDF) (66 pp, 474K) - See pages 36762 to 36778 for and overview of water quality criteria policy and EPA's thinking on program development in 1998.
- Final Water Quality Guidance for the Great Lakes System (1995) This guidance contains numeric criteria to protect aquatic life for 15 pollutants and a two-tiered methodology to derive criteria (Tier I) or values (Tier II) for additional pollutants discharged to the Great Lakes System.
- National Toxics Rule (1992) - This EPA action promulgates for 14 States the chemical-specific, numeric criteria for priority toxic pollutants necessary to bring all States into compliance with the requirements of section 303(c)(2)(B) of the Clean Water Act (CWA).

Magnitude for Aquatic Life Criteria

Water quality criteria for aquatic life contain two expressions of allowable magnitude: a criterion maximum concentration (CMC) to protect against acute (short-term) effects; and a criterion continuous concentration (CCC) to protect against chronic (long-term) effects. EPA derives acute criteria from 48- to 96-hour tests of lethality or immobilization. EPA derives chronic criteria from longer term (often greater than 28-day) tests that measure survival, growth, or reproduction. Where appropriate, the calculated criteria may be lowered to be protective of commercially or recreationally important species.

Duration for Aquatic Life Criteria

The quality of an ambient water typically varies in response to variations of effluent quality, stream flow, and other factors. Organisms in the receiving water are not experiencing constant, steady exposure but rather are experiencing fluctuating exposures, including periods of high concentrations, which may have adverse effects. Thus, EPA's criteria indicate a time period over which exposure is to be averaged, as well as an upper limit on the average concentration, thereby limiting the duration of exposure to elevated concentrations. For acute criteria, EPA recommends an averaging period of 1 hour. That is, to protect against acute effects, the l-hour average exposure should not exceed the CMC.

upon a report from the National Academy of Sciences, the Administrator should set target levels for contaminants in drinking water at which "no known or anticipated adverse effects occur and which allow an adequate margin of safety." MCLGs do not take treatment, cost, and other feasibility factors into consideration. Section 304(a)(l) criteria are, in concept, related to the health-based goals specified in the MCLGs.

MCLs of the SDWA, where they exist, control toxic chemicals in finished drinking water. However, because of variations in treatment, ambient water criteria may be used by the States as a supplement to SDWA regulations. When setting water quality criteria for public water supplies, States have the option of applying MCLs, section 304(a)(l) human health effects criteria, modified section 304(a)(l) criteria, or controls more stringent than these three to protect against the effects of contaminants by ingestion from drinking water.

For treated drinking water supplies serving 25 people or greater, States must control contaminants down to levels at least as stringent as MCLs (where they exist for the pollutants of concern) in the finished drinking water. However, States also have the options to control toxics in the ambient water by choosing section 304(a)(1) criteria, adjusted section 304(a)(1) criteria resulting from the reduction of the direct drinking water exposure component in the criteria calculation to the extent that the treatment process reduces the level of pollutants, or a more stringent contaminant level than the former three options.

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3.3 State Criteria Requirements

Section 131.11(a)(1) of the Regulation requires States to adopt water quality criteria to protect the designated use(s). The State criteria must be based on sound scientific rationale and must contain sufficient parameters or constituents to protect the designated use(s). For waters with multiple use designations, the criteria must support the most sensitive use.

In section 131.11, States are encouraged to adopt both numeric and narrative criteria. Aquatic life criteria should protect against both short-term (acute) and long-term (chronic) effects. Numeric criteria are particularly important where the cause of toxicity is known or for protection against pollutants with potential human health impacts or bioaccumulation potential. Numeric water quality criteria may also be the best way to address nonpoint source pollution problems. Narrative criteria can be the basis for limiting toxicity in waste discharges where a specific pollutant can be identified as causing or contributing to the toxicity but where there are no numeric criteria in the State standards. Narrative criteria also can be used where toxicity cannot be traced to a particular pollutant.

Section 131.11(a)(2) requires States to develop implementation procedures which explain how the State will ensure that narrative toxics criteria are met.

To more fully protect aquatic habitats, it is EPA's policy that States fully integrate chemical-specific, whole-effluent, and biological assessment approaches in State water quality programs (see Appendix R). Specifically, each of these three methods can provide a valid assessment of *non-attainment* of designated aquatic life uses but can rarely demonstrate use *attainment* separately. Therefore, EPA supports a policy of independent application of these three water quality assessment approaches. Independent application means that the validity of the results of any one of the approaches does not depend on confirmation by one or both of the other methods. This policy is based on the unique attributes, limitations, and program applications of each of the three approaches. Each method alone can provide valid and independently sufficient evidence of non-attainment of water quality standards, irrespective of any evidence, or lack thereof, derived from the other two approaches. The failure of one method to confirm impacts identified by another method does not negate the results of the initial assessment.

It is also EPA's policy that States should designate aquatic life uses that appropriately address biological integrity and adopt biological criteria necessary to protect those uses (see section 3.5.3 and Appendices C (PDF) (60 pp, 4.5MB), K (PDF) (17 pp, 1.1MB), and R (PDF) (19 pp, 1.1MB)).

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3.4 Criteria for Toxicants

Applicable requirements for State adoption of water quality criteria for toxicants vary depending upon the toxicant. The reason for this is that the 1983 Water Quality Standards Regulation (Appendix A (PDF) (27 pp, 2.3MB)) and the Water Quality Act of 1987 which amended the Clean Water Act (Public Law 100-4) include more specific requirements for the particular toxicants listed pursuant to CWA section 307(a). For regulatory purposes, EPA has translated the 65 compounds and families of compounds listed pursuant to section 307(a) into 126 more specific substances, which EPA refers to as "priority toxic pollutants. " The 126 priority toxic pollutants are listed in the WQS regulation and in components of a State's narrative criterion implementation procedure (*e.g.*, WET controls or biological criteria) may not ensure full protection of designated uses. For some pollutants, a combination of chemical-specific and other approaches is necessary (*e.g.*, pollutants where bioaccumulation in fish tissue or water consumption by humans is a primary concern).

Biologically based monitoring or assessment methods serve as the basis for control where no specific numeric criteria exist or where calculation or application of pollutant-by-pollutant criteria appears infeasible. Also, these methods may serve as a supplemental measurement of attainment of water quality standards in addition to numeric and narrative criteria. The requirement for both numeric criteria and biologically based methods demonstrates that section 303(c)(2)(B) contemplates that States develop a comprehensive toxics control program regardless of the status of EPA's section 304(a) criteria.

The whole-effluent toxicity (WET) testing procedure is the principal biological monitoring guidance developed by EPA to date. The purpose of the WET procedure is to control point source dischargers of toxic pollutants. The procedure is particularly useful for monitoring and controlling the toxicity of complex effluents that may not be well controlled through chemical-specific numeric criteria. As such, biologically based effluent testing procedures are a necessary component of a State's toxics control program under section 303(c)(2)(B) and a principal means for implementing a State's narrative "free from toxics" standard.

Guidance documents EPA considers to serve the purpose of section 304(a)(8) include the *Technical Support Document for Water Quality-based Toxics Control (USEPA, 1991a) (PDF)* (335 pp, 26.6MB); *Guidelines for Deriving National Water Quality Criteria for the Protection of Aquatic Organisms and Their Uses (PDF)* (59 pp, 557K); *Guidelines and Methodology Used in the Preparation of Health Effect Assessment Chapters of the Consent Decree Water Criteria Documents; Methods for Measuring Acute Toxicity of Effluents to Freshwater and Marine Organisms (USEPA, 1991d); Short-Term Methods for Estimating the Chronic Toxicity of Effluents and Receiving Waters to Freshwater Organisms (USEPA, 2002);* and *Short-Term Methods for Estimating the Chronic Toxicity of Effluents and Receiving Waters to Marine and Estuarine Organisms (USEPA, 2002).*

—3.4.2 Criteria for Nonconventional Pollutants

Criteria requirements applicable to toxicants that are not priority toxic pollutants (e.g., ammonia and chlorine), are specified in the Water Quality Standards Regulation (see 40 CFR 131.11). Under these requirements, States must adopt criteria based on sound scientific rationale that cover sufficient parameters to protect designated uses. Both numeric and narrative criteria (discussed in sections 3.5.1 and 3.5.2, below) may be applied to meet these requirements.

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3.5 Forms of Criteria

States are required to adopt water quality criteria, based on sound scientific rationale, that contain sufficient parameters or constituents to protect the designated use. EPA believes that an effective State water quality standards program should include both parameter-specific (e.g., ambient numeric criteria) and narrative approaches.

Updated Information

- *Water Quality Criteria for Nitrogen and Phosphorus Pollution - This website provides basic information about nitrogen and phosphorus pollution and the development of numeric nutrient criteria. Links to status of state criteria development.*
- *Technical Support for Numeric Nutrient Criteria Development - This website provides technical resources to aid in the development of numeric nitrogen and phosphorus criteria per the goals of EPA's comprehensive framework issued in 2011.*

—3.5.1 Numeric Criteria

Numeric criteria are required where necessary to protect designated uses. Numeric criteria to protect aquatic life should be developed to address both short-term (acute) and long-term (chronic) effects. Saltwater species, as well as freshwater species, must be adequately protected. Adoption of numeric criteria is particularly important for toxicants known to be impairing surface waters and for toxicants with potential human health impacts (e.g., those with high bioaccumulation potential). Human health should be protected from exposure resulting from consumption of water and fish or other aquatic life (e.g., mussels, crayfish). Numeric water quality criteria also are useful in addressing nonpoint source pollution problems.

In evaluating whether chemical-specific numeric criteria for toxicants that are not priority toxic pollutants are required, States should consider whether other approaches (such as whole-effluent toxicity criteria or biological controls) will ensure full protection of designated uses. As mentioned above, a combination of independent approaches may be required in some cases to support the designated uses and comply with the requirements of the Water Quality Standards Regulation (e.g., pollutants where bioaccumulation in fish tissue or water *consumption by humans is a primary concern).*

—3.5.2 Narrative Criteria

To supplement numeric criteria for toxicants, all States have also adopted narrative criteria for toxicants. Such narrative criteria are statements that describe the desired u'water quality goal, such as the following:

> *All waters, including those within mixing zones, shall be free from substances attributable to wastewater discharges or other pollutant sources that:*

1. *Settle to form objectional deposits;*
2. *Float as debris, scum, oil, or other matter forming nuisances;*
3. *Produce objectionable color, odor, taste, or turbidity;*
4. *Cause injury to, or are toxic to, or produce adverse physiological responses in humans, animals, or plants; or*
5. *Produce undesirable or nuisance aquatic life (54 F.R. 28627, July 6, 1989).*

EPA considers that the narrative criteria apply to all designated uses at all flows and are necessary to meet the statutory requirements of section 303(c)(2)(A) of the CWA.

Narrative toxic criteria (No. 4, above) can be the basis for establishing chemical-specific limits for waste discharges where a specific pollutant can be identified as causing or contributing to the toxicity and the State has not adopted chemical-specific numeric criteria. Narrative toxic criteria are cited as a basis for establishing whole-effluent toxicity controls in EPA permitting regulations at 40 CFR 122.44(d)(l)(v).

To ensure that narrative criteria for toxicants are attained, the Water Quality Standards Regulation requires States to develop implementation procedures (see 40 CFR 131.11(a)(2)). Such implementation procedures (Exhibit 3-3) should address all mechanisms to be used by the State to ensure that narrative criteria are attained. Because implementation of chemical-specific numeric criteria is a key component of State toxics control programs, narrative criteria implementation procedures must describe or reference the State's procedures to implement such chemical-specific numeric criteria (e.g., procedures for establishing chemical-specific permit limits under the NPDES permitting program). Implementation procedures must also address State programs to control whole-effluent toxicity (WET) and may address programs to implement biological criteria, where such programs have been developed by the State. Implementation procedures therefore serve as umbrella documents that describe how the State's various toxics control programs are integrated to ensure adequate protection for aquatic life and human health and attainment of the narrative toxics criterion. In essence, the procedure should apply the "independent application" principle, which provides for independent evaluations of attainment of a designated use based on chemical- specific, whole-effluent toxicity, and biological criteria methods (see section 3.5.3 and Appendices C, K, and R).

EPA encourages, and may ultimately require, State implementation procedures to provide for implementation of biological criteria. However, the regulatory basis for requiring whole-effluent toxicity (WET) controls is clear. EPA regulations at 40 CFR 122.44(d)(l)(v) require NPDES permits to contain WET limits where a permittee has been shown to cause, have the reasonable potential to cause, or contribute to an in-stream excursion of a narrative criterion. Implementation of chemical-specific controls is also required by EPA regulations at 40 CFR 122.44(d)(l). State implementation procedures should, at a minimum, specify or reference methods to be used in implementing chemical-specific and whole-effluent toxicity-based controls, explain how these methods are integrated, and specify needed application criteria.

In addition to EPA's regulation at 40 CFR 131, EPA has regulations at 40 CFR 122.44 that cover the National Surface Water Toxics Control Program. These regulations are intrinsically linked to the requirements to achieve water quality standards, and specifically address the control of pollutants both with and without numeric criteria. For example, section 12?.44(d)(l)(vi) provides the permitting authority with several options for establishing effluent limits when a State does not have a chemical-specific numeric criterion for a pollutant present in an effluent at a concentration that causes or contributes to a violation of the State's narrative criteria.

Exhibit 3-3. Components of a State Implementation Procedure for Narrative Toxics Criteria

State implementation procedures for narrative toxics criteria should describe the following:

- *Specific, scientifically defensible methods by which the State will implement its narrative toxics standard for all toxicants, including:*
  - *methods for chemical-specific criteria, including*

CERTIFICATE OF SERVICE

I hereby certify that I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the Ninth Circuit by using the appellate CM/ECF system on May 28, 2013.

I certify that all participants in the case are registered CM/ECF users and that service will be accomplished by the appellate CM/ECF system.

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