ORAL ARGUMENT SCHEDULED FOR OCTOBER 15, 2004

No. 96-1062 and Consolidated Cases

IN THE UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

EDISON ELECTRIC INSTITUTE, et al.,

Petitioners,

v.

U.S. ENVIRONMENTAL PROTECTION AGENCY, et al.,

Respondents.

ON PETITION FOR REVIEW OF A RULE OF THE UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

REPLY BRIEF OF PETITIONERS AND INTERVENOR

John C. Hall
Hall & Associates
1101 15th Street, N.W., Suite 203
Washington, DC 20005
202-463-1166

David E. Evans
Richard H. Sedgley
Stewart T. Leeth
McGuireWoods LLP
901 East Cary Street
Richmond, VA 23219
804-775-1112

Fredric P. Andes
Erika K. Powers
Barnes & Thornburg
One North Wacker Drive, Suite 4400
Chicago, IL 60606-2809
312-214-8310

James N. Christman
Penny A. Shamblin
Andrea W. Wortzel
Hunton & Williams
Riverfront Plaza, East Tower
951 E. Byrd Street
Richmond, VA 23219-4074
804-788-8368

Alexandra D. Dunn
General Counsel
Association of Metropolitan Sewerage Agencies
1816 Jefferson Place, N.W.
Washington, DC 20036-2505
202-533-1803

July 19, 2004

ORAL ARGUMENT SCHEDULED FOR OCTOBER 15, 2004

No. 96-1062 and Consolidated Cases

IN THE UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

EDISON ELECTRIC INSTITUTE, et al.,

Petitioners,

v.

U.S. ENVIRONMENTAL PROTECTION AGENCY, et al.,

Respondents.

ON PETITION FOR REVIEW OF A RULE OF THE UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

REPLY BRIEF OF PETITIONERS AND INTERVENOR

CERTIFICATE AS TO PARTIES, RULINGS, AND RELATED CASES

Pursuant to Rule 28(a)(1) of the Circuit Rules of the United States Court of Appeals for the District of Columbia Circuit, counsel for the Petitioners, who join in this Brief, certify this 30th day of January, 2004, as follows:

A. Parties and Amici. The parties, intervenors, and amici are the following:

Petitioners:	AMSA, CASA, MAMWA, SCWQA, TAMSA, VAMWA, WVMWAQ, WESTCAS, the WET Coalition, and the Utility Petitioners
Intervenor:	American Petroleum Institute
Respondents:	Environmental Protection Agency

All Petitioners that join in this Brief have previously made the disclosure required by Circuit Rule 26.1. Nevertheless, pursuant to the Federal Rules of Appellate Procedure 26.1(b), the Petitioners disclose the following:

Corporate Disclosure Statement of AMSA

The Association of Metropolitan Sewerage Agencies ("AMSA") is a nonprofit corporation membership association that has no outstanding shares or debt securities and has no parent companies, subsidiaries or affiliates which have any outstanding shares or debt securities in the hands of the public. AMSA is comprised of nearly 300 publicly-owned treatment works members, which operate municipal wastewater treatment plants under federal and state laws and regulations across the nation and which are impacted by the challenged regulation.

Corporate Disclosure Statement of CASA

The California Association of Sanitation Agencies ("CASA") is a nonprofit public benefit corporation formed under the laws of the State of California that has no outstanding shares or debt securities and has no parent companies, subsidiaries or affiliates which have any outstanding shares or debt securities in the hands of the public. CASA's 106 members are local public agencies that provide wastewater collection, treatment, disposal and water recycling service to millions of Californians.

Corporate Disclosure Statement of MAMWA

The Maryland Association of Municipal Wastewater Agencies, Inc. ("MAMWA") is a nonprofit corporation membership association that has no outstanding shares or debt securities and has no parent companies, subsidiaries or affiliates which have any outstanding shares or debt securities in the hands of the public. MAMWA is comprised of publicly-owned treatment works members, which operate numerous municipal wastewater treatment plants under federal and state laws and regulations across Maryland and which are impacted by the challenged regulation.

Corporate Disclosure Statement of SCWQA

The South Carolina Water Quality Association, Inc. ("SCWQA") is a nonprofit corporation membership association that has no outstanding shares or debt securities and has no parent companies, subsidiaries or affiliates which have any outstanding shares or debt securities in the hands of the public. SCWQA is comprised of publicly-owned treatment works members, which operate numerous municipal wastewater treatment plants under federal and state laws and regulations across South Carolina and which are impacted by the challenged regulation.

Corporate Disclosure Statement of TAMSA

The Texas Association of Metropolitan Sewerage Agencies ("TAMSA") is a nonprofit corporation membership association that has no outstanding shares or debt securities and has no parent companies, subsidiaries or affiliates which have any outstanding shares or debt securities in the hands of the public. TAMSA represents 21 of the largest municipal publicly-owned treatment works and water authorities in the State of Texas, which are impacted by the challenged regulation.

Corporate Disclosure Statement of VAMWA

The Virginia Association of Municipal Wastewater Agencies, Inc. ("VAMWA") is a nonprofit corporation membership association that has no outstanding shares or debt securities and has no parent companies, subsidiaries or affiliates which have any outstanding shares or debt securities in the hands of the public. VAMWA is comprised of publicly-owned treatment works members, which operate numerous municipal wastewater treatment plants under federal and state laws and regulations across Virginia and which are impacted by the challenged regulation.

Corporate Disclosure Statement of WVMWAQ

The West Virginia Municipal Water Quality Association, Inc. ("WVMWAQ") is a nonprofit corporation membership association that has no outstanding shares or debt securities

and has no parent companies, subsidiaries or affiliates which have any outstanding shares or debt securities in the hands of the public. WVMWAQ is comprised of publicly-owned treatment works members, which operate numerous municipal wastewater treatment plants under federal and state laws and regulations across West Virginia and which are impacted by the challenged regulation.

Corporate Disclosure Statement of WESTCAS

The Western Coalition of Arid States ("WESTCAS") avers that it is a not-for-profit association, whose voting members are municipalities or other governmental entities that have no parent corporation. WESTCAS has not issued stock.

Corporate Disclosure Statement of the WET Coalition

The WET Coalition is an unincorporated trade association composed of the Alliance of Automobile Manufacturers, the American Forest and Paper Association, and the Utility Water Act Group. The purpose of this association is to participate in Environmental Protection Agency ("EPA") rulemakings relating to the use of whole effluent toxicity ("WET") test methods. The goals of the association are to ensure that WET test methods are used successfully as one tier of evaluation in the regulation of toxic discharges into the nation's waters, and that the methods themselves have been properly validated and based on sound science. The trade associations that are members of the WET Coalition have members that are impacted by the challenged WET regulation because many of their members own and operate facilities with National Pollutant Discharge Elimination System permits which will be affected directly by the use of the EPA-approved WET methods. The WET Coalition is a trade association within the meaning of this Court's Rule 26.1(b) and is not a parent, subsidiary, or affiliate of any corporation or other entity which has issued shares or debt securities to the public.

The Alliance of Automobile Manufactures (the "Alliance") is a trade association composed of 10 car and light truck manufacturers who account for more than 90% of U.S. vehicle sales. Member companies employ more than 600,000 employees at 250 facilities in 35 states. The Alliance is especially committed to improving the environment and motor vehicle safety. The Alliance of Automobile Manufacturers is a trade association within the meaning of this Court's Rule 26.1(b) and is not a parent, subsidiary, or affiliate of any corporation or other entity which has issued shares or debt securities to the public.

The American Forest and Paper Association ("AF&PA") is the national trade association of the forest, pulp, paper, paperboard, and wood products industry. AF&PA represents approximately 550 member companies and related trade associations (whose members are in the thousands), which grow, harvest and process wood and wood fiber; manufacture pulp, paper, and paperboard products from both virgin and recovered fiber; and produce solid wood products. AF&PA represents the forestry products industry on numerous public policy issues, including environmental issues.

The Utility Water Act Group ("UWAG") is an unincorporated trade association composed of 158 individual electric utilities and national trade associations of electric utilities. The individual utility companies own and operate power plants and other facilities that generate, transmit, and distribute electricity to residential, commercial, industrial, and institutional customers. UWAG's purpose is to participate on behalf of its members in EPA's rulemakings under the Clean Water Act. UWAG is a trade association within the meaning of this Court's Rule 26.1(b) and is not a parent, subsidiary, or affiliate of any corporation or other entity which has issued shares or debt securities to the public.

Corporate Disclosure Statement of Edison Electric Institute, *et al.* ("Utility Petitioners")

The original Corporate Disclosure Statement for the Utility Petitioners was filed on February 21, 1996. Since that time, several of the Utility Petitioners have decided not to pursue this Petition for Review, and some of the Utility Petitioners' name and/or corporate structure has changed. On May 5, 2003, this Court granted the Utility Petitioners' Motion to Amend Petition on Review to delete some of the original Utility Petitioners and amend the names of others. Subsequent to that Order, the remaining Utility Petitioners filed a Revised Corporate Disclosure Statement. Since the filing of the Revised Corporate Disclosure Statement, the Central Hudson Gas & Electric Corporation elected to discontinue its participation in this proceeding.

The remaining Utility Petitioners are 46 individual electric utilities that operate power plants and other facilities that generate, transmit, and distribute electricity to residential, commercial, industrial, and institutional customers. Each of the remaining Utility Petitioners is also a member of UWAG. The Utility Petitioners also include three trade associations of electric utilities:

(1) the Edison Electric Institute, the association of the nation's investor-owned electric utilities;

(2) the National Rural Electric Cooperative Association, the association of nonprofit electric cooperatives supplying central station service through generation, transmission, and distribution of electricity to rural areas of the United States; and

(3) the American Public Power Association, the national trade association that represents publicly-owned electric utilities in the United States.

The following chart identifies the individual Utility Petitioners, their parent companies, and any publicly-held companies that own 10% or more of that utility:

Petitioner	Parent Company, if any	10% Stockholder, if any
Ameren	none	none
American Electric Power Service Corporation Appalachian Power Company Columbus Southern Power Company Indiana Michigan Power Company Kentucky Power Company Ohio Power Company AEP Utilities, Inc.	American Electric Power Company, Inc.	AEP Co., Inc.
Constellation Energy Group, Inc.	none	none
Carolina Power & Light Company	Progress Energy, Inc.	none
Cinergy Corp. Cincinnati Gas & Electric Company PSI Energy, Inc	Cinergy Services, Inc.	none
Cleco Corporation	none	none
Consolidated Edison Company of New York, Inc.	Consolidated Edison, Inc	none
The Dayton Power & Light Company	DPL Inc.	none
Conectiv Energy	Pepco Holding, Inc.	none
Detroit Edison Company	DTE Energy Company	none
Duke Power Company	Duke Energy	none
Duquesne Light Company	DQE	none
Dynegy Midwest Generation, Inc.	Dynegy	none
Entergy Services, Inc.	Entergy Corporation	none
Exelon Generation Company, LLC	Exelon Corporation	Exelon Corporation
First Energy Corp.	none	none
Ohio Edison Company	First Energy Corp.	First Energy Corp.
Pennsylvania Power Company	Ohio Edison Co.	First Energy Corp.
Florida Power Corporation	Progress Energy, Inc.; Florida Progress Corporation	none
Kansas City Power & Light Company	Great Plains Energy	none
Kentucky Utilities Company	LG&E Energy	none
MidAmerican Energy Company	MidAmerican Energy Holdings Company	none
Minnesota Power, an Operating Division of ALLETE, Inc.	ALLETE, Inc.	none
Northern Indiana Public Service Company	NiSource Inc.	none

Petitioner	Parent Company, if any	10% Stockholder, if any
Ohio Valley Electric Corporation	none	American Electric Power Company, Inc. Ohio Edison Company Allegheny Energy, Inc.
PPL Generation, LLC	PPL Energy Supply LLC PPL Energy Funding Corporation PPL Corporation	PPL Corporation
Public Service Enterprise Group, Inc.	none	none
Reliant Resources, Inc.	none	none
Southern Company Services, Inc. Alabama Power Company Georgia Power Company Gulf Power Company Mississippi Power Company Savannah Electric and Power Company	Southern Company	none
Tampa Electric Company	TECO Energy, Inc.	TECO Energy, Inc.
Virginia Electric and Power Company (d/b/a Virginia Power)	Dominion Resources, Inc.	Dominion Resources, Inc.
Wisconsin Electric Power Company	Wisconsin Energy Corporation	none
Wisconsin Public Service Corporation	WPS Resources, Inc.	none

B. Rulings Under Review. The ruling at issue in this Court is EPA's ratification of several whole effluent toxicity (WET) test procedures, published at 67 Fed. Reg. 69,952 (November 19, 2002), promulgated December 3, 2002, effective December 19, 2002, J.A. ___.

C. Related Cases. These cases have been consolidated per this Court's Order dated April 9, 2003:

- No. 96-1062, *Edison Electric Institute v. EPA* (consolidated with No. 96-1124, 96-1217, 96-1215, 96-1116, 96-1157), reopened by this Court;
- No 03-1087, *Western Coalition of Arid States (WESTCAS) v. EPA;*
- No 03-1091, *AMSA et al. v. EPA*; and
- No. 03-1094, *WET Coalition v. EPA*.

Case No 96-1062 was originally before this Court in 1996. The parties to that litigation negotiated a settlement. Upon promulgation of the final rule, the Petitioners concluded that EPA had not fully complied with the agreement reached during settlement negotiations. Accordingly, the parties to the original litigation requested that the Court reopen the original litigation appealing the rule. By Order dated April 9, 2003, the Court granted the motion to reopen the proceedings.

TABLE OF CONTENTS

TABLE OF AUTHORITIES*

FEDERAL CASES

* Authorities upon which we chiefly rely are marked with asterisks.

RULES, REGULATIONS, AND REGULATORY PREAMBLES

FEDERAL STATUTES

MISCELLANEOUS

GLOSSARY

APA	Administrative Procedure Act
CETTP	Complex Effluent Toxicity Testing Program
CV	Coefficient of Variation
CWA	Clean Water Act
DL	Detection Limit
DMRs	Discharge Monitoring Reports
DQOs	Data Quality Objectives
EAB	Environmental Appeals Board
EPA	U.S. Environmental Protection Agency
IC_{25}	Inhibition Concentration (25%)
J.A.	Joint Appendix
NOEC	No Observable Effect Concentration
NPDES	National Pollutant Discharge Elimination System
QA	Quality Assurance
QC	Quality Control
SETAC	Society of Environmental Toxicology and Chemistry
TSD	Technical Support Document
TU	Toxic Unit
TU_c	Toxic Unit (Chronic)
WESTCAS	Western Coalition of Arid States
WET	Whole Effluent Toxicity

I. INTRODUCTION

Once adopted, "the chronic WET methods challenged here will not be subject to judicial review in a subsequent permitting or enforcement proceeding, as any future challenge to their validity will be barred." Brief of Respondents of June 8, 2004 ("EPA Br.") 75 (citing 33 U.S.C. § 1369(b)(2)). This Court's review will therefore be the only opportunity for any court to verify that whole effluent toxicity ("WET") methods produce evidence sufficient to establish civil or criminal liability under the Clean Water Act ("CWA"). Unlike any other rulemaking case where

substantial deference is given to the Agency's decisionmaking process, this rulemaking necessarily prescribes the evidence courts must accept as *prima facie* or even conclusive proof of guilt. It is a case of first impression.[1]

Both federal evidentiary standards and APA review standards apply in this case, not the lowest possible standard of "minimal rationality" suggested by EPA. The CWA does not give EPA authority to ignore evidentiary standards when it develops regulatory programs and test methods. Nor does the CWA abolish the requirement that EPA have "substantial evidence" for its decisions. Thus a central issue in this case is whether EPA may, by rule, force courts to accept toxicity test data as reliable and conclusive proof of federal statute violations, without ever demonstrating that the test methods meet evidentiary requirements.

In defending its WET test chronic growth and reproduction methods, EPA would have this Court accept that:

(1) The Federal Rules of Evidence ("FRE"), Supreme Court precedent (*Daubert v. Merrell Dow Pharms.*, 509 U.S. 579 (1993)), the 1998 EPA/WET Coalition Settlement Agreement ("Settlement Agreement"), and the 1988 Report to Congress (developed to ensure that methods produce "reliable and legally defensible data") do not impose "any binding legal requirements or create any standard by which this Court could measure the reasonableness of EPA's actions ratifying the WET test methods." EPA Br. 37-38. EPA makes these assertions even while confirming in the Federal Register and elsewhere that the requirements of the Report to Congress and *Daubert* justify what it has done.

[1] This is the only reported challenge to a Part 136 method adoption.

(2) Even if EPA was bound by such regulatory safeguards and historically applied them to biological methods, it may discard them to achieve programmatic objectives. EPA Br. 14-15.

(3) EPA has virtually unlimited discretion and authority to presume that test results are "reliable and representative" at zero and low toxicity based on evaluations of much higher toxicity levels and different test endpoints (acute and chronic lethality) from the ones challenged (chronic growth and reproduction), despite EPA's own expert staff's and peer reviewers' contrary conclusions.

This Court should not allow EPA to circumvent the administrative review process and abandon long-established legal and regulatory safeguards that ensure Part 136 method results are documented to be reliable at the levels used in NPDES permits. EPA cannot cloak itself in "deference" to avoid complying with procedures required by law and agreed to by EPA itself. Finally, EPA cannot avoid this Court's obligation to examine the record to determine whether substantial evidence supports the decision to adopt the methods that are challenged here: the nonlethal chronic endpoints (growth and reproduction) for WET test organisms *Ceriodaphnia dubia*, Fathead Minnow, *Selanastrum capricornutum* (Green Alga), Sheepshead Minnow, and Inland Silverside and the proper consideration of dilution for all methods.[2] Substantial evidence must be demonstrated, not presumed. Applying the appropriate legal requirements and analyzing the factual basis for this rulemaking will require vacating the challenged methods.

---

[2] EPA's references to field and laboratory studies addressing acute and chronic *lethality* endpoints are irrelevant, because Petitioners do not challenge those methods. EPA's references to support for WET methods in general do not refute the specific issues raised by Petitioners. *Appalachian Power Co. v. EPA*, 249 F.3d 1032, 1059 (D.C. Cir. 2001) (court is obligated to "overturn a rulemaking where the EPA has failed to respond to specific challenges that are sufficiently central to its decision") (quoting *Int'l Fabricare Inst. v. EPA*, 972 F.2d 384, 389 (D.C. Cir. 1992)).

II. BINDING STANDARDS APPLY TO METHOD ADOPTION

EPA's response casts aside various legal standards identified by Petitioners and asserts that there are no "binding legal requirements...by which this Court could measure the reasonableness of EPA's actions." EPA Br. 37-38. EPA therefore asserts the court must uphold the WET methods if they are only "minimally rational."[3] *Id.* 31. We disagree.

EPA's reading of the CWA would violate the nondelegation doctrine, because there would be no "intelligible principle" guiding EPA's exercise of discretion in promulgating test methods, making CWA § 304(h), 33 U.S.C. § 1314(h), unconstitutional. *Whitman v. Am. Trucking Ass'ns*, 531 U.S. 457, 472-76 (2001).[4] Courts avoid interpretations of statutes that raise constitutional questions, and so EPA's attempt to make its discretion unlimited should be rejected. *Johnson v. Robison*, 415 U.S. 361, 366-67 (1974).

Alternatively, if there is a statutory standard but it is EPA that has never set "binding legal requirements" (EPA Br. 37-38), then EPA has violated its duty under § 304(h) to set "guidelines" for biological testing procedures. *See* 33 U.S.C. § 1314(h) ("The Administrator shall...promulgate guidelines establishing test procedures for the analysis of pollutants."); *E. I. du Pont de Nemours & Co. v. Train*, 430 U.S. 112, 130-31 (1977) (§ 304(b) guidelines "are not merely aimed at guiding the discretion of permit issuers in setting limitations for individual plants....The guidelines are then to describe the methodology EPA intends to use in the § 301 regulations to determine the effluent limitations for particular plants."). Thus, accepting EPA's

---

[3] The Supreme Court cautions that agencies cannot claim the "minimum rationality" standard but are subject to the higher "arbitrary and capricious" standard. *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 n.9 (1983).

[4] "Minimal rationality" as a standard cannot save EPA's reading of the CWA from being an unlawful delegation because it is not a substantive statutory standard. It is a standard of judicial review.

position would either make CWA § 304(h) unconstitutional or constitute an admission that EPA violated a statutory duty in adopting the WET methods.

It is axiomatic that WET methods must produce results that are "legally defensible." Report to Congress 4-14, J.A. ___. EPA's assertion that the WET methods should be sustained if only "minimally rational" lowers the standard of proof necessary to convict NPDES permittees of both civil and criminal CWA violations. NPDES permittees must report test results on monthly discharge monitoring reports ("DMRs"). In enforcement proceedings a DMR establishes a *prima facie* or even conclusive showing of liability. If the reliability of this evidence need be only "minimally rational," how can it be proof beyond a reasonable doubt or by a preponderance of the evidence? Since Part 136 method reliability cannot be challenged later, test reliability and adequacy at the enforcement level (1 TU_c)[5] must be fully verified in *this* proceeding, consistent with the FRE. *Natural Resources Defense Council, Inc. v. Outboard Marine Corp.,* 702 F. Supp. 690, 692-93 (N.D. Ill. 1988) (a challenge to test method accuracy must occur before enforcement); *Portland Cement Ass'n v. Ruckelshaus*, 486 F.2d 375, 401 (D.C. Cir. 1973) (failing to confirm method reliability at the level required for compliance is arbitrary and capricious), *cert. denied*, 417 U.S. 921 (1974); *see also National Petrochemical & Refiners Ass'n v. EPA*, 287 F.3d 1130, 1140 (D.C. Cir. 2002) (argument that it was impermissible for EPA to extrapolate data from 70-400 ppm to the 15 ppm range might have been a winning argument if that had been EPA's sole basis).

---

[5] EPA's brief does not dispute that the compliance level for the chronic test is 1 TU_c. Indeed it confirms that the need to monitor at this level is established in federal rules and guidance for the Great Lakes basin. EPA Br. 88 n.56. *See also* EPA, Summary Report, Peer Review of "Preliminary Report: Interlaboratory Variability Study of EPA Short-Term Chronic and Acute Whole Effluent Toxicity Test Methods" 3 § 2 (March 2001) ("an end-of-pipe permit limit of 1 TU_c may be established when there is little or no dilution"), J.A. _____.

Finally, it is settled that EPA cannot abandon established rules or historical agency practice, in this case those designed to ensure test reliability, without having a rulemaking and providing a detailed basis for the new agency position. *Louisiana PSC v. FERC*, 184 F.3d 892, 897 (D.C. Cir. 1999), *cert. dismissed*, 531 U.S. 975 (2000) ("For the agency to reverse its position in the face of a precedent it has not persuasively distinguished is quintessentially arbitrary and capricious.").

Contrary to EPA's position, Petitioners assert that several legal standards apply to EPA's approval of Part 136 methods, as described below.

A. EPA Applies *Daubert* to Determine the Scientific Validity of Some Part 136 Procedures

Part 136 methods are required for generating evidence of permit compliance under the CWA. 40 C.F.R. § 136.1. EPA's claim that Supreme Court precedent applying the FRE does not apply to adopting Part 136 methods is unsupportable. EPA Br. 74 n.42 ("*Daubert* has no applicability to this Court's review of an EPA rulemaking."). It is refuted by EPA's use of *Daubert* to assess the scientific validity of Part 136 methodologies just last year:

> [A] detection/quantitation approach or methodology will be considered scientifically valid if...:
>
> - It can be (and has been) tested,
> - It has been subjected to peer review and publication,
> - The error rate associated with the approach or methodology is either known or can be estimated,
> - Standards exist and can be maintained to control its operation..., and
> - It has attracted (i.e., achieved) widespread acceptance within a relevant scientific community.
>
> ...EPA has adopted the conditions cited because they reflect those discussed by the U.S. Supreme Court as considerations pertaining

> to assessments of scientific validity when considering the admissibility of expert scientific testimony [citing *Daubert* and *Kumho Tire Co. v. Carmichael*].

EPA, *Technical Support Document for the Assessment of Detection and Quantitation Approaches*, EPA-821-R-03-005 (February 2003) 4-1 ("2003 TSD"), J.A. ___.

EPA cannot rationally embrace *Daubert*'s standards for detection and quantitation levels while flatly rejecting them for WET methods under the rubric of "agency discretion."[6] *Morton v. Ruiz*, 415 U.S. 199, 235 (1974) ("[W]here the rights of individuals are affected, it is incumbent upon agencies to follow their own procedures."); *MCI Worldcom, Inc. v. General Services Admin.*, 163 F. Supp.2d 28, 37-38 (D.D.C. 2001); s*ee ANL Pipeline Co. v. FERC*, 71 F.3d 897, 901 (D.C. Cir. 1995) ("[W]here an agency departs from established precedent without a reasoned explanation, its decision will be vacated as arbitrary and capricious."), *Louisiana PSC,* 184 F.3d at 897. As Part 136 test data must be "legally defensible" (Report to Congress 4-14, J.A. ____) and subsequent challenges to the method are barred, *Daubert* reliability must be proven at method adoption.

B. The Report to Congress Binds EPA

EPA's argument that its 1988 Report to Congress imposes no "binding legal requirements" (EPA Br. 37-38) is equally flawed. The Report to Congress describes EPA's standards for judging the adequacy of CWA testing methods. *See* Pub. L. No. 100-4 § 518(a), 101 Stat. 7, 86-87; Report to Congress 3-1 (a "thorough understanding of...performance characteristics is...essential in assessing" test adequacy, and the validation process "verifies" that the method is capable of "reliably producing results of a known quality"), J.A. ____.

[6] Nor can EPA decide, without reasoned explanation, to ignore its guidance, the Report to Congress it drafted, and regulations outlining agency guidelines for adopting new test methods.

Contrary to EPA's response, EPA has used the Report's criteria as standards of WET method adequacy and informed the public that WET tests were "adequately validated according to all of the applicable criteria" in the Report. 67 Fed. Reg. 69,952, 69,964 (Nov. 19, 2002), J.A. ___.[7] EPA also agreed to use the Report to evaluate its interlaboratory validation study results. Settlement Agreement ¶ 3, J.A. ___.

EPA's disavowal of the Report is mere post-hoc rationalization, which is not allowed on judicial review. *Martin v. OSHRC*, 499 U.S. 144, 156 (1991). As EPA has taken inconsistent positions on the legal applicability of the Report without a rational explanation, EPA's latest position, advanced for the first time in these pleadings, is not entitled to deference. *Id.* Consequently, the validation criteria in the Report to Congress provide another set of objective requirements for assessing the scientific validity of the challenged WET methods.

C. EPA Cannot Ignore the Advice of its Experts and Peer Reviewers

It is a clear principle of administrative law that an agency cannot disregard the advice of its own experts. *Texas Oil & Gas Ass'n v. EPA*, 161 F.3d 923, 935 (5th Cir. 1998); *Humana of Aurora, Inc. v. Heckler*, 753 F.2d 1579, 1583 (10th Cir. 1985), *cert. denied*, 474 U.S. 863 (1985). EPA does not dispute this principle, which goes beyond EPA's "minimal rationality" standard.

D. The Substantial Evidence Test Applies

This Court has found that "arbitrary and capricious" and "substantial evidence" are essentially the same standard. *Pacific Legal Foundation v. Department of Transp.*, 593 F.2d 1338, 1343 n.35 (D.C. Cir. 1979), *cert. denied,* 444 U.S. 830 (1979); *International Union, United Mine Workers v. Mine Safety & Health Admin.*, 830 F.2d 289, 293 n.6 (D.C. Cir. 1987).

[7] Contrary to EPA's disavowal (EPA Br. 37-38), a mere two pages later (EPA Br. 40) EPA offers criteria from the Report to justify its actions. Similarly, EPA cites its Final Rule Notice as the source of "the relevant performance aspects of WET testing." EPA Br. 40 (citing 67 Fed. Reg. 69,955). However, that page reveals that EPA ratified the WET methods "[i]n accordance with EPA's Report to Congress." 67 Fed. Reg. 69,955.

Agency action is arbitrary and capricious if it is not supported by substantial evidence. *Motor Vehicle Mfrs. Ass'n v. Ruckelshaus*, 719 F.2d 1159, 1164 (D.C. Cir. 1983). Substantial evidence does not include unsupported assumptions. *See National Gypsum Co. v. EPA*, 968 F.2d 40, 43-44 (D.C. Cir. 1992).

The Report to Congress and EPA Part 136 guidance are clear that EPA must verify test performance characteristics at the regulatory level. Pet'r Br. 19-21, 26-28. Since EPA does not limit the range over which WET tests are presumed accurate for permit compliance, EPA bears the burden of showing, by substantial evidence, that WET tests are reliable over their most common range of use, 1-3 TU_c.

III. ARGUMENT

A. EPA Fails the *Daubert* and FRE Requirements

As EPA admits, WET test results are *prima facie* evidence of liability in CWA enforcement cases. EPA Br. 81.[8] EPA also admits that permittees cannot impeach their own DMRs, because each test is considered valid and reliable. Nor can they challenge WET test methods, once adopted, because of 33 U.S.C. § 1369(b)(2). EPA Br. 75, 82. Thus, the only opportunity for a court to consider whether the challenged WET methods meet *Daubert* and other FRE requirements[9] is in this proceeding.

---

[8] "A number of courts have found DMRs to constitute not simply prima facie, but *conclusive* evidence of CWA violations." *In re: City of Salisbury*, Docket No. CWA-III-219, CWA Appeal No. 00-01, slip op. 28 n.27 (EAB Jan. 16, 2002) (emphasis in original) (citations omitted); *see also Outboard Marine Corp.*, 702 F. Supp. at 692-93.

[9] When EPA seeks nonadministrative CWA enforcement remedies or when a citizen suit is filed, the proceedings take place in federal district court, where the FRE are binding. For these proceedings *Daubert* states factors for ensuring that scientific evidence is valid and thus reliable. *See Daubert*, 509 U.S. at 590 n.9. Even if *Daubert* does not strictly apply to EPA's Part 136 rulemakings, standards of scientific validity similar to *Daubert* but from other sources govern. *See* 2003 TSD 4-1; *cf.* EPA Br. 74 n.42. The Report to Congress criteria, for example, mirror *Daubert* and thus ensure that the "resulting data will be of adequate, known quality and *legally defensible*." Report to Congress 4-14 (emphasis added), J.A. ___. Another *Daubert*-type standard, arising from administrative law, is that EPA cannot ignore the findings of its peer reviewers or experts, and it cannot regulate

(continued...)

As discussed below, EPA's admissions and the administrative record demonstrate that the challenged WET methods fail *Daubert's* criteria for scientific reliability. Consequently, EPA's action is arbitrary and capricious and "not in accordance with law," especially the law of how courts assess scientific evidence. *See* 5 U.S.C. § 706(2)(A).

1. EPA Admits It Never Tested Essential Measures of Reliability

EPA does not dispute Petitioners' assertion that EPA never assessed the methods at the level where chronic toxicity will be regulated (1-3 TU_c). Pet'r Br. 34 n.22, 55, 56-57. EPA furthermore admits that it did not, and indeed could not, assess accuracy, bias, detection levels, dynamic range, or calibration requirements for WET methods. *See* EPA Br. 43-45.[10] Without these components a permittee cannot know, and has no way to check, whether a test result is true.[11] As EPA states, "[i]f a test is properly conducted and correctly interpreted, identifying any particular outcome as a 'false positive' is impossible." EPA, *Understanding and Accounting for Method Variability in Whole Effluent Toxicity Applications Under the National Pollutant Discharge Elimination System* 5-6 § 5.3.2.1, EPA 833-R-00-003 (June 2000) ("WET Variability Guidance"), J.A. ___.

Thus, ignoring these components makes it impossible for WET test results to be "challenged in some objective sense" or to determine whether EPA's WET methods are simply "a subjective, conclusory approach that cannot reasonably be assessed for reliability." FRE 702

---

within the known error band of a test method. *See supra* 8. Whether *Daubert* governs or not, EPA must prove the scientific validity and thus the "evidentiary reliability" of its test methods.

[10] Strangely, EPA first represents in its brief that "EPA explained at length how it addressed bias in a variety of contexts" but then admits (as it does in the Final Rule Notice) that "it is the bias component of accuracy that cannot be addressed by biological testing." See EPA Br. 44 n.18; 67 Fed. Reg. 69,965, J.A. ___.

[11] EPA's "Format Guidelines" are explicit that all "elements given in these Guidelines...are mandatory for all methods proposed at 40 CFR Part 136" and must be evaluated. EPA, *Guidelines and Format for Methods to be Proposed at 40 CFR Part 136 or Part 141* at 1, 22 (July 1996), J.A. ___. There is no exception for biological methods.

(Advisory Committee Notes on 2000 Amendments). Thus, EPA's action fails *Daubert's* first criterion for scientific validity, because the reliability of any single WET test result is unknown, cannot be "tested," and cannot be "falsified." *See Daubert*, 509 U.S. at 593.

2. EPA Ignored Its Own Staff and Peer Reviewers

Daubert mirrors the administrative law principle that an agency cannot disregard the advice of its own experts or take action inconsistent with facts in the record. *Daubert*, 509 U.S. at 593; *supra* 8.

EPA's own staff concluded that using WET methods as a single-test trigger for enforcement is a "misuse":

> Because the USEPA toxicity tests were intended to be early warning signals of biological community impacts, the results of a single toxicity test should not constitute a violation of a water quality standard, or of an effluent limitation. Unfortunately, such misuses have occurred....

De Vlaming and Norberg-King, A Review of Single Species Toxicity Tests: Are the Tests Reliable Predictors of Aquatic Ecosystem Community Responses?, EPA/600/R-97/114 at 2, J.A. ___ (1999) ("1999 Report"); 4, J.A. ___ ("USEPA's toxicity tests were designed as screening tools"). EPA's 1999 Report explains that a determination that toxicity tests predict instream impacts "must be based on a series of test results (persistent toxicity) not on a single test result." *Id.* 23, J.A. ___. SETAC[12] confirmed this position. *See* D. Grothe *et al.* (eds.), *Whole Effluent Toxicity Testing* 182, 188-89 (1996) ("SETAC"), J.A. ___.

Nevertheless, EPA disregarded these express warnings of its experts. EPA admits that single WET tests will be used to trigger CWA enforcement and liability like any other test

[12] EPA recognizes SETAC, the Society of Environmental Toxicology and Chemistry, as "leading experts" who conducted multiple WET workshops at EPA's request. EPA Br. 5 n.2.

method. *See* EPA Br. 75, 76 n.43; 54 Fed. Reg. 23,868, 23,875 (June 2, 1989), J.A. ___. EPA's promise of enforcement discretion does not change permittees' CWA liability or insulate them from civil action.[13] Consequently, EPA's adoption of the WET tests is arbitrary and capricious. It fails to satisfy the peer review standard of *Daubert* and the standard of consistency with the agency's own experts.[14]

3. WET Methods Regulate Within Expected Measurement Error

Daubert requires that a test method's "known or potential rate of error" be considered so that courts do not make decisions using unreliable data. *Daubert*, 509 U.S. at 594. EPA data confirm that WET methods are subject to well-documented, unexplainable variation for identical samples. *Infra* 22-29. The SETAC Report concurs:

> [T]he scientific community familiar with WET procedures recognizes that tests performed on presumably identical materials in presumably identical circumstances do not typically yield identical results....
>
> ...an effluent may pass or fail a WET test solely on the basis of the laboratory chosen to perform the test and not on the basis of the toxicity of the effluent.

SETAC 147, 181, J.A. ___. Nonetheless, EPA responds that there is "no basis to second-guess EPA's considered, technical judgment that the chronic WET tests are appropriate." EPA Br. 77.

EPA's method manual admits that the expected error band for chronic growth and reproduction endpoints results is at least "± 100%," though results outside this range are still

---

[13] Courts have not favored EPA's promises to address regulatory defects through "enforcement discretion." *See Portland Cement*, 486 F.2d at 398 n.91; *National Ass'n of Metal Finishers v. EPA*, 719 F.2d 624, 640 n.12 (3d Cir. 1983) (expressing concern that EPA's promise to construe CWA regulatory definition in subsequent enforcement actions fails to provide "adequate certainty or guidance to dischargers who must comply in the present with the prohibited discharge standard"), *rev'd on other grounds*, 470 U.S. 116 (1985). Moreover, EPA's enforcement discretion does not bind States, and the rules of evidence apply in citizen suits under CWA § 505, 33 U.S.C. § 1365.

[14] Having a peer review but then ignoring its key recommendations on test reliability makes this peer review exercise a nullity. *See* Pet'r Br. 50-51.

considered valid.[15] Pet'r Br. 29-30, 33; Table 1, *infra*. EPA also does not dispute that individual test reliability cannot be known. *See supra* 10 (identifying an outcome as a "false positive" is impossible). Consequently, there is no way to determine if a test result is influenced by measurement error.

This plainly fails *Daubert*. *See also Amoco Oil Co. v. EPA*, 501 F.2d 722, 743 (D.C. Cir. 1974) (statistical measurement error "deprives the agency of the power to find a violation of the standards in enforcement proceedings where the measured departure from them is within the boundaries of probable measurement error"); *Int'l Fabricare,* 972 F.2d at 398 (before setting an enforceable drinking water limit EPA first ascertains how low a concentration reliably can be measured). Here EPA set an enforceable limit, in effect, by requiring an instream criterion of 1 TU_c in the Great Lakes states and "recommending" it for everyone else. Only now do we get to the question of how to measure the limit.

Nonetheless, EPA asserts that WET tests are highly reliable because test precision (as evidenced by the coefficient of variation ("CV")) is in the range of chemical testing. EPA Br. 28-29. At the same time, EPA acknowledges that precision does *not* demonstrate test reliability for any individual test. *See, e.g.*, EPA, *NPDES Permit Writer's Guide to Data Quality Objectives* (November 1990) 1-6, J.A. ___; SETAC 148 ("[T]he CV...ignores the...[uncertainty]

[15] EPA's assertion that test results for identical samples are not subject to 300% variation (EPA Br. 44 n.19) is wrong. Petitioners' observation (Pet'r Br. 25 n.11, 30-32) is based on EPA's WET Variability Guidance 3-6, which shows that the data vary by over 300% for identical samples. This is also documented by EPA, *Final Report: Interlaboratory Variability Study of EPA Short-Term Chronic and Acute WET Test Methods*, Vol. 1, EPA 821-B-01-004 (Sept. 2001) ("Validation Study"), J.A. ___, which showed that valid nontoxic results varied from 1-16 TU_c (a range of 1500%). Table 2, *infra*.

associated with each [individual measurement]."), J.A. ___. Thus, EPA's reliance on CVs to demonstrate individual test reliability is misplaced.[16]

Responding to Petitioners' assertion that EPA's calibration approach (using reference toxicants) provides no objective basis to identify erroneous results (Pet'r Br. 39-40), EPA provides only a vague assurance that results "well outside expected ranges" will be further evaluated. EPA Br. 49. A review of EPA's reference toxicant results demonstrates the emptiness of this promise.

In its annual DMR QA/QC studies, EPA sends out reference toxicant samples of known toxicity to assess how consistent laboratory results are. (These studies were analyzed in the WET Coalition Comments 37-39, J.A. ___, using NOEC data. Table 1 below uses IC_{25} data from the 1993 and 1994 studies.) EPA calls the median (middle) result the "True Value" and lists the range of "acceptable" results.

To put these "acceptable" results in context, Table 1 shows what the similar range of radar gun results would be if the "True Value" was 55 miles per hour:

Table 1

Reference Toxicant Study	"True Value"	EPA's Accepted Range of Results	Range of Results for Car Traveling 55 mph
DMR-QA #13 (1993) Fathead Minnow IC25 growth	2.9 TU_c	1.6-28.8 TU_c	30-546 mph
DMR-QA #14 (1994) Ceriodaphnia IC25 reproduction	3.6 TU_c	2.02 – 18.8 TU_c	31 – 287 mph

[16] EPA suggests that the claimed low "false-positive rate" of dilution water samples somehow proves individual test reliability. EPA Br. 34 n.28. However, the false-positive rate of *dilution water* is irrelevant to the error band of *toxic effluent* samples, as demonstrated by Table 1, *infra*.

(For example, the low end (1.6 TU_c) divided by the median (2.9 TU_c) is 0.55, which multiplied by 55 mph gives 30 mph.) These data confirm that EPA has no meaningful controls on the test's error band. No court would accept a radar gun that could measure 55 as anything from 30 to 546. Because the WET error band encompasses almost the entire range of possible results, any attempt to initiate enforcement using this method would be arbitrary and capricious. *See Amoco Oil*, 501 F.2d at 743.

EPA's failure to address the WET test's well-documented error band will arbitrarily classify many permittees as CWA "violators" with no reliable evidence. This is contrary to *Daubert* and other court precedent.

4. The Challenged WET Methods Are Not Widely Accepted as Reliable Tools for Predicting Instream Impacts

Another *Daubert* criterion is widespread acceptance in the scientific community. *Daubert*, 509 U.S. at 594. EPA requires proof of "representativeness" for WET methods (the ability to "accurately predict that an effluent showing toxicity will correspond to an observed negative impact on the aquatic life in the receiving waters"). EPA Br. 58. However, EPA's assertions that the challenged chronic WET endpoints are reliable indicators of instream impacts with a low probability of false positive results are contradicted by the data.

EPA's experts and SETAC both concluded that the chronic WET tests are *not* reliable predictors of instream impacts, especially for low levels of toxicity (sublethal), and that false-positive rates will increase substantially at lower exposure levels. EPA's 1999 Report explained that data from non-impact sites reveal "that toxicity tests were reliable predictors in 32% of the cases, with 68% 'false positives.'" 1999 Report 8, J.A. ___. This is a far cry from EPA's false positive estimate of no more than 5%. 67 Fed. Reg. 69,968, J.A. ___; EPA Br. 29. The 1999 Report further states, "[t]his potential...high rate of 'false positives' is disturbing and confirms

that the results of a single toxicity test should not be used to characterize wastewater or an ambient water toxicity." 1999 Report 8, J.A. ___. EPA is not entitled to deference regarding its conclusion that low toxicity samples have a "low false positive rate" given this directly conflicting conclusion from the 1999 Report. *See also id.* 10 (Parkhurst found no strong correlation to instream impacts if he "omitted lethality data"), J.A. ___; *see infra* 30. EPA's experts also concluded that the algal and marine tests were *not* demonstrated to be "representative." *Infra* 32-34.

At no point does EPA's 1999 Report conclude that *low-level toxicity associated with growth or reproduction endpoints* is related to instream effect. In fact, it supports the opposite conclusion, that WET non-lethality endpoints are unreliable for detecting instream impacts.

B. Unlawful Irrebuttable Presumption

EPA's response to Petitioners' "irrebutable presumption" issue misses the point and proves Petitioners' argument. EPA Br. 80-82.

EPA admits that the accuracy of any individual test cannot be known, with results typically varying by ± 100%. The SETAC Report also acknowledges that no one expects to receive similar results, even for identical samples. *See* SETAC 147, J.A. ___. Normally this is the quintessential definition of an unreliable test, and split sample evidence could be submitted to disprove liability.[17] However, split samples are useless for invalidating WET test results because all results are presumed valid and accurate, regardless of how inconsistent, if method procedures are followed.[18] *Supra* 14 (listing range of "acceptable" results of DMR QA/QC studies). If

[17] *See, e.g., Salisbury*, slip op. 40 n.42 ("[D]irect evidence (e.g., split sample data) is unquestionably the surest path to invalidating DMR results....").

[18] This is because EPA views each WET test result, even for identical samples, as unique. 67 Fed. Reg. 69,963, J.A. ___.

identical split samples are tested, based on the *proven* error band of the WET methods, one result could come back at 1 TU_c and another at 16 TU_c. See Table 2 *infra* 25. As EPA considers both tests reliable, the permittee will be in noncompliance regardless of the actual quality of its effluent. Thus, EPA's WET approach makes split sample evidence to assess test validity meaningless and creates an unlawful, irrebuttable presumption of test reliability for individual measurements, though no such reliability exists.

This violates Federal Rule of Evidence 301's mandate against evidentiary presumptions shifting the risk of nonpersuasion to the party against whom the presumption is directed. *See* FRE 301. Because certified DMR results are *prima facie* evidence of liability and such evidence is presumed reliable, permittees will be found liable if they fail to rebut their own DMRs; thus they bear the risk of nonpersuasion. And there is no way to rebut such evidence.[19]

C. EPA's Claim that Certain Method Validation Criteria Are "Inapplicable" to Biological Methods Is Unsupported

1. The Report to Congress Does Not Eliminate Criteria for WET Methods

EPA asserts it did not establish WET test accuracy, bias, detection limits, dynamic range, and method calibration because these requirements are "inapplicable" to biological test methods. EPA Br. 37 n.16, 40, 43. EPA did not identify specific language in the Report to Congress to support this position because there is none. To the contrary, Chapter 3 of the Report informs the public otherwise:

> A thorough understanding of a method's performance characteristics is therefore essential in assessing its adequacy for a given need....

[19] Furthermore, as explained in *Black v. Snow,* irrebutable presumption arguments "have a strong procedural [due process] flavor as well." *Black v. Snow*, 272 F. Supp.2d 21, 33-34 (D.D.C. 2003).

....

> The first part [of this chapter] discusses the criteria for chemical procedures and the second part ... for biological methods. Where there is overlap between the two sections the overlapping discussion has been placed in the first section.

Report to Congress 3-1 to 3-2, J.A. ____. The Biological Methods section states that the same characteristics "must be known":

> The generation of scientifically accurate and valid biological measurements...requires approximately the same criteria for assessing the adequacy of a method as previously described for chemical analyses. The same performance characteristics and development states of the method must be known in order to make an assessment of adequacy....

Id. 3-10 to 3-11, J.A .____. There are "differences" between chemical and biological methods, to be sure: First, for biological methods that do not use instruments, the operating characteristics of instruments (capacity, for example) are not involved. Second, for biological tests the health of the test organism or biological system is a "unique attribute without a complimentary [sic] attribute for analytical methods." *Id.* 3-11, J.A. ____. Third, certain WET endpoints (*e.g.*, reproduction) have high natural variability that also "must be accounted for." *Id.* Machines do not have this problem.

For WET tests, the health of the organism has a profound effect on the quality of the data and "must...be considered a key criterion." *Id.* Thus, the Report to Congress is plainly *not* saying that generally applicable criteria can be disregarded for WET methods; it is saying that WET methods have *additional* requirements. The additional source of variability created by using organisms rather than instruments is why those additional factors must be addressed.

Thus, EPA's interpretation of the Report to Congress to eliminate accuracy, bias, dynamic range, detection limits, and calibration is untenable. Rather, EPA's failure to address all the validation criteria contradicts the Report and is therefore arbitrary and capricious. *See*

Christensen v. Harris County, 529 U.S. 576, 588 (2000) (no deference to agency interpretation contrary to clear language of regulation).

2. The Detection Limit Concept Is Applicable and Workable

Petitioners' brief detailed EPA's deficiencies regarding essential performance characteristics (Pet. Br. 19-22, 26-42) that remain unrebutted by specific evidence and therefore will not be repeated here. EPA's response on the detection limit (DL) issue provides the clearest example of how EPA's approach to adopting WET methods is flawed. *See* EPA Br. 46-47. EPA does not deny that 40 C.F.R. Part 136 has a specific procedure, designed for a "broad variety of physical and chemical methods," to set a detection limit for the minimum concentration of analyte that allows 99% confidence that the analyte concentration is greater than zero. 40 C.F.R. Part 136 App. B; Pet'r Br. 26-27. EPA does not deny that detection limits for other methods are designed to offer 99% confidence that a measurement is not a false positive (*compare* Pet'r Br. 27 to EPA Br. 46-49). Thus, EPA's approach to WET methods plainly deviates from past practice.

EPA offers three justifications for not determining a DL: The Report to Congress states it is not required, Part 136 DL requirements do not apply to biological methods, and it is "impossible" to determine a DL. These are unpersuasive.

First, the Report to Congress contains a section entitled "Biological Detection Limits" that explains the need to address DL issues because:

> [A] single living organism is far more complex than the most sophisticated analytical instrumentation ever conceived....
>
> The precision of toxicity measurements is similar to that of finely tuned instruments operating at detection limits. The users of biological methods must account for the inherent variability in response. Typically, for toxicity test methods, this means...that the natural variability...will have to be accounted for...when permit limits, criteria, or standards are set.

Report to Congress 3-11, J.A. ___. Thus the Report discusses biological detection limits; it does not just declare them "inapplicable," as EPA counsel now asserts.[20] The SETAC and 1999 Reports also refer to "detection limits" for these methods. 1999 Report 15 ("biological responses...are less reliable near detection limits..."), J.A. ___;[21] SETAC 45 ("Proper method development and evaluation requires validation that includes determining the MDL [citation omitted]; therefore, it is apparent that the detection levels of the individual WET tests should be established..."), J.A. ___.

Second, Part 136, the only "guideline" published for test methods under 33 U.S.C. § 1314(h), does not state that DLs are *inapplicable* to biological methods. It is silent on this point. Therefore, how EPA has applied Part 136 to other approved biological methods is persuasive as to whether DLs are "applicable." *Paralyzed Veterans of Am. v. D.C. Arena, L.P.*, 117 F.3d 579, 586-87 (D.C. Cir. 1997), *cert. denied*, 523 U.S. 1003 (1998). EPA does not deny that it has applied the DL concept to prior Part 136 biological methods. Pet'r Br. 26. For example, the BOD, CBOD, and coliform tests, all of which use organisms to generate a monitored response, have established DLs.[22] EPA is therefore required to apply these regulatory provisions consistent with its historical practice unless it amends Part 136 formally. *Paralyzed*

---

[20] EPA's reading of the text on detection limits and dynamic range (EPA Br. 46-47) is equally misplaced. The quoted language states that such concepts may not be appropriate for "*all* biological methods," not that they are applicable to *none*. Page 3-12 of the Report to Congress specifically discusses how dynamic range applies to WET methods. J.A. ___.

[21] Even EPA's DMR QA/QC studies indicate that the WET methods have a "Detection Limit."

[22] *See Standard Methods* 5-6 (BOD and CBOD), J.A. ___. The coliform test is a biological test similar to WET methods, assessing reproduction by the analyst's count of the number of bacteria that grow in test dishes. No "instruments" are employed, but DLs are nevertheless established. *Id.* 9-64, J.A. ___. As this has been done for bacteria, it can be done for larger organisms that are easier to count. In any event, WET growth methods require use of a scale (*i.e.*, "instrumentation"). The Report to Congress specifically states that a DL is appropriate where a biological method employs "instrumentation." Report to Congress 3-11, J.A. ___.

Veterans, 117 F.3d at 586-87. EPA must impose a 99% detection limit consistent with its other Part 136 methods.

Third, EPA's assertion that DLs are "impossible" to develop because toxicity tests do not produce data in fractional increments (EPA Br. 47 n.25) is nothing more than a *post hoc* rationalization. EPA recommends translating toxicity results into numeric "toxic units." EPA, *Technical Support Document For Water Quality-based Toxics Control*, EPA 505/2-90-001, at 6 (March 1991) ("1991 TSD"), J.A. ___. A toxic unit may range from 1 to infinity and any fractional part in between. *See Id.* Thus, based on EPA's own documentation, such data are amenable to developing a DL. Moreover, the distinction is a fiction nowhere supported in the record. Coliform tests do not measure bacteria levels in fractions, only whole numbers, yet a DL is established for this procedure. *Supra* n.22.

Even if developing a specific DL were "impossible," this would not render EPA's decision rational. EPA nonetheless is required to establish test reliability in the range most commonly applied in permits (1-3 TU_c) (Report to Congress 3-1, J.A. ____), with 99% certainty that the "toxicity" analyte is present to be consistent with 40 C.F.R. § 136.2. EPA did not do this. Such analysis would have shown, at least qualitatively, whether the test becomes unreliable at such low readings. *American Trucking Ass'ns, Inc. v. EPA*, 175 F.3d 1027, 1053 (D.C. Cir. 1999) (inability to quantify effects does not justify ignoring them), *aff'd in part and rev'd in part, Whitman*, 531 U.S. 457 (2001). Failure to assess this issue makes the challenged WET methods arbitrary and capricious. *Motor Vehicle Mfrs. Ass'n*, 463 U.S. at 43 (failure to consider an important factor renders an agency decision arbitrary and capricious.).

D. EPA Lacks Substantial Evidence of Test Reliability or Representativeness at the Intended Level of Regulation

The central flaw in both EPA's laboratory validation study and the field studies it cites is that all the tests were conducted under highly toxic conditions, with acute mortality, and not at the level required for regulatory compliance, 1 TU_c for growth and reproduction.

In approving the low-level mercury method, EPA took pains to test the method at the regulatory level, as required by the Report to Congress.[23] EPA acknowledges that the "main objective in conducting...studies was to demonstrate that effluent samples containing mercury at or near the ambient water quality criteria levels...could be analyzed with little or no difficulty." 64 Fed. Reg. 30,417, 30,428 (June 8, 1999), J.A. ___. EPA also states that it "gathered additional data...and evaluated them at the low concentration levels of interest." *Id.* For WET, the chronic criterion for instream waters is 1 TU_c, and permit limits will be at this level wherever no dilution is allowed. Yet EPA has no substantial evidence validating the WET tests near 1 TU_c. This is reversible error.

1. Test Variability and Reliability Were Not Properly Documented

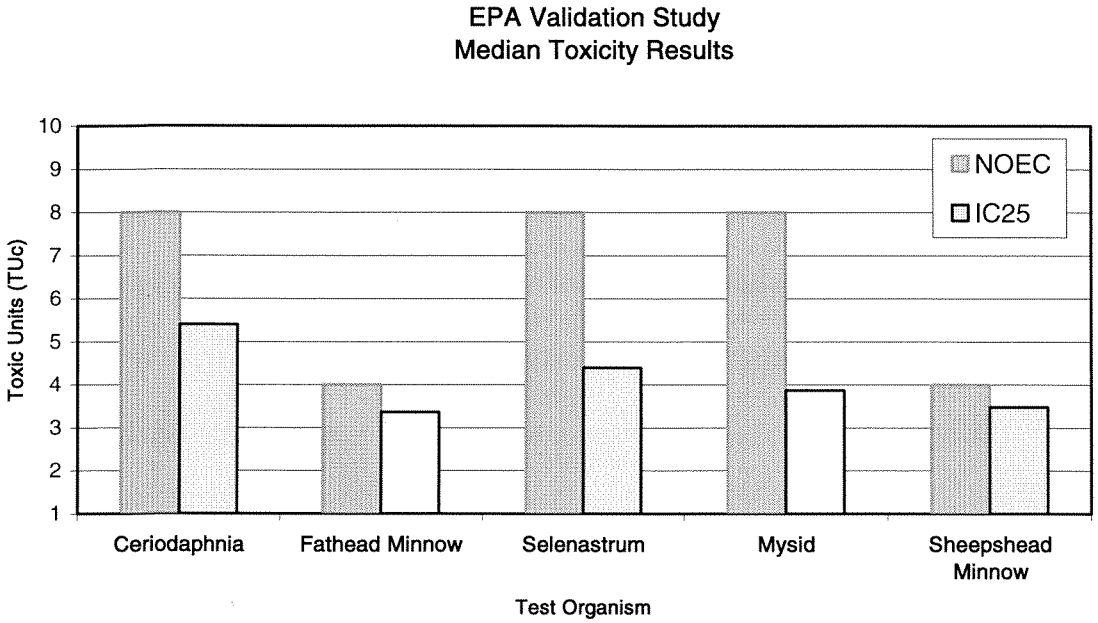
The graph below, using chronic test results from Chapter 9 of the Validation Study,[24] demonstrates that all these tests were conducted at levels far above the 1 TU_c level regulated in

---

[23] "[A] method developed to measure...at...10 mg/L is adequate for measuring...an effluent limitation of 100 mg/L but is inadequate for measuring the same pollutant...at...0.1 mg/L." Report to Congress 3-1, J.A. ___; *accord, Portland Cement,* 486 F.2d at 401 (requiring EPA to demonstrate that the opacity test could record measurements at the level of the standard within reasonable accuracy).

[24] This graph presents the median IC25 and NOEC values reported for the data used by EPA to determine the average CV presented in the Federal Register. 67 Fed. Reg. 69,955, 69,965, J.A. ___. These data are found in the Validation Study for *Ceriodaphnia* (pp. 83-86), fathead minnow (pp. 98-103), *Selenastrum* (pp. 109, 111, 113), Mysid (pp. 120-123), and Sheepshead minnow (pp. 130-133), J.A. ___. Petitioners combined the data from the relevant charts, consistent with EPA's combining the various sample results to determine CVs, to calculate the median and TU_c.

permits. The measured toxicity levels generally exceeded 3 TU_c; two studies, *Ceriodaphnia* and *Selenastrum*, were evaluated at 4 TU_c or greater. This is a long way from "no toxicity" of 1 TU_c.



The *Ceriodaphnia* NOEC tests were very toxic, causing a high death rate in all the tests. Validation Study 83-85 (LC_{50} column), J.A. ___. Testing an acutely toxic sample proves nothing about the reliability and variability of chronic reproduction and growth endpoints at much less toxic 1-3 TU_c levels where there is little or no mortality.

An agency may not rely on test readings conducted at much higher levels to claim reliability at lower levels. *See Nat'l Petrochemical & Refiners Ass'n v. EPA*, 287 F.3d 1130, 1140 (D.C. Cir. 2002). There is no evidence in the record that WET tests produce reliable results in the 1-3 TU_c range, though permittees with such effluent limits must use the tests to show compliance.

The graph above reveals another fatal flaw: the two evaluation methods (NOEC and IC_{25}) provide conflicting answers. Pet'r Br. 30-31. NOEC methods predict more toxic units than the IC_{25}. How can permittees be required to certify that test results are true when the two

methods for measuring toxicity do not agree, *even on average*? NOEC and IC_{25} cannot both be right.[25]

a. Available Information Confirms the High False-Positive Rate

The SETAC Report relied on by EPA warns that conducting the "validation" process only on very toxic or nontoxic water gives misleading results:

> WET test variability is a function of the toxicity of the effluent: variability in survival or reproduction in very toxic or nontoxic solutions is relatively low....

SETAC 181,[26] J.A. ___. This, however, is precisely what EPA did, and it seriously biased the analysis. "A test material that is moderately toxic will have the greatest variability...." *Id.* 174, J.A. ___.

There have been four studies confirming that WET tests are unable to distinguish between toxic and nontoxic samples. Three of the four confirm a false-positive rate of over 28%. Pet'r Br. 30-31. EPA ignored the only valid data set it developed that evaluated a nontoxic, nondilution water sample that showed a 28% false-positive rate (10 of 36 valid test results) when no toxicity was actually present. *See* Table 2 below. EPA's claim that these tests were "rejected" (EPA Br. 84) is nowhere supported in the administrative record. Neither the Validation Study nor EPA's Response to Comments says that the results were invalid, only that the samples were less toxic than EPA intended. EPA, *Response to Comments on Proposed*

---

[25] EPA, *Short-term Methods for Estimating the Chronic Toxicity of Effluents and Receiving Waters to Freshwater Organisms*, EPA-821-R-02-013 (4th ed. Oct. 2002) ("Chronic Method Manual") § 9.2.5 (p. 39), J.A. ___, states that EPA lacks data showing NOEC and IC25 results are correlated (*i.e.*, agree with each other).

[26] EPA apparently relies upon its blank/dilution water results to claim high precision for whole effluent samples in the 1-3 TU_c range. EPA Br. 49-51. These dilution water tests would be expected to give misleadingly low indications of actual test variability associated with a barely toxic/nontoxic *whole effluent* because the makeup of an effluent, even a nontoxic effluent, is different from dilution water. Information in the record confirms that the false-positive rate in dilution water is not the same as the false-positive rate in a whole effluent sample. *See* Table 2, *infra*.

Whole Effluent Toxicity Rule 255-56 (Nov. 8, 2002), J.A. ___; Validation Study 31-32, J.A. ___. These results, ignored by EPA, were identified as valid tests but characterized as representing "only slightly toxic" samples. Validation Study 81-82, J.A. ___; 67 Fed. Reg. 69,966, J.A. ___. EPA provides no rational basis for ignoring these critical results.

Table 2 below compares the *Ceriodaphnia* test results from the highly toxic and nontoxic samples and also confirms that test reliability decreases substantially as toxicity decreases:

Table 2

***Ceriodaphnia* Validation Study NOEC Results**[27]

Study	Number Of Valid Tests	True Value (TU_c)	Range of Results (TU_c)	Mortality in 100% Sample	CV[28]	False Positive Rate[29]
EPA Effluent Samples	24	8	4-16	100%	39.6%	12.5%
EPA Dilution Water Blanks	27	1	1-4	< 5%	NA	4%
EPA Reference Toxicant Sample	36	1	1-16	< 5%	179.3%	28%
WESTCAS 1997 Study[30]	14	1	1-16	< 5%	85%	36%
WESTCAS 2004 Study[31]	16	1.25	1-16	< 5%	205%	56%

[27] The "EPA Effluent Samples" row is based on data in Table 9.9 (Validation Study 83-84), "EPA Dilution Water Blanks" is based on Table 9.7 (*id.* 79-80), and "EPA Reference Toxicant Sample" is based on Table 9.8 (*id.* 81-82), J.A. ___.

[28] EPA did not calculate CVs for the NOEC. *See* 1991 TSD 5-6, J.A. ___. For comparison purposes, Table 2 CVs were calculated in accordance with Appendix E of the 1991 TSD.

[29] The false-positive rate is based on the number of samples with toxicity greater than the median reported toxicity, which EPA calls the "True Value." *See* Validation Study, Table 9.12, J.A. ___.

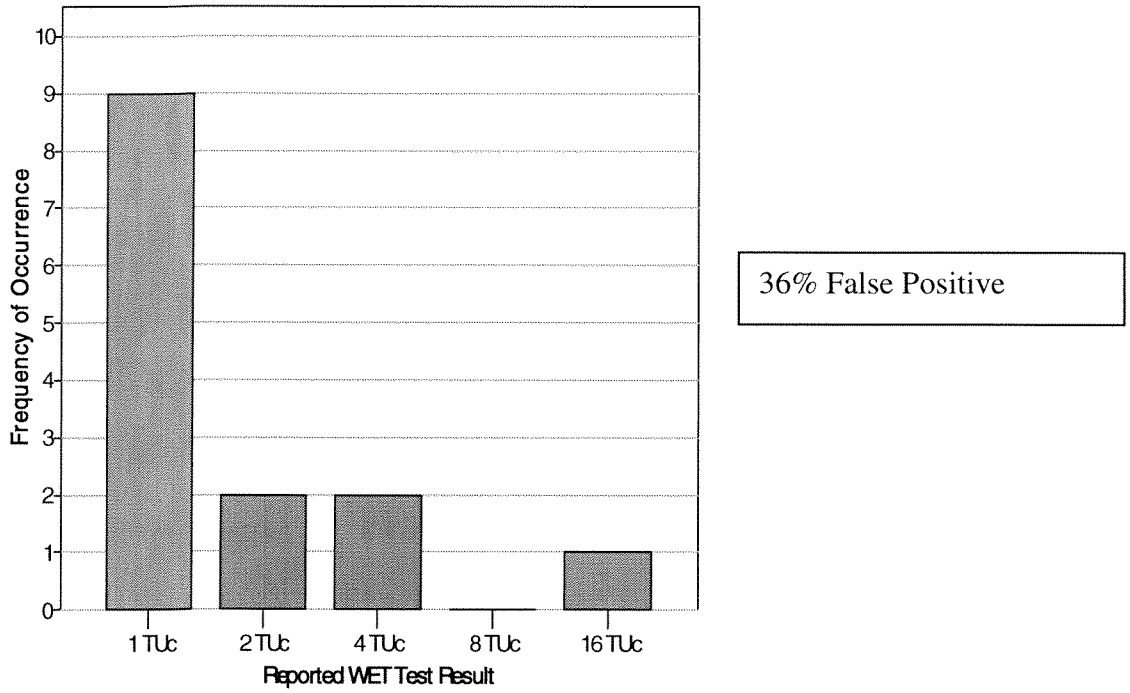
[30] EPA's assertion that the first WESTCAS Study failed to meet holding time requirements (EPA Br. 83-84) is incorrect and nowhere documented in the record. The WESTCAS study used moderately hard *dilution* water, for which the holding time is 14 days. EPA also wrongly asserts that the study was "too small" to be evaluated. *Id.* However, as the above table demonstrates, the WESTCAS study tested a number of samples comparable to EPA's own *Ceriodaphnia* studies.

[31] The second WESTCAS Study was submitted to the Court by Motion of June 30, 2004. If the Court declines to review that information, this part of the table may be ignored. *But see Portland Cement*, 486 F.2d 375, 394-95 (court ordered EPA to consider new information presented to the court).

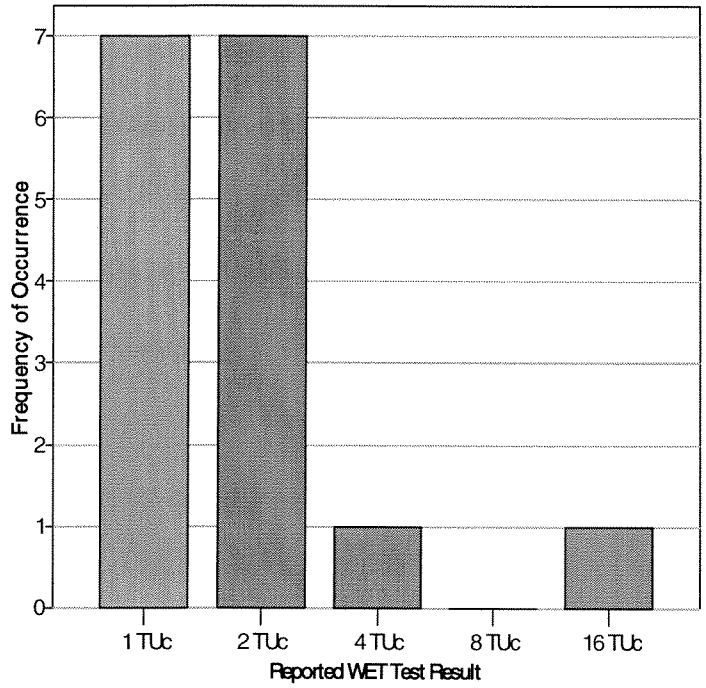
The test variability (CV) increased fivefold (from 39.6% for highly toxic to 179.3% for mildly toxic), placing the result well above the accepted range of variation for approved test methods. EPA Br. 51. This is precisely what SETAC warned would happen and why no single test result should be considered reliable evidence. Thus, EPA's reliance on the high-toxicity exposure data to evaluate precision is flawed in light of low-toxicity data showing much greater variability. *See, e.g., Portland Cement*, 486 F.2d at 400-01*; Nat'l Petrochemical*, 287 F.3d at 1140*; Leather Indus. of Am. v. EPA*, 40 F.3d 392, 405 (D.C. Cir. 1994).

Graphs of the four "no toxicity" studies show the number and type of false-positive results that will occur, disproving EPA's statement that "the tests rarely provide a false indication of toxicity" (EPA Br. 34):

Ceriodaphnia Reproduction in WESTCAS-1997 Study – Figure 1

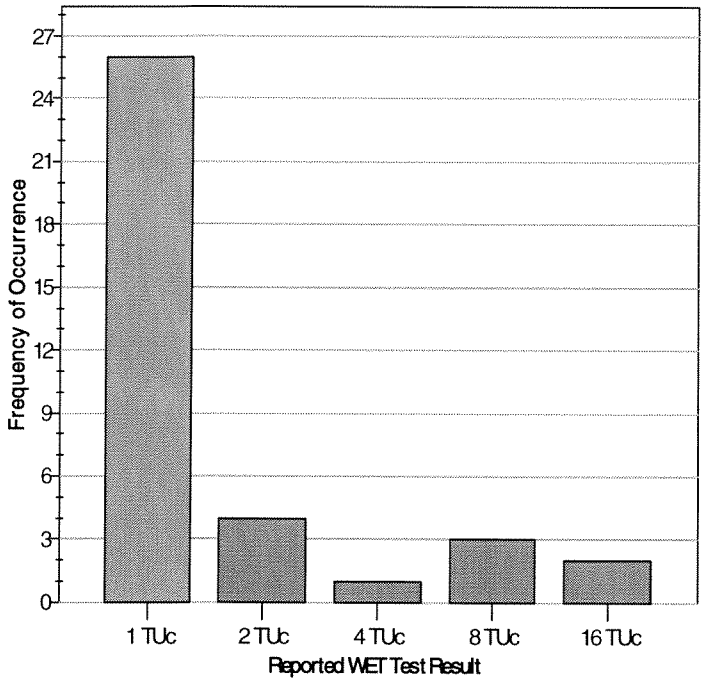


Ceriodaphnia Reproduction in WESTCAS-2004 Study – Figure 2



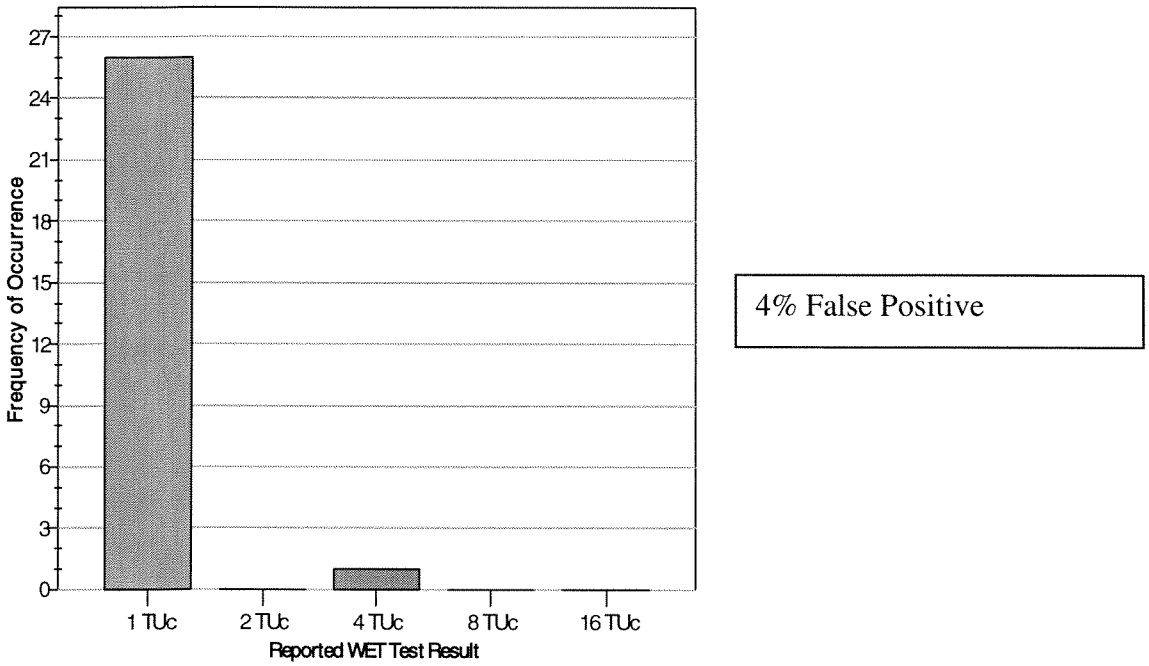
56% False Positive

Ceriodaphnia Reproduction in EPA's Reference Toxicant Sample – 2000 – Figure 3



28% False Positive

Ceriodaphnia Reproduction in EPA's Blank Sample-2000 – Figure 4



As these graphs show, only the dilution water blank (Figure 4) had a low false-positive rate. For all the other studies, between 28 and 56% of the results would be reported as 2-16 TU_c, though toxicity is not present. These data confirm that the false-positive rate for a nontoxic sample is far greater than 5%.

The validation data that EPA ignored (Table 9.8 of the Validation Study) also provide essential information about the reliability of the growth and reproduction endpoints (the focus of Petitioners' action) when substantial mortality is absent. The samples EPA relied on to assess chronic method reliability were acutely toxic, causing a high level of mortality in the chronic tests. *Supra* 23. Obviously, a dead organism cannot grow or reproduce. As demonstrated in Table 2, the variability of chronic effects increases dramatically when mortality does not occur in a test sample. Thus, EPA's selection of highly toxic samples masks chronic endpoint variability. Because chronic method endpoints are independently evaluated to determine permit compliance

(no significant reduction in growth, reproduction, *or* mortality), EPA should have independently documented their reliability at the reporting level that many permittees routinely must meet.

In summary, EPA lacks substantial evidence that WET methods will perform reliably on effluent samples where the level of toxicity is less than 3 TU_c. EPA's refusal to evaluate its own validation study data showing high false-positive rates for a nontoxic sample is unsupported. EPA also has provided no information that the growth or reproduction endpoints, in the absence of lethality, have (1) a precision comparable to chemical methods or (2) a low false-positive rate at the 1-3 TU_c reporting level. *Supra* 25. Consequently, EPA's promulgation of the chronic growth and reproduction endpoints is unsupported by substantial evidence, arbitrary, and capricious.

2. EPA Lacks Substantial Evidence of Representativeness At or Near the Intended Level of Enforcement of 1 TU_c

Petitioners argued that representativeness of WET growth and reproduction endpoints at or near 1 TU_c are undocumented because EPA's field correlation studies evaluated only sites where conditions were acutely lethal. EPA responded that the record contains "overwhelming evidence of a correlation between WET tests and instream impacts" (EPA Br. 64) and provided a general reference to the Complex Effluent Toxicity Testing Program ("CETTP"), SETAC, and 1999 EPA Reports. But EPA provided no *specific* citation in any of these documents to contradict Petitioners' *specific* arguments, because none exists. These documents are general defenses of toxicity testing based on acute and chronic *mortality* data, not the particular *sublethal* endpoints at issue here. EPA's references are therefore insufficient to rebut Petitioners' claims. *Appalachian Power*, 249 F.3d at 1059.

Contrary to EPA's representation that "[t]hese eleven studies [(CETTP)] focused on the chronic effects of toxicity," EPA acknowledges that the CETTP studies focused on sites with a

"higher degree of toxicity" (*i.e.*, acute mortality), but asserts that there is "no reason that toxic effluents would not similarly impact organisms in less toxic receiving waters." EPA Br. 59-60, 65. Thus, EPA only *assumed* that the chronic method growth and reproduction endpoints were representative. Likewise EPA admits that even though the new fathead minnow biomass endpoint was not proven to be "representative," it was based on *Ceriodaphnia* tests that were "assumed" representative. EPA Br. 72.

Attempting to rehabilitate its inadequate record, EPA now seeks to place the burden of proving representativeness on Petitioners, abandoning its prior assertion that it had done so. EPA asserts that "petitioners offer no evidence that WET tests are incapable of predicting instream impacts in waterbodies with lower levels of toxicity." EPA Br. 64.

Contrary to EPA's claim of "no evidence," the 1999 Report stated that the CETTP studies were acknowledged to be biased to sites where impacts were known or expected due to high toxicity levels (*see* 1999 Report 15, J.A. ___) and that a review of non-impacted sites "reveals that toxicity tests were reliable indicators in 32% of the cases, *with 68% 'false positives.'*" *Id.* 8 (emphasis added). This is far worse than the 5% false-positive rate EPA asserts is acceptable. The 1999 Report further notes that Parkhurst (1996) found that "ambient toxicity did not show a strong relationship with measures of instream biological communities...[but] only sublethal endpoints...were used in the correlation analysis; that is, Parkhurst (1996) omitted lethality data from his analysis." *Id.* 10.[32]

[32] The primary researcher in the CETTP program, Dickson, also confirmed this fact. SETAC 287 ("In that study [evaluation of CETTP and three others], a statistically significant and predictable relationship between ambient toxicity and receiving system community response was found. However, the predictive relationship was based on data from sites receiving *highly toxic* effluents. Whether or not the predictive relationship...is valid for moderately or slightly impacted sites was not examined.") (emphasis added), J.A. ___. Thus, EPA's experts and SETAC have confirmed Petitioners' criticisms.

This is precisely Petitioners' point. SETAC also agreed with Parkhurst. SETAC 276, J.A. ___. The Water Environment Research Foundation, under EPA grant, made similar findings. Pet'r Br. 57 n.48. Thus, the 1999 Report acknowledged a poor correlation between growth and reproduction endpoints and instream adverse effects in the absence of lethal toxicity. *See* 1999 Report 24, J.A. ___.

This Court has held that using high exposure data to justify regulating at low exposure levels is arbitrary and capricious. *Leather Industries*, 40 F.3d at 405. As EPA's own experts agree with Petitioners that the chronic method, absent lethality, has a very high rate of "false-positives" and EPA has ignored the conclusions of its experts in asserting that representativeness has been "extensively documented," it has committed reversible error. *See Walter O. Boswell Memorial Hospital v. Heckler*, 628 F. Supp. 1121, 1125-26 (D.D.C. 1985).

Furthermore, EPA's claim that its conclusion that growth and reproduction endpoints were valid is a reasonable extrapolation from the studies conducted on acutely toxic waters (EPA Br. 64-65) is a new argument now advanced by counsel. Such "post hoc" rationalizations cannot cure an otherwise flawed agency action. *Martin*, 499 U.S. at 156. In any event, to rely upon "extrapolation" for concluding that chronic-level impacts on growth and reproduction correlate to instream impacts based on lethality data, EPA must fully discuss and evaluate the uncertainties and justify the merits of its assumptions. *National Gypsum*, 968 F.2d at 43-44; *Leather Industries*, 40 F.3d at 405.

EPA claims that some universal "concentration/response relationship" justifies its regulation of impacts at chronic levels. EPA Br. 65. Logically, however, the "concentration/ response" concept applies to the same test endpoint, not entirely distinct endpoints. EPA has not adequately supported its assumptions. Accordingly, they cannot be the basis for upholding the

methods. *Mossville Envtl. Action Now v. EPA*, 370 F.3d 1232, 1242-43 (D.C. Cir. 2004); *National Gypsum*, 968 F.2d at 43-44 (may not regulate on speculation of toxicity of pollutant). Moreover, EPA must explain why data on lethality confirm test "representativeness" with a "small likelihood of false positive results," when the record indicates a 68% false positive result if lethality is absent. *Chemical Mfrs. Ass'n v. EPA*, 28 F.3d 1259, 1265-66 (D.C. Cir. 1994) (finding agency's assumptions contrary to the available data and therefore arbitrary and capricious).

EPA may not presume that a more restrictive approach is reasonable when the available data and analyses show that the presumption is flawed. *Id.* Thus, EPA lacks substantial evidence that the growth and reproduction endpoints are representative of instream effects.

a. Algal Tests Lack Documentation that Test Results Are Representative of Instream Effects

Petitioners asserted that EPA conducted no studies documenting that the WET algal test accurately predicts instream effects. EPA's rebuttal identifies only a two-paragraph summary of two studies in an appendix to its 1999 Report as proof that the algal method is representative of waters nationwide. EPA Br. 62-63. These two paragraphs are not substantial evidence.

Neither the 1999 Report nor the SETAC Report concluded that the algal test has been documented to predict instream impacts, and EPA has identified no other record information. The studies identified were not even conducted in natural waterbodies or on whole effluent. Kettle *et al.* studied an artificial pond, and Stay *et al.* used a wide-mouth pickle jar. Both studies assessed the chemical atrazine, not a whole effluent. 1999 Report 43-44 (discussing Larsen *et al.*), J.A. ___. The summary does not conclude that *Selenastrum* is a good indicator of instream

impacts, and none of the essential exposure information (magnitude, duration, and frequency) needed to confirm the representativeness of the adopted method is presented.[33] *Id.*

Moreover, EPA recently published an atrazine criteria document demonstrating that algal tests in general are *not* a valid indicator of potential instream effects and that these tests overestimate real world impacts on plants because plants recover rapidly from stress. EPA, *Draft Ambient Aquatic Life Water Quality Criteria for Atrazine*, EPA-822-R-03-023 (Oct. 2003). The atrazine criterion proposed in the document is significantly higher than the level found to affect *Selenastrum* in these short-term algal tests. *Compare id.* 1,16, and 34, J.A. ___.

In addition, contrary to EPA's assertion that the seven-day algal test is documented to be a good indicator of instream impacts for all waters, EPA's Office of Pesticide Regulation explains that atrazine impacts are less likely to occur in "flowing waters," as distinguished from impacts in the laboratory where the water is not moving:

> [E]ffects found in Kansas ponds on the loss of vegetative cover, were erroneously extrapolated to streams...plants in rivers and flowing streams most likely would not be exposed...for a sufficient period of time to be killed.

EPA, *EFED Review of Public Comments in Response to the EPA EFED Revised Environmental Risk Assessment for Atrazine* (April 10, 2002) 5, J.A. ___.

Thus, EPA has no information whatsoever showing that the algal methods are reliable indicators of instream effects, and the recent actions of the Office of Pesticide Regulation and Office of Water confirm that they are not. EPA's assertion that the algal methods are "representative" is not based upon substantial evidence.

---

[33] "[F]ield bioassessment approaches are needed to compensate for the limitations of WET tests to predict phytotoxicity [(i.e., impacts on plant life)]..." SETAC 338, J.A. ___. Thus, it is clear to SETAC that the proposed algal method has not been shown to be a reliable indicator of instream impacts.

b. Chronic Marine Tests Are Not Documented to Be Representative of Instream Impacts

Petitioners argued that there is no documentation that the marine chronic tests are correlated to instream impacts. EPA again counters that such correlation is documented, citing a 1989 EPA document and a 1989 study by Schimmel. EPA Br. 62-63.

In fact, the documents cited by EPA as documenting an instream correlation say that no such demonstration exists for marine waters. Schimmel himself reported in 1995 as follows:

> We have discovered no case studies in the scientific literature that describe a detailed analysis of the toxicity of an effluent discharging to the estuarine or marine environments or that also describe a corresponding impact on the water column and benthic communities of the receiving system...Case studies relating effluent toxicity to receiving system impacts are very valuable in evaluating the biological significance of percentage reduction in WET test endpoints. *No one marine case study exists, however, that allows such an evaluation.*

SETAC 323 (emphasis added), J.A. ___.

Thus, the very expert EPA relies on to claim that a correlation exists confirms that no such demonstration has been made. As with the algal test, SETAC also concludes that "field bioassessment approaches are needed to compensate for the limitations of the WET tests...to predict effects for different ecosystems such as wetlands, *estuaries* and large rivers." *Id.* 338 (emphasis added), J.A. ___. Thus, the method cannot stand alone as an indicator of instream impacts.

EPA's other main reference, the 1999 Report, agrees with SETAC that only a paucity of bay and estuary studies exist. It observes that for marine waters, only sediment toxicity (not water column toxicity) has been evaluated. *Id.* 218, J.A.___; 1999 Report 3, 22, J.A. ___. Such studies are irrelevant to this rulemaking, because *sediment* toxicity is not evaluated with a *whole effluent* toxicity test. Likewise, EPA's reference to mysid shrimp and sheepshead minnow tests

in Appendix B of the 1999 Report is as empty of substance as its reference to the algal test. The Dorn study did not show any correlation to instream impacts in marine waters; the correlation was in *fresh water.* 1999 Report 45-46 ("Effect concentrations...were assessed in outdoor artificial streams."), J.A. ___.

Likewise, the studies referenced on pages 42-43 of the 1999 Report do not support EPA's claims. The Clark (1987) study was not of a whole effluent, but an insecticide, with exposures only at lethal (LC50) levels. The brief description of the study concludes that lethal doses "were not effective predictors of sublethal effects." *Id.* 42, J.A. ___. This test therefore provided no information regarding the "representativeness" of the chronic (sublethal) endpoints, as EPA asserts.

EPA claims there is "abundant record evidence" to conclude that the chronic WET tests are "representative." EPA Br. 58. As confirmed by SETAC, EPA's own report, and the expert report relied upon by the Agency (Schimmel), however, this statement is not only wrong; it is directly refuted by these very documents. Thus EPA lacks substantial evidence that the marine methods are "representative."

E. EPA Ignores Documented Sources of Interference

In response to Petitioners' argument that EPA ignored known sources of test interference for Western waters, such as ionic imbalance, EPA claims that Petitioners "offer no specific evidence...that certain features inherent to western waters will have negative effects on test organisms that mimic the effect of toxicity." *Id.* 62, 69-70. EPA's denial that ionic interference is a documented concern is directly contradicted by both the WET Method Guidance (which

recognizes that ionic imbalance affects test performance) and the federally funded Western waters study. Pet'r Br. 41; *see also* Chronic Method Manual § 11.3.2,[34] J.A. ___.

The fact that water with a different ionic makeup than water used to culture (raise) *Ceriodaphnia* may adversely impact reproduction has been widely recognized as causing false indications of toxicity in otherwise nontoxic samples. SETAC 141 ("Parameters such as TDS (hardness, salinity, conductivity)...must be within the prescribed range in order for each effluent toxicity test method to minimize variability."), J.A. ___. EPA discarded several validation study results for minor changes in hardness and alkalinity, fearing that the results were compromised. Validation Study, Table 9.1 (fathead chronic results), J.A. ___. Goodfellow specifically identified ionic imbalance as one of the leading causes of test failures in Western waters. Comments of WET Coalition 52 (January 11, 2002), J.A. ___. EPA misinforms the Court that this problem is not well-documented in the administrative record.[35]

EPA's claim that permittees can correct this problem by conducting their own studies and having EPA approve them flies in the face of EPA's responsibility not to impose test methods that are deficient and likely to lead to misreporting. *Petroleum Communications v. FCC,* 22 F.3d 1164, 1172 (D.C. Cir. 1994) ("An agency must justify its failure to take account of circumstances that appear to warrant different treatment for different parties."). EPA cannot place Western dischargers in violation of the CWA by requiring a faulty method and imposing the burden of correcting the method on the permittees.

---

[34] Adjusting dilution water cannot "correct" this problem, because there is no dilution in dry/intermittent streams. The CETTP studies, which found a low level of "false negatives," did not address any streams in the arid West.

[35] While EPA claims that the "mere existence of the 1999 EPA Report refutes Petitioners' claim that EPA conducted no new studies after 1995," the 1999 Report merely *reviews* existing studies, as its title indicates. *See* EPA Br. 62. Conducting a review of entirely pre-1996 studies in 1999 does not mean that any new data were considered by EPA in 1999.

Anticipating that EPA would, once again, claim this issue was unsupported by Petitioners, WESTCAS conducted a study, using the latest approved methods, confirming that *Ceriodaphnia* tests will be highly biased toward finding toxicity in nontoxic waters typical of the arid West.[36] Over a 50% false-positive rate and toxicity up to 20.5 TU_c was documented by sending samples to 17 EPA-certified Western laboratories in the blind. This study confirms, once again, the reality that EPA seeks to deny.

In light of (1) data in the administrative record confirming ionic interference as a problem for Western waters and (2) the latest study, again confirming interference with a high false-positive rate, the chronic sublethal method should be vacated until EPA confirms that the ionic interference problem has been fully addressed.

F. Actual Dilution Must Be Considered

EPA's response to Petitioners' arguments that the methods must contain a specific limitation regarding dilution relies on its generic regulation involving consideration of instream dilution "where appropriate." EPA Br. 67 n.39. EPA's standard drought flow statistics for dilution may work for chemical-specific criteria, where calculations reveal a specific worst-case pollutant concentration to compare with numeric criteria. But, as Petitioners' representativeness presentation demonstrates, the linkage between WET results and narrative criteria is unproven, and EPA's experts warned that WET tests are an effective predictive tool only when the actual dilution and exposure duration in the receiving water are accounted for. Pet'r Br. 60. SETAC confirmed this critical point. *See* SETAC 281, J.A. ___.

Because EPA's approach again conflicts with the findings of its own experts, the WET methods must be amended to require that actual dilution be accounted for in applying the

[36] This study was filed by motion on June 30, 2004.

methods in any NPDES context. EPA's failure to include a method limitation regarding proper consideration of dilution, knowing that its existing approach to dilution is inconsistent with the validation studies, is arbitrary and capricious.

G. Marine Acute Methods

EPA is incorrect that Intervenor API's position is inconsistent with Petitioners'. API and Petitioners agree that EPA's failure to approve the "East Coast" Acute Marine Methods for the West Coast was arbitrary and capricious. EPA asserts that it has thoroughly established the reliability and representativeness of the Marine Acute Methods but nowhere documents that West Coast waters will not be protected by these species. Thus, there is no rational basis for EPA's refusal to adopt these methods.

Further, EPA's Pacific Ocean decision criteria were wholly illegitimate: EPA decided not to ratify the Marine Acute Methods for the Pacific Ocean specifically to allow the continued use of unvalidated state test methods. EPA Br. 91. EPA admitted that those unvalidated methods do not meet the Part 136 criteria for method ratification. *See, e.g.*, 67 Fed. Reg. 69,961, J.A. ___. The purpose of Part 136 is to establish reliable, legally defensible methods, not to promote utilization of admittedly unvalidated methods for CWA enforcement. EPA's action directly harms API/Petitioners' interests by forcing our members to argue against their use on a case-by-case basis in current and future permit reissuance.

CONCLUSION

For the reasons stated above, this Court should vacate and remand EPA's approval of the nonlethal chronic endpoints of the five methods identified on page 3 above, its failure to require proper consideration of dilution for all methods, and its arbitrary limiting of the Marine Acute Methods to the East Coast.

Respectfully submitted,

John C. Hall
Tad S. Foster
Counsel for WESTCAS

Alexandra D. Dunn
David E. Evans
Richard H. Sedgley
Stewart T. Leeth
Counsel for Association of Metropolitan Sewerage Agencies

Of Counsel:

F. Paul Calamita
Christopher D. Pomeroy
AquaLaw PLC
801 E. Main Street, Suite 1002
Richmond, VA 23219

Roberta L. Larson
Somach, Simmons & Dunn
Hall of Justice Building
813 Sixth Street, Third Floor
Sacramento, CA 95814

James N. Christman
Andrea W. Wortzel
Penny A. Shamblin
Counsel for WET Coalition

Fredric P. Andes
Barnes & Thornburg
750 17th Street, N.W.
Suite 900
Washington, DC 20006-4607
(202) 408-6934

Erika K. Power
Barnes & Thornburg
One North Wacker Drive
Suite 4400
Chicago, IL 60606
(312) 338-5904
Counsel for Intervenor
American Petroleum Institute

CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the foregoing REPLY BRIEF OF PETITIONERS AND INTERVENOR was served this 19th day of July, 2004, by first class mail, on the following:

Stephen J. Sweeney, Esq.
Office of General Counsel
U.S. Environmental Protection Agency
1200 Pennsylvania Ave. N.W., 2355A
Washington, DC 20460

David S. Gualtieri, Esq.
Christina Bechak Parascandola, Esq.
Environmental Defense Section
Environment & Natural Resources Division
United States Department of Justice
P.O. Box 23986
Washington, DC 20026-3986

Fredric P. Andes, Esq.
Barnes & Thornburg
750 17th Street, N.W.
Suite 900
Washington, DC 20006-4607

Erika K. Powers, Esq.
Barnes & Thornburg
One North Wacker Drive
Suite 4400
Chicago, IL 60606-2809

John C. Hall, Esq.
Hall & Associates
1101 15th Street, N.W.
Suite 203
Washington, DC 20005

Tad S. Foster, Esq.
20 Boulder Crescent
Colorado Springs, CO 80903

David E. Evans, Esq.
Richard H. Sedgley, Esq.
Stewart T. Leeth, Esq.
McGuireWoods LLP
901 East Cary Street
Richmond, VA 23219

Alexandra D. Dunn, Esq.
General Counsel
Association of Metropolitan Sewerage Agencies
1816 Jefferson Place, N.W.
Washington, DC 20036-2505

F. Paul Calamita, Esq.
Christopher D. Pomeroy, Esq.
AquaLaw PLC
801 E. Main Street
Suite 1002
Richmond, VA 23219

Roberta L. Larson, Esq.
Somach, Simmons & Dunn
Hall of Justice Building
813 Sixth Street, Third Floor
Sacramento, CA 95814

_____
Kristy A.N. Bulleit

CERTIFICATE OF COMPLIANCE WITH RULE 32(a)

Certificate of Compliance with Type-Volume Limitation,
Typeface Requirements, and Type Style Requirements

1. This brief complies with the type-volume limitation of Fed. R. App. P. 32(a)(7)(B) as modified by the Court's order of November 25, 2003, because it contains 11,105 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(a)(7)(B)(iii).

2. This brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type style requirements of Fed. R. App. P. 32(a)(6) because it has been prepared in a proportionally spaced typeface using Microsoft Word 2000 in 12 point Times New Roman.

(s)_____

Attorney for _____

Dated: _____