ORAL ARGUMENT SCHEDULED FOR OCTOBER 15, 2004

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

No. 96-1062 and Consolidated Cases

EDISON ELECTRIC INSTITUTE, *et al.,*

Petitioners,

v.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY, *et al.,*

Respondents.

On Petitions for Review of a Final Rule of the
United States Environmental Protection Agency

BRIEF OF RESPONDENTS UNITED STATES ENVIRONMENTAL PROTECTION AGENCY, *et al.*

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June 8, 2004

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Respondents.	)	

RESPONDENT'S CERTIFICATE AS TO PARTIES, RULINGS, AND RELATED CASES

Pursuant to Circuit Rule 28(a)(1), the undersigned counsel of record for Respondent United States Environmental Protection Agency ("EPA") submits this certificate as to parties, rulings, and related cases.

A. Parties and Amici:

The Petitioners are the: Association of Metropolitan Sewerage Agencies; California Association of Sanitation Agencies; Maryland Association of Municipal Wastewater Agencies, Inc.; South Carolina Water Quality Association, Inc.; Texas Association of Metropolitan Sewerage Agencies; Virginia Association of Municipal Wastewater Agencies, Inc.; West Virginia Municipal Water Quality

Association, Inc.; Western Coalition of Arid States; WET Coalition; and Edison Electric Institute, et al. ("Utility Petitioners"), comprising 46 individual electric utilities and three trade associations identified in the "Corporate Disclosure Statement of Edison Electric Institute, et al. ('Utility Petitioners')" at pages 6-8 of Petitioners' Certificate as to Parties, Rulings and Related Cases.

The Intervenor is: American Petroleum Institute.

The Respondents are: EPA and Michael O. Leavitt, the Administrator of EPA.[1/]

B. Rulings Under Review: Petitioners and Intervenor challenge EPA's ratification, withdrawal and revision 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.

C. Related Cases: The following cases have been consolidated and reopened as indicated by 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*;

[1/] Mr. Leavitt is automatically substituted for his predecessor pursuant to Fed. R. App. P. 43(c)(2).

- No 03-1091, *AMSA et al. v. EPA*; and
- No. 03-1094, *WET Coalition v. EPA*.

There are no other related or pending cases.

Respectfully submitted,

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GLOSSARY

ADD	Addendum to EPA's Brief
APA	Administrative Procedure Act
CETTP	Complex Effluent Toxicity Testing Program
CV	Coefficient of Variation
CWA	Clean Water Act
DMRs	Discharge Monitoring Reports
DQOs	Data Quality Objectives
EAB	Environmental Appeals Board
EDTA	Ethylenediaminetetraacetic acid
EPA	U.S. Environmental Protection Agency
IC25	Inhibition Concentration (25%)
J.A.	Joint Appendix
LOEC	Lowest Observable Effect Concentration
MDL	Method Detection Limit
NOEC	No Observable Effect Concentration
NPDES	National Pollutant Discharge Elimination System
PMSD	Percent Significant Minimum Difference
QA	Quality Assurance
QC	Quality Control
RTC	Response to Comments Document
SETAC	Society of Environmental Toxicology
TSD	Technical Support Document
TRE	Toxicity Reduction Evaluation
TUc	Toxic Unit (Chronic)
WET	Whole Effluent Toxicity
WQBEL	Water Quality Based Effluent Limitation

JURISDICTION

This case concerns action by the United States Environmental Protection Agency ("EPA") ratifying, withdrawing and revising methods and procedures to measure whole effluent toxicity ("WET" or "toxicity"), as required by the Clean Water Act ("CWA" or the "Act"), 33 U.S.C. § 1314(h). 67 Fed. Reg. 69,952 (Nov. 19, 2002) (hereinafter the "2002 WET Rule"). EPA agrees with Petitioners that this Court has jurisdiction pursuant to CWA Section 509(b)(1), 33 U.S.C. § 1369(b)(1), because the WET test procedures constitute an "effluent limitation or other limitation."

In finding jurisdiction under Section 509(b)(1), this Court has previously construed broadly the phrase "any effluent limitation or other limitation" to "include more than numerical limitations." *Natural Resources Defense Council v. EPA*, 673 F.2d 400, 403 (D.C. Cir. 1982) (CWA Consolidated Permit Regulations within scope of Section 509(b)(1)); *Natural Resources Defense Council v. EPA*, 656 F.2d 768, 785-86 (D.C. Cir. 1981) (limit to availability of variance from effluent limitations within scope of Section 509(b)(1)). This Court has jurisdiction over these petitions for review because the WET test methods, though not effluent limitations, are used to determine effluent limitations and are, therefore, "other limitations" under Section 509(b)(1)(E). As this Court has observed, it would be a

"perverse result" if the Court did not have jurisdiction over nationally-applicable procedures relevant to the setting of effluent limitations (such as the WET test methods), while possessing jurisdiction over "numerous individual actions issuing or denying permits." *NRDC*, 673 F.2d at 405-06; *see also* 33 U.S.C. § 1369(b)(1)(F).

The Administrator's action was final for purposes of judicial review on December 3, 2002. *See* 40 C.F.R. § 23.7. The petitions were timely filed.

STATUTORY AND REGULATORY ADDENDUM

Pertinent provisions, including Federal Register notices, are provided in the separately bound Addendum.

STATEMENT OF THE ISSUES

1. Whether EPA acted reasonably by ratifying and approving for use in CWA National Pollutant Discharge Elimination System ("NPDES") permitting and reporting chronic WET test methods using non-lethal endpoints for *Ceriodaphnia*, fathead minnow, marine species, and algae and, specifically, whether EPA adequately validated those chronic WET test methods for use nationwide.

2. Whether Intervenor American Petroleum Institute ("API") can challenge EPA's decision not to ratify for use in the Pacific Ocean three marine acute WET test methods in light of the fact that Petitioners have not raised or

adopted that issue; and whether API has standing to raise this challenge.

3. Whether EPA reasonably decided not to ratify three marine acute WET test methods for the Pacific Ocean.

4. Whether the certification requirement for WET test results in NPDES Discharge Monitoring Reports creates an impermissible irrebuttable presumption.

STATEMENT OF THE CASE

I. INTRODUCTION

Whole effluent toxicity refers to the aggregate toxic effects of all pollutants in a discharger's effluent that impair the health of aquatic organisms. This case concerns EPA's exercise of its judgment and discretion in developing and approving the test procedures to measure that toxicity. Pet. Br. at 4. WET testing, in short, consists of exposing, in a laboratory setting, living aquatic organisms (plants, vertebrates, and invertebrates) to various concentrations of a test sample (*e.g.*, a facility's effluent) to measure the effect of those concentrations on those organisms' ability to survive, grow, and reproduce. Results from organisms exposed to the various concentrations are then compared to the response of a "control" group of organisms that have been exposed only to clean water. WET tests are used to determine both the short-term (acute) and long-term (chronic) effects of toxicity on aquatic organisms. Petitioners in this case challenge only the

tests for determining chronic toxicity. Pet. Br. at 4. WET test are then used by the permitting agency to determine the need for WET permit requirements, as well as the requirements themselves. This last step is governed by existing regulations that are not the subject of this litigation.

EPA's regulation of whole effluent toxicity implements Congress' policy to prohibit the discharge of toxic pollutants in toxic amounts. 33 U.S.C. § 1251(a). Although the CWA and EPA's regulations closely control the discharge of chemicals and other pollutants, WET control strategies are essential to protect aquatic life from the aggregate toxic effects of the numerous pollutants in a given effluent. Courts have recognized the importance of regulating WET and EPA's authority to do so. Congress also directed EPA to promulgate guidelines for test procedures to analyze pollutants regulated by the CWA, like whole effluent toxicity. 33 U.S.C. § 1314(h). However, neither the CWA nor EPA's regulations impose binding standards regarding the content of WET test procedures. In promulgating the challenged methods, EPA exercised its scientific judgment and expertise, informed by relevant data, and evaluated a range of technical performance characteristics that are applicable to the measurement of biological organisms.

EPA began standardizing the WET test procedures through rulemaking in

the 1980s, and the 2002 WET Rule is the culmination a long effort to develop effective procedures and compile evidence demonstrating that those procedures are reliable for use in CWA permitting and reporting. The process included: two rounds of notice-and-comment rulemaking, including the development and compilation of voluminous amounts of scientific data; several opportunities for public comment; negotiations with various stakeholder groups, including the Petitioners here; EPA's successful completion of tasks carefully negotiated in a settlement agreement to resolve challenges to an earlier WET test procedures rulemaking,[1/] including completion of a massive validation study; production of a peer-reviewed report presenting the favorable results of that study; and dozens of field studies of a range of conditions and waterbodies nationwide, demonstrating that, if a WET test shows an effluent to be toxic, toxic effects will be evident in the receiving waters.[2/] These petitions followed, challenging EPA's ratification, revision and withdrawal in the 2002 WET Rule of various WET testing methods

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[1/] The WET test methods at issue in this case were finalized in an earlier rulemaking, the "1995 WET Rule," 60 Fed. Reg. 53,529 (Oct. 16, 1995).

[2/] Multiple workshops and conferences over the course of years – involving leading experts from government, academia and industry – further contributed to EPA's development and refinement of the challenged chronic WET test procedures. In 1996, a conference of such experts published reports confirming that WET tests were effective and that additional field validation of WET testing was unnecessary.

that EPA originally approved in the 1995 WET Rule.

We describe below how, in the course of this rulemaking, EPA established that WET testing can generate reliable test results when performed by competent laboratories and that WET testing adequately predicts toxicity in waterbodies nationwide. We also discuss how EPA effectively addressed the concerns that Petitioners still raise today.

II. STATUTORY AND REGULATORY BACKGROUND

A. The CWA's NPDES Permitting Program

The CWA was adopted "to restore and maintain the chemical, physical, and biological integrity of the Nation's waters." 33 U.S.C. § 1251(a). Among others, one goal of the CWA is "that the discharge of toxic pollutants in toxic amounts be prohibited." *Id*. (a)(3). The CWA seeks to control water pollution by means of two overarching strategies: (1) a technology-based approach that applies exclusively to point source discharges (*e.g.*, a factory pipe or other conveyance) and generally relies upon federally-promulgated, technology-based regulations; and (2) a water quality-based approach that is based upon the quality of water receiving the discharge.

The CWA prohibits the discharge of a pollutant from a point source except in compliance with, among other things, a permit issued under the NPDES

program. 33 U.S.C. §§ 1311(a) & 1342. NPDES permits place limits on the rate, amount, and/or concentration of pollutant that may be discharged and require permittees to monitor their discharges and to file test results and other data with the relevant permitting authority. NPDES permits are issued and administered by EPA or, where authorized by EPA, by a State or tribal agency subject to EPA review. *See* 33 U.S.C. §§ 1342(a)-(d). The CWA gives States "the primary responsibilit[y] and right[] . . . to prevent, reduce, and eliminate pollution." 33 U.S.C. § 1251(b). *District of Columbia v. Schramm*, 631 F.2d 854, 860 (D.C. Cir. 1980).

1. Whole Effluent Toxicity is a "Pollutant" Regulated by the Act.

"Pollutant" is defined broadly under the CWA, *see* 33 U.S.C. §§ 1362(6), (13), and refers not only to individual chemicals but also the toxicity of the combination of individual chemicals in a facility's wastestream (*i.e.*, the effluent as a whole). *See*, *e.g.*, *Natural Resources Defense Council v. EPA*, 859 F.2d 156, 189 (D.C. Cir. 1992) ("While 'toxicity' appears to be an attribute of pollutants rather than a pollutant itself, we see no reason why this should preclude the agency from using it as a measure to regulate effluents that are pollutants."). This pollutant parameter is known as "whole effluent toxicity," which is defined as "the aggregate toxic effect of an effluent measured directly by a toxicity test." 40 C.F.R. § 122.2. This litigation concerns the procedures used to conduct these

toxicity tests.

2. Water Quality Standards and Effluent Limitations

The CWA requires States to establish water quality standards. 33 U.S.C. § 1313. These standards essentially describe the desired condition of a waterway and consist principally of: (a) designated *beneficial uses* for waters, such as water supply, recreation, fish propagation, or navigation; (b) *water quality criteria*, which define the amounts of pollutants, in either numeric or narrative form, that the waters can contain without impairment of their designated beneficial uses; and (c) *antidegradation requirements*, which protect against degradation of waters. 33 U.S.C. § 1313(c)(2)(A); 40 C.F.R. §§ 131.6, 131.10-12.

EPA provides States with guidance in drafting water quality standards by developing and recommending water quality criteria that reflect the latest scientific knowledge. 33 U.S.C. § 1314(a). States are not required to adopt criteria recommended by EPA pursuant to Section 304(a) and are free to rely on other sound bases. *See* 48 Fed. Reg. 51,400, 51,411 (Nov. 8, 1983). EPA's regulations provide that criteria may be based on Section 304(a) guidance, Section 304(a) guidance modified to reflect site-specific conditions, or other scientifically defensible methods. 40 C.F.R. § 131.11(b). Prior to adopting or revising any water quality standard, the State must provide notice and an opportunity for a

public hearing. 40 C.F.R. § 131.20(b). After adoption, the States must submit the water quality standards to EPA for review and approval. 33 U.S.C. § 1313(c)(2); 40 C.F.R. § 131.20(c). EPA reviews the State's water quality standards to ensure they are consistent with the CWA's requirements. 33 U.S.C. § 1313(c)(3).

State water quality criteria normally consist of a numeric level of a pollutant that cannot be exceeded in ambient water to protect each designated use as well as narrative statements applicable to a wide set of pollutants (*e.g.*, "no toxic pollutants in toxic amounts"). As regards WET standards at issue in this case, almost all States have adopted "no toxic pollutants in toxic amounts" as a narrative criterion.

Water quality standards are not self-executing; rather, they are implemented through effluent limits in NPDES permits established through a two-step approach. First, all permits must include limits reflecting various levels of technology-based requirements. 33 U.S.C. § 1311(b)(1)(A). Second, more stringent limits are included when necessary to achieve water quality standards for the particular body of water receiving the discharge. 33 U.S.C. § 1311(b)(1)(C). These latter requirements, known as water quality-based effluent limitations ("WQBELs"), may be a combination of chemical-specific limitations or controls on whole effluent toxicity. 40 C.F.R. §122.44(d)(1)(iii)-(v); *see also* EPA, *Technical Support Document for Water Quality-Based Toxics Control* (March 1991)

("TSD"), J.A. XX.

Put simply, water quality standards are translated into WQBELs, which are then incorporated into discharge permits. WQBELs are required for all pollutant parameters, including whole effluent toxicity, that the permitting authority determines "are or may be discharged at a level which will cause, have reasonable potential to cause, or contribute to an excursion above any [] water quality standard, including [] narrative criteria." 40 C.F.R. §§ 122.44(d)(1)(i), (iv) & (v). In setting a permit limitation to meet a water quality standard, the permit writer calculates how much of the pollutant (including whole effluent toxicity) the permittee may discharge without causing the ambient water quality standard to be exceeded, taking into account the dilution provided by the receiving water. 40 C.F.R. §§ 122.44(d)(1)(iii), (iv) & (v). Permitting authorities have incorporated WET limits into NPDES permits since at least 1984. 49 Fed. Reg. 9016, 9018 (Mar. 9, 1984); 49 Fed. Reg. 23,734 (June 7, 1984).

3. NPDES Reporting and Certification

Effective self-reporting is essential to the CWA. *See Sierra Club v. Simkins Indus., Inc.*, 847 F.2d 1109, 1115 (4th Cir. 1988); *Sierra Club v. Union Oil Co. of Cal.*, 813 F.2d 1480, 1491 (9th Cir. 1987), *vacated & remanded on other grounds*, 485 U.S. 931 (1988). Accordingly, permittees must establish and maintain records, install and use monitoring equipment, sample effluent according to a prescribed schedule and report the results to the permitting agency. *See* 33 U.S.C. § 1318(a); 40 C.F.R. §§ 122.41(j)(3), 122.48, 123.25. The effluent reports, which are submitted in a standardized format, are known as Discharge Monitoring Reports ("DMRs"). *See* 40 C.F.R. §§ 122.2, 123.25. A DMR must be signed by a "responsible corporate officer" or duly authorized representative, who certifies that the reported information was prepared by qualified personnel under his or her direction or supervision, and that the information is "true, accurate and complete." 40 C.F.R. § 122.22. If the permittee becomes aware of any inaccuracy in a DMR, it must promptly notify EPA. 40 C.F.R. § 122.41(l)(8). The submission of false information on a DMR is punishable by fine or imprisonment.
40 C.F.R. § 122.41(k)(2). Criminal penalties also apply to the submission of false statements. *See* 33 U.S.C. § 1319(c)(2).

B. EPA Has Developed Guidelines for Testing Procedures.

The CWA directs EPA to "promulgate guidelines establishing test procedures for the analysis of pollutants," including whole effluent toxicity, which are to be used for permit applications. 33 U.S.C. § 1314(h). Testing procedures promulgated by EPA are published in regulations at 40 C.F.R. part 136. If an NPDES permit requires monitoring or includes a limit for a pollutant for which EPA has published a testing procedure, the permit must require the use of that test procedure. 40 C.F.R. §§ 122.41(j)(4) & 122.44(i)(1)(iv); *see also* 40 C.F.R. § 136.1.

C. EPA Regulations Provide for Use of Alternative Test Procedures.

Any person may apply to EPA for approval of an alternative test method, including an alternative to any chronic WET test method at issue here. 40 C.F.R. § 136.4. The applicant must justify the approval of the alternative test procedure, describe the test method, and identify the pollutants to be monitored. *Id.* (c). An applicant may also seek approval to use an alternative test procedure on a nationwide basis, for instance if an applicant has facilities in multiple states. *Id.* (d).

D. EPA's Approval of Water Quality Standards and the NPDES Permit Process Offer Opportunities for Judicial Review.

In addition to the opportunity to challenge EPA's WET test methods rulemaking in this case, there are two additional circumstances under which an NPDES permittee can obtain federal judicial review of the implementation of the WET requirements. To the extent a State has relied on WET test results to develop State water quality standards, review of EPA's approval or rejection of a proposed State water quality standard is available in the appropriate federal district court under the Administrative Procedure Act ("APA"). *Scott v. City of Hammond*, 741 F.2d 992, 995 (7th Cir. 1984) ("The only recognized avenue for challenge to the substance of EPA's actions taken with respect to state [water quality] submissions is a suit for judicial review under the [APA]"). Review of the State's water quality standard may also be available under State law in the appropriate state forum.

The NPDES permitting process provides additional opportunities for administrative and judicial review of the *implementation* of WET requirements in permits, including the permitting authority's decision to include a WET limit as well as the selection of test organisms and frequency of WET testing required by the permit. Typically, an applicant for an NPDES permit has the opportunity to provide input and confer with the permitting authority in the development of the draft permit to ensure that the draft permit addresses unique or unusual

circumstances in the discharger's operation or the receiving water. A permitting authority's issuance of a draft permit must be accompanied by a Fact Sheet or Statement of Basis explaining how the permit terms and conditions were calculated and developed. 40 C.F.R. §§ 124.7, 124.8 & 124.56. Before issuing the final NPDES permit, the permitting agency must publish the draft permit and solicit public comment. 40 C.F.R. §§ 124.10(c) & 124.11.

After the permitting authority issues the final permit, the discharger may appeal its terms and conditions. Any person may petition EPA's Environmental Appeals Board ("EAB") for review of an EPA-issued permit on issues raised during the public comment period. 40 C.F.R. pt. 124. After the EAB issues its final decision on the permit, judicial review is available in the federal Courts of Appeals. 33 U.S.C. § 1369(b)(1)(F). If the State issued the permit, review may be had in accordance with state procedures. 40 C.F.R. § 123.30.

III. WET ANALYTIC TESTING PROCEDURES RULEMAKING

A. WET Limits and Testing

EPA's WET test methods, in 40 C.F.R. § 136.3(a), Table 1A, are vital to the effective control of toxic pollutants in the Nation's waters under the CWA, because chemical-specific limits alone cannot capture a full picture of the toxic effects of a

facility's effluent.[3/] A facility's effluent may be toxic to aquatic life, even though the causative chemical may not be identified in the relatively short list of pollutants for which the permitting authority must issue WQBELs. Availability, Adequacy, and Comparability of Testing Procedures for the Analysis of Pollutants Established under Section 304(h) of the Federal Water Pollution Control Act 1-3, 2-19 & 2-26 (EPA Sept. 1988) ("Report to Congress"), J.A. XX, XX & XX. In other cases, discharges of several chemicals in a single effluent, each meeting the applicable individual WQBELs, still can be toxic because of the synergistic effects of the chemical mixture.[4/] Thus, WET testing can determine the integrated effects of all chemicals in a single effluent sample and detect toxicity caused by pollutant parameters for which there exist no water quality standards or test methods. Finally, WET testing is the only *direct* way to measure the toxic effects of the effluent on organisms exposed to it.

B. Overview of WET Test Methods

[3/] Understanding and Accounting for Method Variability in Whole Effluent Toxicity Applications Under the National Pollutant Discharge Elimination System, EPA 833-R-00-003 at xi (June 2000) ("Variability Guidance Document"), J.A. XX.

[4/] Existing chemical-specific test methods may not be sensitive enough to measure toxic pollutants at levels of concern. Even at low levels some otherwise indetectable concentrations of pollutants may be toxic.

WET testing applies the same basic principle as all modern biological testing methods: the comparison of a specific biological outcome in an exposed group of organisms (experimental group) to an unexposed group (control group), to test the hypothesis that the biological outcome is associated with the exposure.[5/] Before any conclusions can be made from such comparisons, the results are analyzed statistically, to ensure – with reasonable certainty – that any observed difference was not due to chance.

In the case of WET testing, small groups of organisms in selected species of aquatic life, *e.g.*, fish, invertebrates, plants,[6/] are exposed to specified concentrations of effluent, in a controlled laboratory setting, to determine the acute or chronic effects of the effluent.[7/] Additionally, aquatic organisms are suitable for

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[5/] Biological testing methods are applied in numerous contexts, such as clinical trials of new medicines; epidemiological studies; and animal testing for cosmetics and food additives.

[6/] Known as "indicator" species, these test organisms are typically born and cultured in laboratories for the purpose of toxicity testing. WET test indicator species have been proven to be suitable for WET testing because of their availability, ease of maintenance, and short reproductive cycles. *Casarett & Doull's Toxicology: The Basic Science of Poisons*, 889 (Curtis D. Klaassen, ed., 5th ed. 1998), J.A. at XX; Report to Congress at 2-5, J.A. at XX.

[7/] Petitioners challenge only certain *chronic* WET test methods: *Ceriodaphnia dubia* Survival and Reproduction Test; Fathead Minnow Larval Survival and Growth Test; *Selenastrum capricornutum* (green algae) Growth Test; Sheepshead Minnow Larval Survival and Growth Test; and Inland Silverside Larval Survival

WET testing because they complete almost their entire life cycles in water and, therefore, can serve as monitors of water quality. *Id*.; TSD at 4, J.A. at XX. WET test methods are designed to test for certain chronic biological outcomes, *e.g.*, survival, growth and reproduction.[8/] The results are measured, analyzed and expressed in terms of one or more of three statistical endpoints: (1) No Observable Effect Concentration ("NOEC"), the highest concentration of toxicant that causes no observable adverse effect on the organisms; (2) Lowest Observable Effect Concentration ("LOEC"), the lowest concentration of toxicant to which organisms are exposed that causes adverse effects on the test organisms; and (3) Inhibition Concentration ("IC"), the point estimate of the effluent concentration that would cause a specified percentage reduction, *e.g.*, 25 %, in a measurement such as reproduction or growth.[9/] Replication – exposing not just one organism but, for example, *ten* organisms to *each* concentration level of effluent, taking the average of that result, and comparing it to an average based on *ten* unexposed sets of

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and Growth Test. Pet. Br. at 4. This brief addresses only those test methods.

[8/] Short-term Methods for Estimating the Chronic Toxicity of Effluents and Receiving Waters to Freshwater Organisms, EPA-821-R-02-013, at 37 (4th ed. Oct. 2002) ("Methods Manual"), J.A. XX-XX.

[9/] For example, if exposing test organisms to a solution composed of equal parts clean dilution water and a facility's effluent causes a 25% reduction in the growth of the organisms, the IC_{25} for growth is 50% effluent.

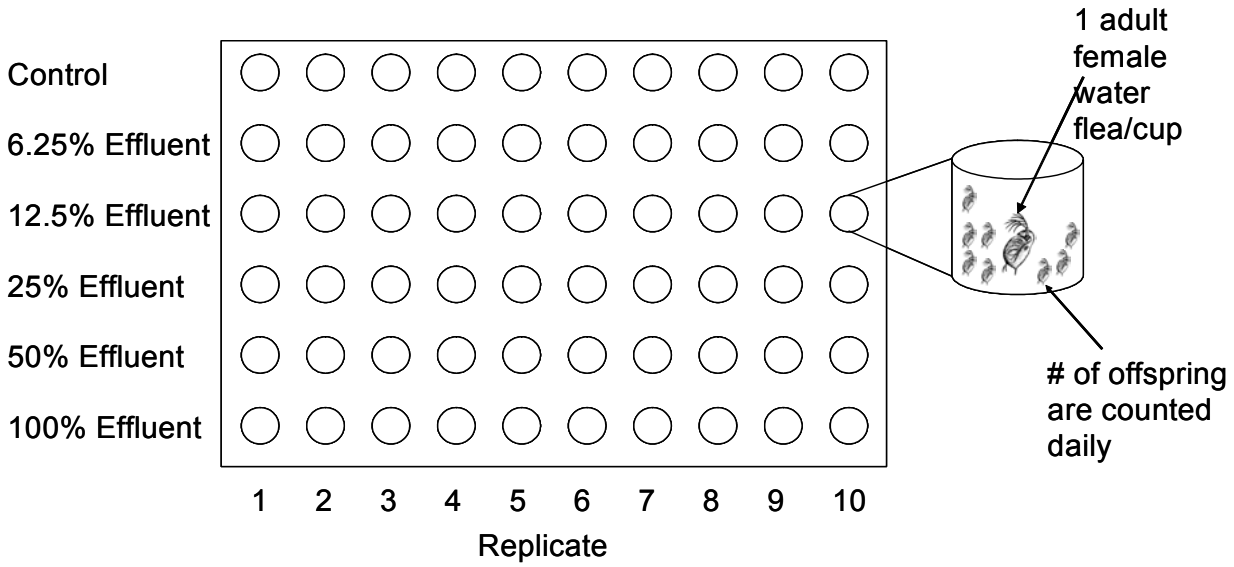

Figure 1 - Example of WET Test Design, Ceriodaphnia dubia Survival and Reproduction Test Method 1002.0

control organisms – is an integral part of WET test method design. WET test methods typically require the use of 60 to 200 organisms per test, and the algae-based WET test methods use millions. Chemical test methods, in comparison, are based on a single measurement of a sample. The large number of replicates, the use of averaging, and statistical methods account for variability and protect against small changes being interpreted as findings of toxicity.

C. Example of a WET Test Procedure

Figure 1 depicts the design of one of the ratified WET test methods, *Ceriodaphnia*, Survival and Reproduction Test. This test is designed to determine the effect of effluent on the ability of *Ceriodaphnia* (a common water flea) to survive and reproduce, expressed statistically as an NOEC or IC_{25}. Each circle in

Figure 1 represents a cup. At the beginning of the test, each cup contains one juvenile female *Ceriodaphnia* less than 24 hours old. The top row represents the control group, which is exposed only to clean water containing no effluent. The experimental groups of test organisms are exposed to the specified concentrations of effluent (in this example, 6.25, 12.5, 25, 50 and 100%). At the end of the test (typically seven days) the total offspring produced by each adult in each cup are summed. Figure 2, below, provides an example of hypothetical test data collected after the seven-day test period. The results are reported as an average of the number of fleas in each cup, at each effluent level (last column). Each treatment, *i.e.*, effluent dilution, is compared statistically to the control.

In this example, even though the average number of *Ceriodaphnia* in each

	1	2	3	4	5	6	7	8	9	10	Average
Control	26	7	25	24	23	26	30	24	28	26	**23.9**
6.25%	24	26	21	29	23	20	24	25	27	18	**23.7**
12.5%	18	25	27	20	17	19	24	20	17	19	**20.6**
25%	19	25	24	13	24	18	16	17	18	24	**19.8**
50%	0	17	12	0	5	9	13	0	16	0	**7.2***
100%	0	0	0	0	0	0	0	0	0	0	**0.0***

Figure 2 - Example of WET Test Data from Ceriodaphnia dubia Survival and Reproduction Test Method 1002.0, showing number of offspring

cup declines after being exposed to even the lowest concentration of effluent (6.25%) and declines progressively as the samples are exposed to increasing concentrations of effluent, the test methods require that the results at each concentration be compared to the control using statistical tools before the analyst can make any conclusions about toxicity. Two basic statistical tools, point estimation and hypothesis testing, can be used to determine effluent toxicity. EPA recommends the first technique, point estimation, by which the results are plotted on a graph, as the effect (*e.g.*, number of *Ceriodaphnia* offspring produced) versus the effluent concentration levels, to determine IC at a specified percentage. In the example, the IC_{25} is approximately 29% effluent – the effluent level above which there would be a 25% reduction in the number of *Ceriodaphnia* compared to the control group. Permittees also may use hypothesis testing to determine the LOEC and NOEC. In hypothesis testing, the laboratory applies statistical tools to determine whether the hypothesis that the effluent does *not* have a toxic effect (the "null hypothesis") can be rejected. Conversely, the test hypothesis is that the effluent *is* toxic. If the laboratory observes a difference between the organisms exposed to a particular concentration of effluent and the control group, and the difference is so significant that it can be concluded, with reasonable certainty, that the difference is *not* due to chance, the null hypothesis must be rejected. Under

WET test methods, a finding of toxicity *cannot* be made unless the null hypothesis is rejected. In our example, it cannot be concluded, with reasonable certainty, that the difference in the average of the number of *Ceriodaphnia* in the control group versus the average number in the group exposed to 25% effluent (23.9 versus 19.8), was not due to chance. However, the reduction in the average number of *Ceriodaphnia* at 50% effluent was so significant that it *can* be concluded, with reasonable certainty, that it was not a chance occurrence. Thus, the null hypothesis must be rejected at a value greater than 25% effluent. Accordingly the NOEC for this effluent is >25%.

WET methods use statistical design to control for and limit the potential for errors. All test methods come with an associated possibility of error. Biological test methods pose two possibilities of error: false positives (also known as "Type I" error), in which a nontoxic effluent tests positive for toxicity; and false negatives (also known as "Type II" error), in which a toxic effluent tests negative for toxicity. WET test methods that rely on hypothesis testing are designed to produce a false negative result no more than 20% of the time. Variability Guidance Document 5-6 to 5-7, J.A. XX-XX. WET test methods also are statistically designed to produce a false positive result no more than 5% of the time. Methods Manual at 40-41, J.A. XX-XX. The 5% false positive error rate has widespread

acceptance in the field of biostatistics. Method Guidance and Recommendations for Whole Effluent Toxicity (WET) Testing (40 C.F.R. Part 136) (2000) ("Method Guidance") at 2-3, J.A. at XX. In practice, though, WET test methods exhibit even lower false positive rates than are contemplated in their statistical design. 67 Fed. Reg. 69,968; Final Report: Interlaboratory Variability Study of EPA Short-term Chronic and Acute Whole Effluent Toxicity Test Methods, Vol. 1, EPA 821-B-01-004 (Sept. 2001) ("Interlaboratory Study"), J.A. XX-XX. Furthermore, EPA incorporated additional measures into WET test methods to protect against false positive results. Basically, if a WET test shows toxicity, but the result was close, as determined by a calculation of the minimum significant difference, a statistical tool for determining the sensitivity of a test, the results must be invalidated and the test redone. Method Guidance at 2-4 to 2-6; J.A. at XX-XX; 67 Fed. Reg. 69,957-58. Accordingly, the chance of a false positive finding in a properly conducted WET test is extremely low.

D. WET Testing and Permits

Most discharge permits require dischargers to test for whole effluent toxicity quarterly or less frequently. In some cases, the WET test requirement serves as the basis for permit limits. For example, a permit may state that the reproductive capability of *Ceriodaphnia* exposed to a specified percentage of facility effluent may not be suppressed by more than 25%. In other cases, the permit limit is based on a WET test but the limit is expressed in terms of Toxicity Units ("TUs"). For chronic biological outcomes, the unit is expressed as TU_C. The TU_C may be calculated by dividing 100 by the NOEC. Thus, effluent that shows no observable effect at 100%, has a TU_C of 1.0. If the effluent has a NOEC of 25%, then its toxicity is 4.0 TU_C.

The exceedance of a WET permit limit can trigger a requirement to perform a site-specific study, called a Toxicity Reduction Evaluation ("TRE"), to investigate the causes of and identify corrective actions for difficult toxicity problems. *See* TSD at 114-19, J.A. at XX-XX. In other cases, the permittee's repeated exceedances of WET permit limits may trigger enforcement actions by the regulatory authority.

E. The 1995 WET Testing Regulations

In 1989, EPA proposed to approve certain WET test methods for NPDES purposes. 54 Fed. Reg. 50,216 (Dec. 4, 1989). Specifically, EPA proposed to incorporate by reference in 40 C.F.R. part 136 three WET testing manuals: (1) acute toxicity – freshwater and marine; (2) chronic toxicity – freshwater; and (3) chronic toxicity – marine. After consideration of comments and revising the testing manuals, EPA standardized and approved 17 WET test methods in the 1995 WET Rule. 60 Fed. Reg. 53,529 (Oct. 16, 1995).

F. Petition for Review of the 1995 WET Rule and the Settlement Agreement

In 1996, various groups representing industrial and municipal dischargers, including several Petitioners here, petitioned for judicial review of EPA's approval of the WET test methods. *Edison Electric Inst. v. EPA*, No. 96-1062 and consolidated cases. Following extensive negotiations, EPA entered into a July 1998 Settlement Agreement ("Settlement Agreement"), J.A. XX, with those parties. In the Settlement Agreement, the parties agreed to future steps that would respond to concerns raised about the 1995 WET Rule and that would be completed before EPA issued a revised final WET Rule. The parties agreed that EPA would publish a technical corrections notice in the Federal Register; publish a method guidance document and a variability guidance document; conduct an

interlaboratory variability study based on a peer-reviewed study design; publish a peer-reviewed report of that study; propose specific technical method changes; and propose to ratify or withdraw the twelve specified WET test methods that EPA evaluated in the Interlaboratory Study. The Interlaboratory Study would evaluate those test methods in accordance with specified EPA guidance documents. Settlement Agreement, Ex. B, ¶ 1, J.A. XX. Of particular importance, the Settlement Agreement provided that the Interlaboratory Study would be designed to: (1) quantify interlaboratory variability; (2) determine the rate at which participating laboratories successfully completed the tests; and (3) determine the rate at which the tests produced false positives. *Id*. at 2, J.A. XX. In short, the Interlaboratory Study was designed to determine whether the WET test methods could be applied consistently by a number of different laboratories, thus providing critical assurance of the methods' reliability.

EPA moreover agreed, at Petitioners' request, to include certain technical changes in the test methods. EPA also agreed to issue guidance to clarify that a nominal error rate of 0.05 or 0.01 in the WET test results is acceptable, depending upon the circumstances. While EPA undertook the various actions listed in the Settlement Agreement, the 1995 WET Rule was not stayed. Thus, since 1995, every WET test method at issue in this litigation has been approved and must be

used by permitting agencies in setting discharge limits and monitoring requirements in NPDES permits.

G. WET Analytic Test Procedures Rulemaking in 2002

In accordance with the Settlement Agreement, EPA issued a technical corrections notice, 64 Fed. Reg. 4975 (Feb. 2, 1999); a 185-page Variability Guidance Document; and a 60-page Method Guidance document containing guidance and recommendations on the conduct of approved WET test methods and interpretations of WET test results. Most importantly, EPA completed the Interlaboratory Study and had it peer-reviewed,[10/] updated the test Method Manuals as appropriate, and developed and incorporated into the test methods additional quality assurance/quality control ("QA/QC") requirements for test data review. As EPA agreed to do, it timely proposes to either retain or withdraw each of the 12 WET methods examined in the Interlaboratory Study. 66 Fed. Reg. 49,974 (Sept. 28, 2001) (proposing rule). EPA issued its final decision on November 19, 2002, approving ten methods, some with modifications, and withdrawing two. 67 Fed. Reg. 69,952.

[10/] *See* Summary Report Peer Review of "Preliminary Report: Interlaboratory Variability Study of EPA Short-term Chronic and Acute Whole Effluent Toxicity Test Methods" (WET Study Report) (Versar, Mar. 2001) ("Peer Review Report"), J.A. XX.

H. Interlaboratory Variability Study

The Interlaboratory Study was the largest study EPA had ever conducted for CWA test methods. *See* 66 Fed. Reg. 49,804 (Sept. 28, 2001). Fifty-six laboratories participated, each testing three or four different "blind" test samples, *i.e.*, the content of the samples was unknown to the laboratory,[11/] of the following types: reagent "blank"[12/] water; reference toxicant;[13/] municipal or industrial effluent; and receiving water, for each WET test method in which that laboratory participated. In all, more than 700 blind samples were tested. 66 Fed. Reg. 49,806; Interlaboratory Study at xiii, J.A. XX. For each WET test method, the Interlaboratory Study was designed to evaluate data from a minimum of six

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[11/] 66 Fed. Reg. 49,806. All samples (blanks and test) were sent to the participating laboratories in identical containers labeled "toxicant." Only the referee testing laboratory and the EPA contractor conducting the Interlaboratory Study knew the contents of the individual samples. Petitioners speculate that the Interlaboratory Study was not blind because the laboratories knew they would be participating in the study, and thus were likely to have exercised a higher standard of care than a "broad range" of laboratories. Pet. Br. at 45-46. Although they commented on the Study Plan, Petitioners only now raise the blank-blinding concern.

[12/] A "blank" sample is one of clean, nontoxic dilution water, containing no effluent.

[13/] A "reference toxicant" is a known toxic chemical that is routinely used to evaluate the consistency and precision of toxicity tests.

laboratories. Settlement Agreement, Ex. B, ¶ 6, J.A. XX.[14/] For each of the ten methods that EPA ratified in the 2002 WET Rule, seven to 35 laboratories participated in the study. The Interlaboratory Study found that the WET test methods performed well as measured by: (1) interlaboratory precision; (2) a low false positive rate; and (3) a high successful completion rate. 67 Fed. Reg. 69,955 (Table 1).

1. WET Tests Are Precise

The Interlaboratory Study demonstrated high levels of precision for all of the ratified WET test methods. 66 Fed. Reg. 49,805, Table 3. Precision is a measure of agreement among individual measurements of the same property. Report to Congress at 3-2, J.A. XX. For purposes of WET testing, EPA defined precision as a measure of reproducibility within a data set. Variability Guidance Document at xviii, J.A. XX. The Interlaboratory Study measured precision by calculating the coefficient of variation ("CV"), a statistic used to quantify the relative variation in the distribution of data in a test method. In the Settlement Agreement, the parties identified CV as an acceptable way to measure the precision of the WET test methods. Settlement Agreement, Ex. B, ¶ 2, J.A. XX. For each WET test method,

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[14/] EPA withdrew two methods, the *Champia* and *Holmesimysis* methods, because it could not procure services of the minimum six laboratories. 66 Fed. Reg. 49,806-09. EPA's withdrawal of these methods is not challenged here.

the Interlaboratory Study reported three CV values, one for each type of test sample: effluent, reference toxicant, and receiving water. The CVs among laboratories performing WET tests were all within a range consistent with the range of variability of chemical-specific methods that EPA has already promulgated in 40 C.F.R. part 136. 66 Fed. Reg. 49,804 (Table 2).

2. Low False Positive Rate

The Interlaboratory Study showed that, in practice, the WET test methods have a very low false positive rate. 66 Fed. Reg. 49,804. Eight of the ten WET test methods that EPA ratified produced zero false positives; the other two tests demonstrated low false positive rates (3.7% and 4.35%). There were only two false positive results reported in the 150 valid tests on blank samples – a false positive rate of only 1.3%. *Id.*

3. High Successful Completion Rates

The Interlaboratory Study revealed that most WET test methods could be consistently and reliably performed by qualified testing laboratories. 67 Fed. Reg. 49,804. For the purposes of the study, "successful" test completion rates referred to the percentage of initiated and properly terminated tests that met the test acceptability criteria specified in the WET method manuals. Interlaboratory Study at xxi, J.A. XX. Successful test completion rates were well above 90% for eight of

the ten methods evaluated during interlaboratory testing. 67 Fed. Reg. 69,955, Table 1.[15/]

In the 2002 WET Rule, EPA approved the ten WET test methods that met EPA's evaluation criteria, withdrew two that did not meet the criteria, and modified the methods to include updates, minor corrections and clarifications and specific technical changes responding to Petitioners' concerns. 67 Fed. Reg. 69,954. Petitioners now challenge EPA's approval of certain chronic test methods, the sufficiency of the record, and EPA's responses to comments during the rulemaking.

STANDARD OF REVIEW

This Court's review is governed by the APA, which establishes a deferential standard of review for agency action, such that agency action is valid unless, *inter alia*, it is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A). This standard "is a narrow one,"

[15/] The remaining two tests produced successful test completion rates of 82% for a freshwater chronic test using *Ceriodaphnia dubia*. This already high completion rate would have been higher were it not for a a subset of poor performing laboratories. 66 Fed. Reg. 49,806. The successful completion rate for the *Selenastrum* (green algae), Growth Test method was 63.6%. The relatively low successful completion rate and high false positive rate were due to laboratories' inexperience in running the test without EDTA, a nutrient additive. Accordingly, EPA withdrew the test method done without EDTA. In tests done with EDTA, the successful completion rate was 100%. 67 Fed. Reg. 69,957.

under which the Court is not "to substitute its judgment for that of the agency." *Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 416 (1971). A party seeking to have a court declare an agency action to be arbitrary and capricious carries "a heavy burden indeed." *Transmission Access Policy Study Group v. FERC*, 225 F.3d 667, 714 (D.C. Cir. 2000). If the "agency's reasons and policy choices . . . conform to 'certain minimal standards of rationality' . . . the rule is reasonable and must be upheld." *Small Refiner Lead Phase-Down Task Force v. EPA*, 705 F.2d 506, 521 (D.C. Cir. 1983) (citation omitted).

Particular deference is given to an agency with regard to scientific matters in its area of technical expertise. *E.g., Baltimore Gas & Elec. Co. v. NRDC*, 462 U.S. 87, 103 (1983); *City of Waukesha v. EPA,* 320 F.3d 228, 247 (D.C. Cir. 2003) (courts "will give an extreme degree of deference to [EPA] when it is evaluating scientific data within its technical expertise") (citation and quotes omitted); *New York v. Reilly*, 969 F.2d 1147, 1152 (D.C. Cir. 1992) (same). Where the agency decision turns on issues requiring the exercise of technical or scientific judgment, the court "'must look at [EPA's] decision not as the chemist, biologist, or statistician that [it is] qualified neither by training nor experience to be, but as a reviewing court exercising . . . certain minimal standards of rationality." *Chemical Mfrs. Ass'n v. EPA*, 870 F.2d 177, 199 (5th Cir. 1989) (citation omitted). "The

Administrator may apply his expertise to draw conclusions from suspected, but not completely substantiated, relationships between facts, from trends among facts, from theoretical projections from imperfect data, from probative preliminary data not yet certifiable as 'fact,' and the like." *Ethyl Corp v. EPA*, 541 F.2d 1, 28 (D.C. Cir. 1976).

Judicial deference to an agency's decision extends to an agency's interpretation of a statute it administers, particularly in a notice and comment rulemaking context. *United States v. Mead Corp.*, 533 U.S. 218, 226-31; *Chevron, U.S.A., Inc. v. NRDC*, 467 U.S. 837, 842-45 (1984). In reviewing an agency's construction of a statute, this Court must first decide "whether congress has directly spoken to the precise question at issue." *Chevron*, 467 U.S. at 842-43. If Congress has spoken and given clear direction, that is the end of the matter and the Court is to apply Congress' directive. *Id.* On the other hand, "if the statute is silent or ambiguous with respect to the specific issue, the question for the Court is whether the agency's answer is based on a permissible construction of the statute." *Id.* at 843. To the extent Petitioners challenge EPA's interpretation of its own regulations, the Court is to give "controlling weight" to EPA's construction "unless it is plainly erroneous or inconsistent with the regulation." *Thomas Jefferson Univ. v. Shalala*, 512 U.S. 504, 512 (1996).

SUMMARY OF THE ARGUMENT

Petitioners bear a heavy burden in their challenge to EPA's promulgation of the chronic WET test methods. Neither the CWA nor EPA's regulations prescribe substantive requirements regarding the development and approval of test procedures; thus, EPA applied its technical expertise and judgment to identify and evaluate relevant decision-making criteria. In such circumstances, EPA has considerable discretion, and its determinations are entitled to the highest degree of deference.

EPA consulted appropriate sources to identify the applicable criteria and made reasoned judgments in deciding that the WET test methods are reliable and adequate for use in NPDES permitting and reporting based on their availability and applicability, repeatability and reproducibility, and representativeness. EPA identified significant technical differences between biological (*e.g.*, WET) test methods and chemical test methods, and reasonably decided not to apply criteria that are inapplicable to biological testing.

Based on an enormous administrative record, data generated and compiled by EPA (including the massive Interlaboratory Study and dozens of field tests), and the public comments generated through two notice-and-comment rulemakings, EPA reasonably determined that it adequately addressed all applicable criteria.

EPA reasonably relied on record evidence showing that WET tests are highly precise, in that there is acceptably low variability between results obtained between and within laboratories; the tests can be performed successfully by a broad range of commercial laboratories; and the tests rarely provide a false indication of toxicity. EPA also incorporated safeguards to limit analytic sources of variability. Field validation studies addressing various water types and conditions nationwide demonstrate that WET test results showing toxicity reliably predict negative impacts on aquatic life (such as death or impaired growth or ability to reproduce) in the receiving stream. EPA adequately responded to every significant comment that Petitioners discuss in their brief and reasonably rejected flawed data and theories presented in public comments. Thus, EPA is entitled to deference.

The demonstrated reliability of WET testing – and EPA's further demonstration that WET testing is as reliable and is *less* variable than other methods approved for NDPES use – refutes Petitioners' claim that WET testing is inappropriate for use in NPDES permitting, monitoring and enforcement. There is no reason that NPDES permittees cannot attest to the accuracy of the WET information they submit in CWA-required reports; thus, Petitioners' due process argument is unfounded.

EPA's approval of standardized WET test procedures does not establish or

impose a *de facto* water quality standard but rather a means to measure attainment of limits based on those standards. Finally, Intervenor API's challenge to EPA's decision not to ratify certain test methods for use in the Pacific Ocean should be dismissed because Petitioners did not raise or adopt this issue. API lacks standing to raise the challenge because permitting agencies still can apply the tests about which API seeks remand. Therefore, neither API nor its members are harmed. Regardless, EPA reasonably determined not to ratify those methods in order to allow California to continue to use and develop promising test procedures.

For the foregoing reasons, the petitions should be denied and API's claims should be dismissed.

ARGUMENT

I. EPA REASONABLY EXERCISED ITS BROAD DISCRETION TO DEVELOP WET TEST PROCEDURES, IDENTIFIED THE RELEVANT CONSIDERATIONS, AND SUPPORTED ITS DECISIONS WITH RECORD EVIDENCE.

In the absence of direction from Congress or its own regulations, EPA applied its expertise in this area to identify relevant criteria by which to evaluate the WET test procedures and painstakingly considered the evidence in the massive administrative record – developed over the course of two notice-and-comment rulemakings dating back to 1989 – to determine whether those criteria were met. As we explain, EPA reasonably determined that the chronic WET test procedures

that Petitioners challenge satisfied all relevant criteria. Because EPA's actions reflect its careful consideration of the record it developed and a rational interpretation of its obligations under the CWA, they should be upheld.

A. The Clean Water Act, EPA's Regulations, the 1988 Report to Congress and the Settlement Agreement Contain No Substantive Requirements as to the Content of WET Test Methods.

Neither the CWA nor EPA's regulations establish requirements for the content of WET test methods. Section 304(h) of the CWA provides that EPA must "promulgate guidelines establishing test procedures for the analysis of pollutants." 33 U.S.C. § 1314(h). The statute is silent, however, on the content of such guidelines. Accordingly, EPA has broad discretion to develop and approve WET testing procedures, and this Court must defer to EPA's choice of procedures as long as that choice is not arbitrary or capricious. *Chevron*, 467 U.S. at 843-44. Recognizing the lack of guidance in Section 304(h), Petitioners argue that EPA failed to comply with its own regulations, Pet Br. at 5. However, the relevant regulatory provision, 40 C.F.R. § 136.1, specifies only *when* WET tests are to be used, not the *content* of WET test methods. Petitioners next cite to 40 C.F.R. § 136.2(f) and Appendix B as establishing requirements for the content of WET test methods, Pet Br. at 26 & 42, but these provisions set forth the procedure for determining a method detection limit ("MDL"), a procedure that was

developed specifically and explicitly for "physical" and "chemical" test methods. As we explain, *infra* at 46-49, the MDL procedure is simply inapplicable to biological test methods, like WET tests. Thus EPA's regulations specify no requirements governing the content of WET test methods.[16/]

Apparently aware that the statute and regulations provide no milepost against which to measure EPA's choice of WET testing methods, Petitioners next argue that EPA's validation of the chronic WET methods was inconsistent with the Settlement Agreement and the Report to Congress. Pet. Br. at 15. Petitioners' argument is simply incorrect, as neither imposes 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.

[16/] Petitioners wrongly interpret a guidance document on the formatting of test methods, *Guidelines and Format for Methods to be Proposed at 40 C.F.R. Part 136 or Part 141* (July 1996) ("Guidelines and Format Document"), as requiring *all* test methods to include a discussion of MDLs, method limitations, restrictions, interferences and calibration. Pet. Br. at 10, n.3. Petitioners, however, cite nothing in the non-binding guidance that suggests that *all* procedures must be applied blindly to *all* test methods, even where the circumstances indicate that those procedures are patently inapplicable. Petitioners' assertion that the Guidelines and Format Document "states that standardized Quality Control ("QC") tests are a '*mandatory component of all new methods,*'" *id.* (emphasis added), is wrong. The phrase that Petitioners purport to quote does not occur anywhere in the cited guidance. In any event, the WET test methods contain extensive QA/QC provisions. *E.g.*, Methods Manual at 7-10, J.A. XX-XX; 67 Fed. Reg. 69,964; RTC at 214-15, JA. XX-XX.

The only purpose of the Settlement Agreement was to avoid further litigation. Settlement Agreement, ¶ 20, J.A. XX. The Settlement Agreement is not judicially enforceable, does not bind EPA or in any way limit EPA's discretion to devise WET test methods. *Id.* ¶ 14, J.A. XX. Rather, EPA merely agreed to take certain additional steps, such as issuing guidance and performing a validation study, before deciding to ratify certain WET test methods. EPA completed each and every task. Even had EPA not performed the tasks in the Settlement Agreement, Petitioners' *sole* remedy under that Agreement was to revive their petition for review. *Id.* ¶¶ 11-12, J.A. XX.

Neither does EPA's 1988 Report to Congress legally bind EPA in promulgating WET test methods. EPA prepared the Report to Congress in response to a congressional directive to study the availability and adequacy of analytic test procedures and methods used under the CWA. Pub. L. No. 100-4, § 518(a), 101 Stat. 7, 86-87 (1987), ADD 204-05. Petitioners state that Congress directed EPA to establish "criteria" for validating test methods. Pet. Br. at 9. However, Congress mandated no such thing. Rather, Congress merely directed EPA to study test procedures for analysis of pollutants under CWA Section 304(h), analyze the adequacy and standardization of such procedures, and submit a report to Congress. *Id.* § 518(a). In so doing, EPA identified and

discussed certain performance characteristics for both chemical-specific and biological test procedures. However, that background discussion did not establish, or even purport to establish, binding legal requirements. The Report to Congress merely documents EPA's review at the time – over 15 years ago – of the availability, adequacy and comparability of those testing methods used for compliance with various CWA provisions.

Thus, neither the CWA nor EPA's regulations establish any requirements governing the content of WET test methods or the manner of their development. Where the statute is silent and where the issue is within the agency's expertise, great deference is given to the agency. *Baltimore Gas & Elec. Co.*, 462 U.S. at 103. In such a case, the Court must grant EPA considerable deference and consider only whether EPA's decision comports with certain minimal standards of rationality. *Ethyl Corp.*, 541 F.2d at 36-37.

B. EPA Reasonably Chose the Criteria It Would Apply in Evaluating and Revising WET Test Methods.

Absent a specific statutory or regulatory directive, EPA applied its technical expertise to identify and assess the criteria applicable to its development and approval of the chronic WET test methods. Although EPA considered numerous factors and a variety of sources, the relevant performance aspects of WET testing that EPA evaluated fall into three broad categories: (1) repeatability and

reproducibility; (2) availability and applicability; and (3) representativeness. 67 Fed. Reg. 69,955. EPA reasonably declined to apply certain criteria that do not apply to biological test procedures.

1. EPA Identified the Appropriate Performance Characteristics.

In identifying the criteria to evaluate WET testing methods, EPA considered the regulatory uses of WET testing (*i.e.*, NPDES permitting and reporting and to determine the need for and a permittee's compliance with WET permit requirements) and then balanced the need for reliable test methods with practical considerations regarding the feasibility of using such methods. *See* Report to Congress at 4-1, J.A. XX (Section 304(h) methods should "provide standardized methods that are near to state-of-the-art as possible that are also practical for routine use"). Because a large number of facilities with differing effluent composition may be required to test for whole effluent toxicity, EPA determined that the test methods should be capable of being repeated in a wide variety of locations and the results reproduced without excessive variability. 67 Fed. Reg. 69,955. EPA also determined that the test methods should be adaptable to a large number of laboratories, and that they should use widely available equipment and test organisms to ensure a sufficient national capacity for laboratories conducting WET testing. *Id.* EPA further decided that the approved WET test procedures

should generate results that represent the toxic effects in receiving water. *Id.*

With these objectives in mind, EPA consulted multiple sources in developing and refining the current approved WET testing protocols, including public comments, peer review comments, the results of the Interlaboratory Study, relevant guidance from independent technical organizations, as well as pertinent EPA guidance materials, including EPA's Report to Congress. *See* 67 Fed. Reg. 69,954-55, 69,971 (citing references); 66 Fed. Reg. 49,813-14 (same). From the Report to Congress, EPA evaluated the WET test methods against several performance characteristics applicable to test methods generally but also considered that "[i]n most cases, no single method will contain all of the desirable characteristics. The selection of a method is therefore based on evaluating which characteristics are important for a given need." Report to Congress at 3-2, J.A. XX.

Importantly, the Report to Congress carefully distinguished between test performance characteristics applicable to many chemical-specific testing procedures and those applicable to biological (*e.g.*, WET) testing. *Id*. at 3-11, J.A. XX. The Report to Congress emphasizes the relevance to biological testing of the following performance characteristics: applicability (*i.e.*, the test method can be applied to wide variety of aquatic organisms); availability (*i.e.*, that numerous laboratories will be capable of obtaining reproducible results); and precision (*i.e.*,

that the variability of test results will be acceptably low both within the same laboratory and between laboratories).[17/] Report to Congress at 3-11 to 3-12, J.A. XX-XX. In the 2002 WET Rule, EPA stated that it determined these factors to be relevant and considered them. 67 Fed. Reg. 69,955, 69,964-65. Subsections C and D, *infra*, explain how EPA evaluated the WET test procedures in light of these performance characteristics. Finally, EPA evaluated the "representativeness" of WET tests, which refers to the field validation of the WET test procedures to ensure that WET test results correlate with adverse impacts observed in receiving water. 67 Fed. Reg. 69,964-65. Subsection E describes EPA's determination that this characteristic was satisfied.

[17/] Precision is the conceptual equivalent to repeatability and reproducibility, which EPA indicated includes both intra- and interlaboratory precision. 67 Fed. Reg. 69,955.

2. EPA Reasonably Declined to Apply Performance Characteristics that Are Inapplicable to Biological Testing.

The Report to Congress identified two instrument-related performance characteristics that apply to chemical testing procedures but that *cannot be applied* to biological testing methods: detection limits and dynamic range. Report to Congress at 3-11, J.A. XX; 67 Fed. Reg. 69,964-65; RTC at 224-25, 292-93, J.A. XX-XX, XX-XX. The related characteristic, calibration, likewise is inapplicable to biological testing. Report to Congress at 3-11, J.A. XX; RTC at 216, J.A. XX. In part for these reasons, EPA concluded that certain aspects of another performance characteristic, "accuracy," are inapplicable to WET testing. 67 Fed. Reg. 69,965; RTC at 219-20, J.A. XX. These characteristics identified in the Report to Congress are the only ones Petitioners claim EPA failed to consider. Pet. Br. at 21, 24-25. However, not only did EPA actually consider these characteristics, EPA reasonably concluded that they were inapplicable to WET testing and that such inapplicability did not preclude the use of WET testing for NPDES regulatory purposes.

a. The Performance Characteristic "Accuracy" Does Not Apply to Whole Effluent Toxicity.

Petitioners contort EPA's usage of a highly technical term that describes a test performance characteristic – "accuracy" – to argue that EPA admits that WET

tests are not "accurate" within the common meaning of that term. Pet. Br. at 4, 21. Such word play misses the mark.[18] "Accuracy," in the context of evaluating the performance of a measurement system, is a measure of the true closeness of an individual measurement to the true value of the things measured. Report to Congress at 3-3, J.A. XX; 67 Fed. Reg. 69,965.[19] The Report to Congress explains that accuracy consists of two components: precision and bias. *Id*. There is no dispute that EPA thoroughly evaluated the precision of WET tests, which is discussed *infra.*

It is the bias component of accuracy that cannot be addressed by biological testing, at least not in the same way that accuracy can be evaluated for many chemical testing procedures. "Bias" represents the deviation of a test result from

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[18] Petitioners vaguely argue, without citation, that EPA did not assess WET test bias. Pet. Br. at 34. Bias arises in numerous contexts, yet Petitioners fail to specify their particular concern about bias. In any event, EPA explained at length how it addressed bias in a variety contexts. *See, e.g.,* 67 Fed. Reg. 69,964; RTC at 19-25, 156-63, 216-20, J.A. XX-XX, XX-XX, XX-XX.

[19] Petitioners repeatedly claim that chronic test variability ranges from 200-300%. Pet. Br. at 25, n.11, 30, 32 (citing Variability Guidance at 3-6 and 65 Fed. Reg. 44,528 (July 18, 2000)). The cited documents do not support Petitioners' claim, nor does any record evidence. The range of variability between laboratories, expressed by the coefficient of variation metric specified in the Settlement Agreement (Ex. B, ¶ 2, J.A. XX) is 10.5-43.8%, well within the accepted range of variability for NPDES permitting and reporting purposes. *See* 67 Fed. Reg. 69,955.

the "accepted true value." 67 Fed. Reg. 69,965 (citing the American Society for Testing and Materials definition). Unlike many chemical testing procedures that can confirm the measured concentration of a chemical analyte by comparing the result to the measurement of a "spiked" sample with a known concentration, toxicity cannot be purified, weighed or diluted to a known concentration. *Id.* Rather, because toxicity is defined and measured by its effect on living organisms, whole effluent toxicity is considered a method-defined analyte (*i.e.*, it cannot be measured independently from a toxicity test). Thus, WET test results cannot be independently confirmed by comparing the results to a known concentration of toxicity. RTC at 219-20, J.A. XX; 67 Fed. Reg. 69,965.[20/]

In this very technical and narrow sense, "bias" and, consequently, the performance characteristic "accuracy" simply do not apply to evaluate the performance of biological testing. Further confirmation of this is the fact that the Report to Congress *does not* identify accuracy as a performance characteristic that is applicable to biological testing. Accordingly, EPA reasonably determined that

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[20/] Other method-defined analytes are regulated and monitored under the NPDES program, including biochemical oxygen demand and characteristics like acidity and turbidity. 40 C.F.R. pt. 136. Regulated entities must comply with limitations based on method-defined analytes in other contexts. *See Clean Air Implementation Project v. EPA*, 150 F.3d 1200, 1203 (D.C. Cir. 1998) (upholding EPA rules regarding the monitoring of air emission opacity – a method-defined analyte).

the performance characteristic "accuracy" is not applicable to WET testing.[21/]

b. Method Detection Limit, Dynamic Range, and Calibration Do Not Apply to Biological Testing, and EPA's WET Test Procedures Include Comparable and Adequate Safeguards.

Petitioners assert that EPA must establish detection limits for WET test methods and that EPA arbitrarily failed to do so. Pet. Br. at 26. They make the related arguments that EPA failed to address the dynamic range[22/] of WET tests and to provide a means to calibrate[23/] WET test organisms. Pet. Br. at 20, 39. These arguments all fail for the simple reason that these characteristics apply only to test methods that make a single measurement through the use of an adjustable analytical instrument. *See* 67 Fed. Reg. 69,968. As the Report to Congress summarized: "These characteristics [detection limit and dynamic range], which

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[21/] To some extent, EPA's consideration of "representativeness," discussed *infra*, addresses some aspects of the otherwise inapplicable performance characteristic of accuracy in that EPA correlated measured WET test results with toxic effects manifested in receiving waters.

[22/] Because its lower limit is defined by a MDL, the dynamic range characteristic (which concerns the range of analyte concentration that can be detected by the "instrument detector") does not apply to WET testing. Report to Congress at 3-4, J.A. XX; RTC at 216, 219 & 224, J.A. XX, XX & XX. In any event, Petitioners make no separate argument related to dynamic range.

[23/] Calibration is the process of determining, by measurement or by comparison with a standard, the correct value of each scale reading on a meter or the correct value of each setting on a control knob. McGraw-Hill Concise Encyclopedia of Science & Technology 316-17 (4th ed. 1998).

measure the capacity, ability or efficiency of the analytical instrument being used to make the chemical measurement, are not usually an appropriate concept for all biological measurements unless instrumentation is required." *Id.* at 3-11. WET testing does not involve the use of such instrumentation. 67 Fed. Reg. 69,968. Moreover, as discussed *supra* at 36-37, EPA's regulations do not require the establishment of MDLs for WET test methods.[24/] Accordingly, establishing a MDL for WET testing would be inappropriate.[25/]

Even though MDLs do not apply to WET testing, EPA incorporated measures in the WET test methods to reduce test variability and address Petitioners' concern that small changes in survival, growth or reproduction could

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[24/] Petitioners incorrectly claim that EPA guidance documents require a detection limit as part of the Data Quality Objectives ("DQO") process. Pet. Br. at 26. EPA's DQO guidance does not require or suggest that detection limits must be incorporated into test methods if they are not relevant. Guidance for the Data Quality Objectives Process (Aug. 2000). The document discusses choices of test methods with reference to their capacity to measure analytes at a desired action level (*e.g.*, a method's detection capacity), rather than requiring any specific test method characteristic. *Id*.

[25/] By way of background, we note that MDLs apply only to data that are continuous, *i.e.*, data that can be graphed over a line or curve and reported along a continuum that includes whole numbers and an infinite number of decimal-based values in between them. International Organization for Standardization, ISO-11843-1, "Capability of Detection - Part 1: Terms and Definitions" at 1-2 (1997), ADD 208-09. WET test method data, on the other hand, are discrete, *i.e.*, reported in whole numbers. For instance, a laboratory cannot report that 1.5 organisms died.

be mistaken for toxicity. *See* Pet. Br. at 27. For WET tests of sublethal (*i.e.*, chronic) endpoints expressed using hypothesis testing, EPA now requires testing laboratories to evaluate WET test results according to the percent minimum significant difference ("PMSD"). Though the details of the procedure are not pertinent here, these more stringent variability criteria mean that overly-sensitive tests are to be repeated on a newly collected sample, Variability Guidance at 13, J.A. XX;[26/] RTC at 112, J.A. XX, in part to avoid detecting small differences as toxic in very precise tests. 67 Fed. Reg. 69,957; RTC at 125-26, J.A. XX-XX.

Nor can WET tests be calibrated. *See* Report to Congress at 3-11 ("The health of test organisms and biological systems cannot be 'calibrated' before the experiment in the way as analytical instrumentation. . . .There are no knobs to turn to adjust for [] factors to achieve consistent performance during a test method."); RTC at 216, J.A. XX. *In lieu* of organism "calibration," to demonstrate acceptable laboratory performance and to ensure data integrity, laboratories must perform reference toxicant testing *before* they perform any toxicity tests to be used for NPDES permits. Methods Manual at 15-17, J.A. XX-XX; 67 Fed. Reg. 69,959-60. Then, at least once per month, laboratories conducting WET tests must conduct a

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[26/] The PMSD procedure is recommended to permitting agencies in the Variability Guidance and may be incorporated as a mandatory permit requirement.

reference toxicant test for each type of WET test method to be performed that month to ensure that the test organisms respond as anticipated to a known toxic substance.[27/] Methods Manual at 15-17, J.A. XX-XX. If reference toxicant test results fall well outside the expected range of results more than one in 20 times, the laboratory must investigate the source of variability, take corrective actions and perform additional reference toxicant tests. *Id*. Reference toxicant testing is an important safeguard to evaluate the sensitivity and consistency of the test organisms and to document ongoing laboratory performance. 67 Fed. Reg. 59,959; RTC at 144, J.A. XX.

C. EPA Reasonably Determined that Chronic WET Test Methods Are Repeatable and Reproducible.

EPA found that the WET test methods are repeatable and reproducible (*i.e.*, that they exhibit adequate intra- and interlaboratory precision).[28/] EPA based this

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[27/] Petitioners argue that laboratories should be required to run a reference toxicant test each and every time they perform a WET test. Pet. Br. at 36. EPA received several adverse comments about requiring reference toxicity testing on a more frequent basis, particularly regarding increased costs on permittees (and the concomitant negative impact on the availability of the WET test methods). RTC at 145, 147, J.A. XX, XX. EPA reasonably determined that monthly reference toxicity testing adequately balances the need to ensure data integrity with cost.

[28/] Petitioners incorrectly state that EPA claims that precision alone proves test reliability. Pet. Br. at 34. Rather, EPA examined several criteria, including precision, successful test completion and false positive rate.

finding on the Interlaboratory Study, which demonstrated that all of the challenged WET test methods have high levels of precision consistent with those of chemical testing methods. Precision was determined by calculating coefficients of variation ("CV"), 66 Fed. Reg. 49,805 (Table 3), which are the best available means of evaluating WET test variability, Variability Guidance Document at 3-2, J.A. at XX, and the *only* means of determining precision identified in the Settlement Agreement. Settlement Agreement, ¶ 3, J.A. XX;[29/] *see also* EPA's Report to Congress at 3-11 to 3-12, J.A. at XX-XX (CVs a means of determining precision). Therefore, EPA's use of CVs to measure precision was reasonable.

EPA found that the CVs for the WET test methods are comparable to, and in some cases are better than, those associated with chemical testing methods approved for NPDES purposes. Memorandum from Marion Kelly, EPA Engineering and Analysis Division (October 16, 2002) ("Comparison Memo"), J.A. XX. For each WET test method, the Interlaboratory Study reported three CV values, one for each type of test sample: effluent, reference toxicant, and receiving

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[29/] Despite their concurrence in the Settlement Agreement to use CVs to evaluate the precision of WET test methods, Petitioners now object to the use of CVs because they purportedly do "not provide substantial evidence of accuracy." Pet. Br. at 34. This Court should not permit Petitioners to attack the validity of the very measure that they specified in the Settlement Agreement. More importantly, EPA does not rely on CVs as evidence of accuracy.

water. The CVs among laboratories doing WET tests ranged from 10.5% to 43.8%, with a median of 31.6%. Comparison Memo at 1, J.A. XX. The observed interlaboratory CV range for WET tests (10.5 to 43.9%) is well within the range of interlaboratory variability of all of the chemical methods that EPA has already approved, including, for instance, metals (3 to 64%) and organics (12 to 104%).[30/]

Petitioners argue that EPA's comparison is inapt. Pet. Br. at 37. First, they argue that EPA used "old chemical-specific data not relevant to the NPDES program today" because EPA has not changed the chemical-specific CVs since 1990 and the CVs for five bacteria-specific test methods since 1986. *Id*. However, every chemical test method that EPA used for comparison is an approved test method that still can be used in NPDES permits. 40 C.F.R. § 136.1. Therefore, EPA reasonably compared the WET test methods to EPA's other 260-plus *currently-approved* test methods. To adopt Petitioners' argument, EPA would have had to conduct interlaboratory variability studies and recalculate CVs *for more than 260 test methods*, a highly burdensome, costly and lengthy undertaking that EPA reasonably chose not to do. Second, Petitioners complain that the more

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[30/] Petitioners' repeated use of a peer reviewer's statement, that "[t]his level of variability is incredible to say the least," Pet. Br. at 24 & 31, is misleading. This reviewer was referring only to the results of referee laboratory testing of the *Champia parvula* chronic method. RTC at 326, J.A. XX, which EPA withdrew in the 2002 WET Rule. 67 Fed. Reg. 69,955.

modern of the current 260-plus chemical testing methods exhibit less variability than the older methods, and that EPA, therefore, should have restricted its comparison to the newer methods. Pet. Br. at 37. Again, this argument should be rejected: all of the test methods used for comparison are approved for use in NPDES permitting, and EPA reasonably considered them in determining that the WET methods exhibited acceptable levels of variability. Third, Petitioners object to EPA's use of multiple methods for a common analyte, *e.g.*, copper, for which EPA has approved three different test methods. *Id*. Petitioners claim EPA should have compared the best of the chemical methods to the best of the WET methods. Permitting authorities, however, have the discretion to incorporate the use of *any* of EPA's approved test methods into NPDES permits; they are not restricted to a subset of them or only the "newest" or "best." EPA's decision to calculate the CV based on multiple methods for a common analyte was reasonable, as it simply reflects the full range of NPDES test methods.

EPA reasonably concluded that WET test methods are repeatable and reproducible, and its conclusion must be upheld.

D. EPA Reasonably Determined that Chronic WET Test Methods Are Available and Applicable.

1. The WET Test Methods Are Available.

The Interlaboratory Study confirmed that the WET test methods are available because of the high number of laboratories that successfully completed WET tests. 67 Fed. Reg. 69,964. For each test method, the Interlaboratory Study determined the percentage of laboratories able to successfully complete the test. The threshold for successful completion was rigorous: the testing laboratory had to meet *all* of the requirements in the WET test method and the test acceptability criteria. Interlaboratory Study at 65, J.A. XX. The Methods Manual alone contains 68 pages of detailed instructions, plus four sections, ranging in length from 24 to 58 pages each, with instructions specific to the particular test methods, such as, *inter alia*, the proper cleaning of test chambers and laboratory equipment; feeding, holding and handling of test organisms; transportation of organisms to the test site; the temperature at which organisms must be kept throughout the test; and instructions for preparing synthetic dilution water. *Id*. Moreover, each test method contains stringent test acceptability criteria that must be met; if they are not, the test results must be invalidated and redone on a newly collected sample. Methods Manual at 49, J.A. XX. Test acceptability criteria ensure that variables such as pathogen contamination or poorly controlled laboratory conditions do not affect

the outcome of the test. That successful completion rates for *all* chronic test methods were well over 90% for the 56 participating laboratories, 67 Fed. Reg. 69,955, demonstrates that WET tests are widely available to the regulated community.

Petitioners argue that EPA misrepresented the rate of successful test completion because EPA considered tests that failed to meet the test requirements as "successfully completed." Pet Br. at 46. However, laboratories that participated in the Interlaboratory Study were required to comply with all mandatory WET test protocols and meet test acceptability criteria. RTC at 232, J.A. at XX. Petitioners' argument confuses mandatory test protocols with recommended, non-mandatory provisions. In the Interlaboratory Study, EPA required laboratories to "flag" data that resulted from deviations from test conditions, sample holding times, sample temperatures, test acceptability criteria, or test water quality. Interlaboratory Study at 59-62, J.A. at XX-XX. Tests that were flagged for failure to meet mandatory protocols, *e.g.*, test acceptability criteria, were invalidated. *Id*. at 59, J.A. at XX. Test results flagged only for not meeting a recommended condition were considered valid. *Id*. EPA made a reasoned judgment to consider these tests valid; not adhering to a recommendation does not constitute a deviation from a test method. Laboratories require some flexibility – as they do when testing for

regulatory purposes – in their application of recommendations and guidance. Furthermore, the peer reviewers agreed with EPA's decision. Peer Review Report, J.A. XX-XX. Because EPA reasonably chose to allow laboratories some flexibility in conducting WET tests EPA's conclusion that WET methods are "available" was reasonable and must be upheld.

2. The WET Test Methods Are Applicable To a Wide Range of Testing Environments.

The WET test methods are statistically designed to be adaptable to various test conditions. RTC at 156, J.A. at XX. The Interlaboratory Study validated the adaptability of WET test methods by demonstrating that they produce an extremely low false positive rate when applied. *Supra* at 29.[31/] With an average false positive rate of only 1.3%, WET test methods are applicable to a wide range of testing environments. 67 Fed. Reg. 69,963.

While the test methods are designed so that the chance of obtaining a false positive result does not exceed 5%, EPA's Method Guidance describes how, in certain circumstances, facilities can reduce the error rate to 1%, by adjusting the statistical design of certain test methods. Method Guidance at 2-1 to 2-13. J.A. at XX-XX. In the Settlement Agreement, EPA agreed to issue guidance and

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[31/] Petitioners aver, without any support whatsoever, that there exists abundant evidence that the false positive rate of WET tests actually is higher. Pet. Br. at 28.

recommendations in the chronic toxicity test methods manuals to clarify that a false positive error rate of either 5% or 1% is acceptable and to identify those circumstances under which a false positive error rate of 1% is acceptable. Settlement Agreement, ¶ 7(a).[32/] In the proposed WET test rule, EPA proposed to lower the false positive error rate in specific circumstances. 66 Fed. Reg. 49,800-01. In their comments to EPA, Petitioners commented that there was no scientific justification for reducing the false positive error rate in only these circumstances and recommended reducing it in all circumstances, but they did not submit any supporting rationale or data. RTC at 71, J.A. XX. EPA agreed that there is no scientific justification to reduce the rate only in certain circumstances, but declined to reduce it in the statistical design of WET test methods in all circumstances. 67 Fed. Reg. 69,956. EPA, instead, retained the 5% false positive error rate but agreed to allow reduction of the error rate in the statistical design of WET tests, in certain circumstances. In light of the fact that WET test methods produce false

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[32/] Petitioners erroneously claim that in the Settlement Agreement EPA "agreed to propose reducing [false positive rate] to 1%, consistent with the 1% definition of MDL." Pet. Br. at 44. The relevant, uncited Settlement Agreement provision, ¶ 7(A), provides nothing of the sort. It discusses only revisions to "guidance and recommendations . . . to clarify that a nominal error rate [false positive rate] of 0.05 or 0.01 is acceptable and identify those circumstances and conditions under which the *recommended* nominal error rate would be 0.01." *Id.* (emphasis added). The paragraph makes no reference to the MDL procedure.

positives at a rate far lower than 5% when applied – indeed, most produce *zero* false positives – and in the absence of any support from Petitioners to the contrary, EPA's decision to keep the 5% error rate in the statistical design of the test methods and allow reduction to 1% in certain circumstances, consistent with the Method Guidance, was reasonable and should be upheld.

Petitioners argue that EPA's consideration of the false negative rates was arbitrary and capricious. Pet. Br. at 42. EPA explained, however, that the statistical procedure that establishes the false positive rate is inversely related to the statistical procedure that establishes the false negative error rate. RTC at 71, J.A. XX. If other study design factors are held constant, lowering one increases the other. The chronic WET test methods are statistically designed to have a false negative rate as high as 20%.[33/] This keeps the false positive rate low. Contrary to Petitioners' suggestion, Pet. Br. at XX, reducing the false positive error rate does not improve confidence in test results because, for instance, a reduced false positive rate lowers the power of the test to detect toxicity (*i.e.,* rendering more questionable test results of "no toxicity"). RTC at 71, J.A. XX. There also are

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[33/] Petitioners' statement that EPA set the false positive rate at 5% to *avoid* false negatives, Pet. Br. at 43-44, is uninformed. To design a test that virtually avoids false negatives, EPA would have to set the false positive rate at an unreasonably high level.

direct and indirect costs associated with both false positives and false negatives. Method Guidance at 2-2, J.A. at XX. False positives can create undue cost and effort in follow-up actions as well as, possibly, increased enforcement exposure; false negatives can cause the continuation of unchecked environmental degradation and increase the long term costs of reclamation and restoration. *Id*. Moreover, false negatives may be more costly than false positives in the end, because false positives can be discovered more quickly by additional testing, while false negatives may continue longer before being discovered. *Id*. EPA struck a well-reasoned balance between two competing public policy interests when it chose to allow a low rate of false positives and a higher rate of false negatives. Accordingly, its decision should be upheld.

E. EPA Reasonably Concluded That Chronic WET Test Methods Are Representative.

EPA relied on abundant record evidence to reasonably conclude that the chronic WET tests are "representative," *i.e.*, they accurately predict that an effluent showing toxicity will correspond to an observed negative impact on the aquatic life in the receiving waters. In disputing this, Petitioners significantly underrepresent and mischaracterize the data EPA considered on this issue and raise a number of technical issues, none of which provides a basis to second guess EPA's conclusion that WET tests accurately predict instream impacts.

1. The Chronic WET Tests Are Reliable Over a Broad Range of Conditions, Waterbodies, and Geographic Regions.

EPA relied on a host of scientific studies that applied WET testing methodology and demonstrated, time and again, that WET tests accurately predict instream impacts. Those studies have been conducted over a number of years at various locations across the country and with a wide variety of ambient water types, effluents, and chemicals. Before addressing Petitioners' specific claims, we briefly describe some of the more significant data sources in the record upon which EPA relied:

The Complex Effluent Toxicity Testing Program ("CETTP") and Related Studies: This series of studies consisted of eight separate studies spread over 80 sites in eight separate watersheds[34/] and three additional studies at multiple sites in Kentucky, North Carolina and Texas. These eleven studies focused on the chronic effects of toxicity on *Ceriodaphnia* and fathead minnows (survival, growth and/or reproduction) and demonstrated 80% of the time that WET test results correlated with ecological/biological impairment of the receiving system.[35/]

[34/] The eight watersheds were located in West Virginia, Maryland, Connecticut, Oklahoma, Alabama and Ohio. *See generally* TSD at 7-11, J.A. XX-XX; RTC at 299-309, J.A. XX-XX (both summarizing studies).

[35/] *See* TSD at 7, J.A. XX ("these studies comprise a large database specifically collected to determine the validity of toxicity tests to predict receiving water

The Society of Environmental Toxicology ("SETAC") 1995 Pellston Workshop Report: SETAC is an independent, nonprofit professional society whose membership draws equally from academia, business, and government. *See* www.setac.org/govern/html. In 1995, SETAC convened a technical forum among leading experts in the field to address scientific issues related to whole effluent toxicity including, *inter alia*, identification of issues that required no additional research or discussion. *Whole Effluent Toxicity Testing: An Evaluation of Methods and Prediction of Receiving Stream Impacts*, Grothe, et al. eds. (1996) at 2 (hereinafter "SETAC Report"), J.A. XX. The experts' "major workshop conclusions" included, among others: "existing WET testing methods are technically sound," "WET testing is an effective tool for predicting impact" in receiving streams, and "[a]dditional laboratory-to-field validation efforts [of the correlation of instream impacts] for these types of ecosystems are not essential for the continued use of WET testing as a component of the NPDES permits program." *Id.* at 337-38, J.A. XX-XX.

EPA's 1999 Review of Single Species Toxicity Tests: In 1999, EPA evaluated the results of 77 studies that addressed the correlation between toxicity

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community impact. . . . The results, when linked together, clearly show that if toxicity is present, after considering dilution, impact will also be present").

data and aquatic ecosystem community responses and re-confirmed that WET tests are predictive of instream impacts. *See* DeVlaming and Norbert-King, *A Review of Single Species Toxicity Tests: Are the Tests Reliable Predictors of Aquatic Ecosystem Community Responses?* (1999) (hereinafter "1999 EPA Report"), J.A. XX; RTC 299-300, J.A. XX-XX.[36/] The report, which re-evaluated the CETTP and related studies, concluded that WET tests are "reliable qualitative . . . predictors of aquatic ecosystem community effects." *Id.* at 26. In 74% of the studies evaluated, the WET test results accurately predicted instream impacts. The WET tests *underestimated* instream effects in another 21% of the studies, and results from only 5% of the studies were inconclusive or mixed. *Id.*

Petitioners mistakenly claim that EPA "relies entirely on eight [CETTP]

[36/] Rather than address the 1999 EPA Report, Petitioners merely note that the document was added to the record after the public comment period. Pet. Br. at 54. This document is properly part of the record because it was cited in response to Petitioners' comments, "EPA's methodology remained constant, and because the added data was used to check or confirm prior assessments." *Solite Corp. v. EPA*, 952 F.2d 473, 485 (D.C. Cir. 1991). EPA's conclusion on the issue of correlation of instream impacts was well-known based on other studies in the record, EPA had proposed the position it was to take, and "the conclusion the EPA reached was one petitioners both had and took the opportunity to criticize"; therefore, EPA properly amassed additional evidence to support its proposed conclusion. *International Fabricare v. EPA*, 972 F.2d 384, 399 (D.C. Cir. 1992). *See also Rybachek v. EPA*, 904 F.2d 1276, 1286 (9th Cir. 1990) ("Nothing prohibits [EPA] from adding supporting documentation for a final rule in response to public comments . . . [otherwise the] comment period would continue in a never-ending circle").

studies" for its conclusion that WET tests for *Ceriodaphnia* and fathead minnows are predictive of instream impacts. Pet. Br. at 54. EPA also relied upon three CETTP-related studies, the SETAC Report and the 1999 EPA Report, *all* of which demonstrate a correlation between instream impacts and chronic WET test results for *Ceriodaphnia* and fathead minnows. RTC at 299-300, J.A. XX; TSD at 7-11. The mere existence of the 1999 EPA Report refutes Petitioners' claim that EPA conducted no new studies after 1995. Pet. Br. at 54. Petitioners' claim that the studies addressed no waters west of Enid, Oklahoma is also wrong. To cite just a few examples, the 1999 EPA Report discusses successful chronic WET tests at multiple sites on the Clark Fork River in Montana, the Colorado River, and streams in Wyoming. 1999 EPA Report at 47-50, J.A. XX-XX.

Just as easily refuted is Petitioners' claim that "no study" shows a correlation between WET test results and impacts for marine species and algae. Pet. Br. at 53. Again, the record includes several such studies, including a 1989 study by Schimmel, *et al*., which documented the correlation between aquatic ecosystem impacts and three chronic marine WET test methods. RTC at 302, J.A. XX; *see also* J.A. XX (August 28, 1989, EPA memorandum summarizing the results). The TSD, at 9 (Box 1-4), references the Schimmel study and three additional studies that address the correlation between WET marine tests and

impacts in marine and estuarine ecosystems. J.A. XX. Two more studies discussed in the 1999 EPA Report, at 42-43 and 45-46, J.A. XX-XX and XX-XX, demonstrated a correlation between WET tests for mysid shrimp and sheepshead minnows and instream impacts. That report also includes discussion of at least one study addressing the correlation between green algae WET tests and aquatic ecosystem impacts. 1999 EPA Report at 43-44, J.A. XX-XX. Thus, Petitioners have understated or ignored altogether the data that support EPA's ratification of the chronic WET test methods.

2. None of Petitioners' Technical Issues Has Merit.

Petitioners raise four technical issues that, they say, call into question EPA's determination that instream impacts are correlated to chronic WET test results for *Ceriodaphnia* and fathead minnows. Pet. Br. at 55-60. However, none of Petitioners' claims effectively contradicts EPA's conclusion.

a. EPA Reasonably Applied the Correlation Studies Results to the Full Range of Water Types.

Petitioners argue that the CETTP studies are based on circumstances where a higher magnitude of toxicity was present in the ambient water. Pet. Br. at 56. Petitioners offer no evidence that WET tests are incapable of predicting instream impacts in waterbodies with lower levels of toxicity.[37/] Nevertheless, EPA effectively responded to this criticism and reasonably relied on record evidence to conclude that WET tests will correlate with instream impacts regardless of waterbody type. TSD at 7-8, J.A. XX-XX. The CETTP studies, the 1999 EPA Report, and the SETAC Report present overwhelming evidence of a correlation between WET tests and instream impacts over a geographically diverse range of waterbodies and under a range of conditions.[38/] In light of EPA's limited resources

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[37/] Rather, the study cited by Petitioners shows merely that WET tests are *more predictive* in streams with a higher magnitude of toxicity, a result consistent with the concentration-response relationship. Pet. Br. at 57.

[38/] Petitioners incorrectly aver that EPA acknowledged a lack of studies in low-flow, intermittent, or effluent-dominated streams, *see* Pet. Br. at 7, 58, and refer to a page of the 2002 WET Rule preamble that contains no such acknowledgment. Pet. Br. at 7. The record contains two studies of the Trinity River in Texas (Dickson, *et al.* 1989 and 1996), which used fathead minnows to confirm the relationship between toxicity and instream impacts. The Trinity River is an intermittent waterway, characterized by low-flow which during those periods consists of 96% effluent from POTWs. This waterway contains many of the same characteristics of the Western waters discussed *infra*. Sampling for the 1996 study was performed during low-flow periods, and that study concluded: "The results of

and the obvious impossibility of testing all WET methods in all types of waterbodies nationwide under all conditions, EPA reasonably concentrated its research funds on waterbodies where at least some impacts from toxicity were anticipated. RTC at 306, J.A. XX. *See American Iron & Steel Inst. v. EPA*, 115 F.3d 979, 1004-06 (D.C. Cir. 1997) (EPA not required to expend resources to conduct "perfect study," and sampling method permissible unless it bears "*no* rational relationship to the reality it purports to represent") (emphasis in original).

Generally speaking, greater toxicity will result in a greater response in an organism due to the concentration-response relationship; therefore, it is predictable that this phenomenon was observed in the waterbodies in the CETTP studies, which had a higher degree of toxicity. 1999 EPA Report at 15, J.A. XX. Absent evidence to the contrary, however, there is no reason that toxic effluents would not similarly impact organisms in less toxic receiving waters. TSD at 7, 9, J.A. XX,

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this case study add to the growing weight-of-evidence to document a relationship between effluent toxicity (even chronic toxicity) and receiving stream impacts for effluent-dominated streams." SETAC Report at 305, J.A. XX. *See also* EPA Report at 36-37 (summarizing 1996 study), J.A. XX-XX; TSD at 8 (summarizing 1989 study), J.A. XX. Additionally, the TSD discusses two more studies that examined ambient toxicity in conditions of both high and low flow. TSD at 9, J.A. XX. Thus, Petitioners' criticisms are misplaced, as is their reliance on an extra-record EPA response to an unrelated Freedom of Information Act request. Pet. Br. at 59, n.50. The Court should disregard this document in the face of clearly contradictory *record* evidence.

XX. Thus, EPA reasonably concurred with the SETAC Report's conclusions that "WET testing is an effective tool for predicting receiving system impacts" and that "[f]urther laboratory-to-field validation is not essential for the continued use of WET testing." SETAC Report at 281, J.A. XX.

b. The WET Test Procedures Adequately Accommodate Site-Specific Considerations.

Petitioners claim that the chronic WET test methods do not adequately address differences in characteristics (such as degree of flow, hardness, alkalinity and ionic balance) between waters in Western states (hereinafter "Western waters") and perennial streams in the East, where some WET correlation studies were conducted. Pet. Br. at 58-60. Petitioners' concerns arise at the point where a State is developing a water quality standard for WET or a permitting authority is crafting individual permit requirements for whole effluent toxicity. In both circumstances, the characteristics of the affected waterway must be taken into consideration. EPA's regulations specify several factors that permitting authorities must consider in determining whether a discharge "causes, has the reasonable potential to cause, or contributes to an instream excursion above a narrative or numeric criteria within a State water quality standard," including: (1) existing controls on point and nonpoint sources of pollution; (2) the variability of the pollutant or pollutant parameter in the effluent; (3) the sensitivity of the test species to toxicity testing;

and (4) the dilution of the effluent in the receiving water.

40 C.F.R. § 122.44(d)(1)(ii).

Application of these factors, and particularly dilution, gives permitting authorities sufficient flexibility to address the types of concerns Petitioners raise in connection with Western waters.[39/] EPA's NPDES regulations and the WET Test Method Manuals specify that permitting authorities may utilize dilution to match WET test conditions with receiving stream conditions.

40 C.F.R. § 122.44(d)(1)(ii); RTC at 274, 340-41, J.A. XX, XX-XX; Methods Manual at 7, J.A. XX. *See also* 67 Fed. Reg. 69,956-57 (describing revisions to Method Manuals on the use of dilution waters). EPA has also developed guidance to assist permitting authorities in performing WET tests under conditions that match the receiving stream's characteristics. *See* Method Guidance at Ch. 6, J.A. XX; *see also* TSD at 57, 68, J.A. XX, XX.

[39/] Petitioners correctly point out that the factor of exposure to receiving waters (particularly dilution) is important to the establishment of WET limits in permits. However, they wrongly claim that EPA has not accounted for dilution. Pet. Br. at 60. EPA's regulations *require* permitting agencies to account for dilution of the effluent in receiving waters, where appropriate. 40 C.F.R. § 122.44(d)(1)(ii); *see also* TSD at 57, J.A. XX. EPA recommends that dilution assumptions be based on low-flow conditions in the receiving water to assure attainment of water quality standards under such conditions. RTC at 308, J.A. XX; TSD at 68, J.A. XX. Also, most of the correlation studies accounted for available dilution in the receiving stream by testing the toxicity of ambient (*i.e.*, instream) waters. RTC at 308, J.A. XX.

EPA's regulations provide additional flexibility to address such circumstances by allowing any person to propose, and seek EPA approval of, an alternative WET test procedure. 40 C.F.R. § 136.4. EPA's regulations require the applicant to support the application with a justification and data showing the applicability of the proposed alternative procedure. *Id.* (3)-(4). A discharger to Western waters with such concerns could take advantage of this process.

Addressing site-specific considerations on a case-by-case basis is not uncommon, and this Court has recognized EPA's authority to address the variability of the nation's water in its CWA regulations. In *American Iron & Steel Institute*, this Court upheld EPA's use of a calculation known as bioaccumulation factors ("BAF") in setting numeric water quality criteria for mercury in the Great Lakes Basin. Though EPA acknowledged that the preferred method to calculate bioaccumulation would have been through a field study in the Great Lakes, no such study was available. Instead, because EPA had "less than perfect information," EPA used a BAF to calculate the mercury criteria. In upholding EPA's mercury criteria, the Court noted that EPA adequately accounted for the variability of mercury concentrations that occur in nature, in part, by allowing permitting authorities to modify mercury BAFs to account for local conditions. *Id.* 115 F.3d at 1005.

This approach, the Court concluded, bore a "rational relationship to the reality it purports to represent." *Id.* (internal quotations and citation omitted); *see also National Wildlife Fed'n v. EPA*, 286 F.3d 544, 566 (D.C. Cir. 2002) (approving case-by-case, site-specific approach to the development of effluent limitation guidelines for color pollution for the pulp and paper industry). The same can be said here, as EPA's decision to allow permitting authorities to tailor WET testing to the characteristics of affected waterbodies furthers the CWA's objective that the discharge of toxic pollutants in toxic amounts be prohibited. 33 U.S.C. § 1251(a)(3).

Again, even accepting as true the proposition that Western waters differ from waters elsewhere, Petitioners offer no specific evidence to support their assertion that certain features inherent to Western waters will have negative effects on test organisms that mimic the effects of toxicity and, therefore, generate false positive results. Pet. Br. at 58-60.[40/] EPA responded to this issue in the Response to Comments document:

> factors that may affect test results, such as hardness, represent test conditions where flexibility is allowed in the method so that these conditions may be matched to specific discharge or receiving system conditions. These conditions for testing are typically specified in the

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[40/] This issue appears to be limited to the chronic test methods using *Ceriodaphnia* and fathead minnows. Pet. Br. at 59.

permit.

RTC at 274, J.A. XX; *see also* RTC at 277, J.A. XX ("EPA guidance [] allows the use of receiving waters for test dilution or the use of synthetic dilution waters adjusted to approximate receiving water characteristics."). Petitioners raise the specific matter of ion imbalance. However, the EPA Method Guidance that Petitioners rely on, Pet. Br. at 59, explains how use of proper dilution waters in the test procedure will "further adjust[] [the test sample] to approximate the ionic balance of the receiving water." Method Guidance at 6-5, J.A. XX. We already discussed the fallacy of Petitioners' claim that EPA did not review data from Western, low flow, ephemeral or effluent-dominated streams. *Supra* at 62 & n. 38.

EPA assessed similar criticisms in connection with the CETTP studies (*i.e.*, that unaccounted for environmental conditions "confound" WET tests) and concluded that these factors did not impair the effectiveness of WET testing because, if Petitioners' theory were correct, there would be a high incidence of false negatives in WET testing (*i.e.*, the WET test would predict *no* stream impact, but the stream would, in fact, be impacted). 1999 EPA Report at 15, J.A. XX. Of the 160 sites addressed by the CETTP and associated studies, only 6.3% produced "false negatives." *Id.*

Other results of WET correlation studies disprove Petitioners' theory. For

instance, the numerous correlation studies demonstrate significant, consistent correlations between WET test results and instream impacts. TSD at 7-11, J.A. XX-XX. Additionally, many studies show that ecosystem impairment occurs on a gradient such that impairment is greatest near the discharge point and decreases as study sites move farther from that point. Upstream communities were generally healthy, as opposed to ecologically impacted sites downstream of the discharge. 1999 EPA Report at 16; RTC at 308, J.A. XX. In short, none of Petitioners' arguments effectively calls into question EPA's reasoned judgment that WET tests are predictive nationwide, including in Western waters.

c. EPA Reasonably Selected Representative Surrogate Indicator Species.

Petitioners claim that *Ceriodaphnia* is not a sufficiently representative species, particularly with regard to Western waters. Pet. Br. at 57-58. Again, Petitioners offer no evidence, and the record offers them no support. Tests using *Ceriodaphnia* in Western waters (in Colorado, Montana, and Wyoming) successfully predicted instream impacts. 1999 EPA Report at 47-50, J.A. XX-XX. More generally, the CETTP and other studies demonstrated that *Ceriodaphnia* and other WET species represent the range of ecosystems analyzed, even if not indigenous. RTC at 309, J.A. XX; TSD at 17, J.A. XX. Based on review of data testing the efficacy of indigenous species, EPA reasonably concluded that it is

"unnecessary to test resident species since standard test species (*e.g.*, *Ceriodaphnia*) have been shown to represent the sensitive range of all ecosystems analyzed." TSD at 17; J.A. XX; *see also* 1999 EPA Report at 25, J.A. XX.

d. By Adopting the Biomass Endpoint, EPA Did Not Significantly Alter the WET Test Procedure, and Re-Validation was Unnecessary.

Petitioners claim that field studies demonstrating instream correlation did not use the same test endpoints as those that EPA ratified in the 2002 WET Rule. Pet. Br. at 55-56. A "biomass" endpoint is a combination of the survival and sublethal (*i.e.*, growth or reproduction) endpoints in which the weight (or other sublethal endpoint) is divided by the number of original organisms rather than only the surviving organisms. *See* RTC at 191-92, J.A. XX; 67 Fed. Reg. 69,960. While the endpoint may result in a more sensitive measure, EPA adopted this endpoint for certain test organisms primarily to make those test endpoints more consistent with other WET test methods *already* applying the biomass endpoint (*e.g.,* the *Ceriodaphnia* Survival and Reproduction test). 67 Fed. Reg. 69,960; RTC at 191-92, J.A. XX-XX. The *Ceriodaphnia* biomass endpoint was extensively field-validated in the CETTP studies (specifically the Skeleton Creek, Five Mile Creek, Wheeling West Virginia, and Lima, Ohio studies). *See generally* 1999 EPA Report, J.A. XX.

While some WET test methods have been refined and improved over time, they remain essentially the same in that they evaluate the same chronic effects by exposing organisms to effluents and observing the effects on survival, growth, and reproduction. *See* RTC at 302, J.A. XX. The biomass endpoint is not a measure of growth *per se*, but an integrated measure of total toxics effects on both survival and growth. EPA merely combined into a single endpoint two separate, closely related endpoints (survival and growth) for which EPA had previously demonstrated a correlation with instream impacts. Coupled with the fact that EPA *did* validate the biomass endpoint for *Ceriodaphnia*, EPA reasonably determined that it was unnecessary to re-validate the aggregated, biomass endpoint for the other organisms. *Ethyl Corp*, 541 F.2d at 28 (EPA can apply its expertise to draw conclusions from, *inter alia,* "trends among facts.").[41/] Thus, EPA reasonably concluded that adoption of the biomass endpoint did not warrant additional field validation.

II. CHRONIC WET TESTS ARE APPROPRIATE FOR USE IN NPDES

[41/] Petitioners' claim that the biomass endpoint results in test bias and increased false positives is unsupported. Pet. Br. at n.45. The sole document they discuss in connection with the biomass endpoint, *see id.* discussing Markle, *et al.* (2000), provides them no help. Markle did not even discuss the matter of "false positives" and the study concludes that the "long-range effects of this change in [endpoint] may not be noticeable or predictable in monitoring programs" depending on the manner in which results are reported. Markle at 128, J.A. XX.

PERMITTING AND REPORTING AND PERMITTEES *CAN* CERTIFY THAT THE WET INFORMATION THEY REPORT IS "ACCURATE."

Petitioners' technical challenges to the chronic WET methods are unavailing, as EPA relied on ample record evidence to reasonably determine that chronic WET tests satisfy all performance characteristics relevant to assessing the adequacy of biological testing;[42/] are *more* precise and *less* variable than NPDES test methods that have been used for years for NPDES purposes; and have been adequately validated in a broad range of conditions and waterbodies. Nevertheless, Petitioners' claim that chronic WET tests are inaccurate and too variable to be used for NPDES permitting and reporting. *See* Pet. Br. at 5-6, 19, 23-24, 32, 38, 40 & 64. They allege that defects in the procedures make it impossible for permittees to certify the accuracy of WET information in their NPDES monitoring reports and

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[42/] Contrary to Petitioners' misplaced analogy to radar detectors and sobriety tests, and related reliance on *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993), *Daubert* has no applicability to this Court's review of an EPA rulemaking. *See* Pet. Br. at 23. Unlike a trial court performing a gatekeeper function with respect to an evidentiary issue, and weighing competing scientific theories, this Court is reviewing a rulemaking that is the culmination of a lengthy notice-and-comment process and that involves issues within EPA's scientific and technical expertise. Thus, EPA's ratification of the WET methods through rulemaking must be upheld so long as the decision meets "minimum standards of rationality." *E.g.*, *Small Refiner Lead Phase-Down*, 705 F.2d at 521; *Ethyl Corp.*, 541 F.2d at 37-38 (EPA's determination on technical issue to be upheld if based on "inconclusive but suggestive results of numerous studies").

that requiring such a certification raises an impermissible irrebuttable presumption. *See* Pet. Br. at 3, 19, 22, 24-25, 38, 64. These claims are unfounded.

A. EPA Reasonably Approved the Chronic WET Test Methods for Use in NDPES Permitting and Reporting.

Assuming the Court upholds EPA's ratification of the chronic WET methods, those methods, like the other test procedures listed in 40 C.F.R. part 136, will be final, binding regulations, and must be used for purposes of NPDES permitting and reporting. 40 C.F.R. §§ 122.41(i) & 136.1; 67 Fed. Reg. 69,955. Thus, WET test results will be used to determine the need for and compliance with permit requirements for whole effluent toxicity. WET test results generated as part of a permit's monitoring requirements must be reported in discharge monitoring reports ("DMRs"). *See* 33 U.S.C. § 1318(a); 40 C.F.R. §§ 122.41(j)(3), 122.48, 123.25. As Petitioners acknowledge, Pet. Br. at 5 & 6, 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. 33 U.S.C. § 1369(b)(2).

Though Petitioners posit hypothetical permitting scenarios, *see* Pet. Br. at

24-25,[43/] no specific claim is before this Court. Any claim that WET test results may be improperly *applied* by a permitting agency – for instance a claim that a permitting agency improperly determined the need for a WET permit limit or improperly evaluated a WET permit limit – would be subject to review only in an appropriate permit proceeding. Thus, any such claim is beyond the scope of this rulemaking[44/] and would be unripe in any event. *Abbott Laboratories v. Gardner*, 387 U.S. 136, 148-49 (1967) (ripeness doctrine "prevent[s] the courts, through avoidance of premature adjudication, from entangling themselves in abstract disagreements over administrative policies" until the agency action "has been formalized and its effects felt in a concrete way"). As discussed *infra*, neither are

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[43/] Petitioners suggest that they could be subject to enforcement action based on a single WET limit exceedance. Pet. Br. at 8, 9. While this is theoretically true, that does not undercut the validity of the test methods. Moreover, in 1995, EPA advised that "EPA does *not* recommend that the initial response to a single exceedance of a WET limit, causing no known harm, be a formal enforcement action with a civil penalty." EPA, National Policy Regarding Whole Effluent Toxicity Enforcement, Jul. 6, 1995 at 2, J.A. XX (emphasis in original). Additionally, the assessment of penalties is subject to the trial court's considerable discretion and the court's review of several statutory factors, including "such other matters as justice requires." 33 U.S.C. § 1319(d). Contrary to Petitioners' claim, Pet. Br. at 6, citizen plaintiffs would lack standing under 33 U.S.C. § 1365 based on a single, wholly past exceedance of WET limits. *Gwaltney v. Chesapeake Bay Found.*, 484 U.S. 49 (1987).

[44/] 66 Fed. Reg. 49,811 ("Today's notice . . . invites comments only on the conduct of WET test methods and not on the implementation of WET control strategies through NPDES permits."); 67 Fed. Reg. 69,968-69 (same).

Petitioners' contentions with respect to DMRs subject to review here.

Moreover, if – even after two rulemakings, EPA's massive validation effort, and the present judicial challenge – Petitioners *still* believe that the chronic WET methods are inappropriate for their situation, they are not without recourse. EPA's regulations allow anyone to propose and seek approval of an alternative WET test method. 40 C.F.R. § 136.4. If EPA were to deny any such application, that decision would be subject to judicial review under the APA, based upon a fully developed record containing facts and evidence about that discharger's specific situation.

Finally, though not mandatory until 1995, the same or very similar WET test methods have been in place and available for use in permitting since at least 1984. No court has questioned the soundness of the procedures, let alone determined that a permitting authority or EPA inappropriately relied on them to set a permit limit or enforce the CWA. Thus, Petitioners have offered this Court no basis to second-guess EPA's considered, technical judgment that the chronic WET tests are appropriate for NPDES permitting and reporting.[45/]

[45/] Petitioners' reliance on *International Fabricare*, 972 F.2d 384, is unavailing and actually supports EPA's actions in the 2002 WET Rule. *See* Pet. Br. at 20. In that case, this Court approved an EPA test method when, in response to comments, EPA subjected it to further validation and "test[ed] [the] method at different laboratories to ensure that it yields reasonably consistent results." *Id.* at 398. EPA

B. Permittees *Can* Certify That the WET Information in Their Discharge Monitoring Reports Is "Accurate."

Petitioners erroneously contend that EPA "insists the accuracy of WET methods cannot be tested," and, therefore, that permittees cannot attest to the "accuracy" of WET test results in DMRs. Pet. Br. at 22. Permittees are required to certify that the information in their DMRs is "true, accurate, and complete." 40 C.F.R. § 122.22(d). Though plainly used in its everyday sense, and in conjunction with the unquestionably non-technical terms "true" and "complete," Petitioners supplant the lay meaning of the word "accuracy" with an inapplicable technical usage.

As EPA explained in the Report to Congress, the Response to Comments document and the preamble to the 2002 WET Rule, "accuracy" is a scientific term of art that very specifically describes a performance characteristic that is not completely applicable to WET testing, because, among other reasons, whole effluent toxicity is considered a method-defined analyte and WET test results cannot independently be confirmed by comparing the results to a known

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has done that here by conducting the Interlaboratory Study pursuant to the Settlement Agreement and with Petitioners' input.

concentration of toxicity. *See* discussion *supra* at 44-45.[46/] By so describing this aspect of biological testing, however, EPA has in no way "insisted," much less conceded, that information from WET test results cannot be certified as "accurate" in the common meaning of that term.

This narrow, technical meaning of the term "accuracy" as a performance characteristic of a measurement system does not prevent permittees from certifying that the WET information in their DMRs is "accurate," much less "true" or "complete." As EPA clarified in a March 2000 memorandum, the DMR certification statement uses the word "accurate" in a very different, non-technical respect, and in an entirely different context. According to the guidance (and common sense), certifying that information submitted in DMRs is "accurate" does not mean that the signatory certifies the accuracy of the measurement system. Rather, it means only that "the results obtained using the WET testing procedure are faithfully and truthfully transcribed . . . and that the results were, in fact, results

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[46/] Despite Petitioners' claim that WET testing is the only approved procedure for which a permittee will be unable to re-test a sample, in light of the 36-72 hour holding time applicable to some WET tests, Pet. Br. at 25, n.8, there are many other circumstances under test procedures listed in 40 C.F.R. part 136 where re-sampling would not be feasible in light of the specified holding time. In fact, sample holding times are much *shorter* for numerous analytes: bacteria (not to exceed six hours); hexavalent chromium (24 hours); and total residual chlorine and sulfites (within *15 minutes* of collection). 40 C.F.R. § 136.3(e), Table II & n.4.

that were obtained using the specified testing procedures." EPA, Certification of "Accuracy" of Information Submissions of Test Results Measuring Whole Effluent Toxicity, Mar. 3, 2000, J.A. XX; *see also* RTC at 345, J.A. XX.[47/] Thus, EPA has not asked permittees to certify something that they cannot know to be true. *See* Pet. Br. at 22.

Finally, Petitioners' vague and unelaborated argument that certifying that DMRs containing WET test results are "accurate" creates an improper "irrebuttable presumption" is misplaced.[48/] This contention is simply a backdoor challenge to the validity of the WET test methods, which we have addressed at length in this brief. As noted above, if the WET test methods are upheld, those methods or their reliability cannot be subject to direct or collateral attacks in any proceeding,

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[47/] This guidance was *requested* by Petitioners and EPA indicated its commitment to prepare such guidance in the Settlement Agreement. Settlement Agreement at 3, J.A. XX. Ironically, Petitioners now criticize EPA for distributing guidance on this issue. Pet. Br. at 22.

[48/] Petitioners' constitutional allegations are vague, at best. They allege, variously, that flaws in the WET test procedures deprive them of the "opportunity to defend themselves," Pet. Br. at 25 (citing 5th and 14th amendments), Pet. Br. at 25; raise an improper irrebuttable presumption, *id.*; and that EPA's alleged failure to follow APA procedures deprived them of due process. *Id.* at 64. This final allegation appears to relate to Petitioners' claim that EPA's "abbreviated validation of the WET procedures" deprived them of due process, *id.* at 19. However, we have already described EPA's extensive validation process and Petitioners' role therein, s*ee supra* at 26-30, 50-51, and Petitioners, in any event, do not specify what was lacking in that process or what allegedly failed to satisfy the APA.

including enforcement proceedings in which DMRs are introduced to establish WET violations. Thus, Petitioners' argument about the conclusiveness of DMRs in establishing liability in an enforcement proceeding is an issue for a trial court or administrative tribunal and is not for this Court to resolve in a challenge to EPA's rulemaking.

Moreover, the irrebuttable presumption doctrine that Petitioners invoke is entirely inapt here.[49/] Indeed, to the extent any "presumption" exists, it stems from the fact that courts have held that DMRs constitute admissions that are sufficient to establish liability under the CWA. *See*, *e.g.*, *Atlantic States Legal Found., Inc. v. Tyson Foods, Inc.*, 897 F.2d 1128, 1135 (11th Cir. 1990).[50/] Case law has simply

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[49/] The doctrine and the lone case that Petitioners cite, *Vlandis v. Kline*, 412 U.S. 441 (1973), have been "limited, if not eviscerated" by the Supreme Court, *Black v. Snow*, 272 F. Supp. 2d 21, 29 (D.D.C. 2003), and the doctrine has been "abandoned as a generally acceptable approach." *Id.* at 30 (citing G. Gunther & K. Sullivan, *Constitutional Law* 915 & n.4 (13th ed. 1997). The doctrine – a hybrid of due process and equal protection – examines the manner in which *statutory classifications* assign a burden or benefit without determining the individual merit of a claim. J. Nowak & R. Rotunda, *Constitutional Law* 580 (6th ed. 2000). No such statutory classification is created by this rule.

[50/] Other courts have gone further to hold that permittees cannot impeach their own DMRs by alleging "laboratory error." *E.g.*, *Union Oil*, 813 F.2d at 1491-92; *Chesapeake Bay Found. v. Bethlehem Steel Corp.*, 608 F. Supp. 440, 452 (D. Md. 1985) *but see United States v. Allegheny Ludlum Corp.*, 366 F.3d 164 (3d Cir. 2004) (DMRs are admissions sufficient to establish liability, but this does not preclude a laboratory error defense in cases of overreporting of discharges).

indicated that test results in certified DMRs are admissions for the purposes of establishing CWA liability and that defendants cannot impeach their own DMRs. Though the burden is great, a defendant is, therefore, not precluded from arguing in a specific case that a DMR reporting a WET limit exceedance should not be conclusive by reason of their failure to follow laboratory procedures. However, a defendant cannot challenge the reliability of the WET test methods ratified in today's rule. 33 U.S.C. § 1369(b)(2). Additionally, no court has suggested, let alone held, that the NPDES monitoring program and the required certification in DMRs raises the sort of impermissible irrebuttable presumption discussed in *Vlandis*. Therefore, EPA reasonably approved the chronic WET test procedures for use in NPDES permitting and reporting.

III. EPA ADEQUATELY RESPONDED TO ALL SIGNIFICANT COMMENTS IN THE WET RULEMAKING.

Petitioners allege that EPA disregarded Petitioners' and peer reviewers' comments. Pet. Br. at 18. EPA is not required to address every comment it receives, but it must respond in a reasoned manner to those that raise significant problems. *City of Waukesha*, 320 F.3d at 257; *Reytblatt v. Nuclear Regulatory Comm'n*, 105 F.3d 715, 722 (D.C. Cir. 1997) (citing *Action on Smoking & Health v. CAB*, 699 F.2d 1209, 1216 (D.C. Cir. 1983)). Even a general response is acceptable, if it shows that the agency considered and rejected petitioners'

arguments and provided support for its decision. *City of Waukesha*, 320 F.3d at 258. EPA provided reasoned responses to all of Petitioners' significant comments during the public comment period, including the arguments Petitioners raise again before this Court.[51/]

A. EPA Appropriately Rejected Commenters' Study That Was Based on Flawed and Inadequate Data.

Petitioners argue EPA's Interlaboratory Study was inadequate because one Petitioner, WESTCAS, conducted its own study, which Petitioners claim showed "extreme inexplicable variation in toxicity in measured samples." Pet. Br. at 7. The WESTCAS study, however, was much smaller than EPA's. *See* Timothy F. Moore, *et al.*, *Investigating the Incidence of Type I Errors for Chronic Whole Effluent Toxicity*, 19 Envtl. Toxicology & Chemistry 118 (2000). The WESTCAS study measured 25 samples in 17 laboratories; EPA's measured 700 samples in 56

[51/] Contrary to Petitioners' claims, EPA complied with its peer review guidelines and did not ignore or contradict the advice of peer reviewers. Other than discrete comments taken out of context that we have addressed, *supra* note 30, Petitioners provide no evidence to support their contention. Petitioners also argue that the study should be vacated and remanded because EPA did not "heed the advice of its own experts." Pet. Br. at 51. As specified in the Settlement Agreement, Ex. B, ¶ 12, J.A. XX, the peer reviewers were not EPA experts (neither staff members nor consultants). Regardless, EPA did not ignore peer review comments, but actually generated a document responding to those comments point-by-point. *See* Response to Comments: Peer Review Report of the Interlaboratory Study (Sept. 2001), J.A. at XX-XX.

laboratories. The WESTCAS study's blank samples were not prepared according to the EPA WET test method requirements for dilution water; holding times were greatly exceeded; and, because of the high false positive rate in that study, contamination of samples could not be ruled out. *Id*. at 118-120, J.A. at XX-XX; RTC at 289, J.A. at XX. Thus, given the number of method errors, it is not surprising that the WESTCAS study showed great variability. Accordingly, EPA appropriately discounted the results of this study.

B. EPA Appropriately Rejected Petitioners' Analysis of Data EPA Rejected from the Interlaboratory Study.

Petitioners produce in their brief a chart they claim shows that WET tests produce extremely variable results when testing a sample designed to be marginally toxic. Pet. Br. at 30-31. The data Petitioners use actually were from a data set *rejected* from the Interlaboratory Study because of an error in sample preparation. RTC at 255-56, J.A. XX-XX, Interlaboratory Study at 31-32, J.A. at XX-XX. While the data may show that some laboratories can detect lower levels of toxicity than others, one cannot make any conclusions from this chart regarding interlaboratory variability. EPA did not report a CV for these results because of the sample preparation errors. RTC at 255-56, J.A. XX-XX; 67 Fed. Reg. 69,966. In sum, Petitioners selectively rely on data EPA properly rejected from the

Interlaboratory Study.[52/] EPA properly rejected the Petitioners' conclusions.

C. EPA Adequately Responded to Petitioners' Comments Regarding Applicability of Method Detection Limits to WET Test Methods.

Petitioners argue that EPA ignored their proposal of three ways to determine a detection limit for biological test methods. Pet. Br. at 28. However, Petitioners' comments make no such proposal. *See* WET Coalition Comments (January 11, 2002), J.A. at XX-XX. Petitioners cite to a paper that was one of 43 attachments to the WET Coalition's comments for the proposition that an MDL can be established for biological testing methods. *See* Risk Sciences, *Developing a Detection Level for Whole Effluent Toxicity Testing* (2001) ("Risk Sciences Paper"). In their 165-page comment document, Petitioner WET Coalition did not cite to this paper to support a comment proposing three ways to determine a detection limit in biological test methods. WET Coalition Comments at 49, n.120. J.A. at XX. EPA responded to the comment WET Coalition actually did raise – that establishing a MDL for biological methods is impossible – by explaining why

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[52/] Petitioners note that approximately 65% of laboratories reported the marginally toxic sample as nontoxic. Pet. Br. at 31. Assuming, *arguendo*, there were no sample preparation errors, this test showed a relatively high *false negative* rate for marginally toxic samples – a result that favors dischargers.

MDLs are not applicable to biological test methods.[53/] RTC at 293, J.A. XX. *See* discussion, *supra*, 46-49. EPA's obligation to give reasoned responses to comments stops at those comments that are significant. *International Fabricare*, 972 F.2d at 389. It would be unreasonable to expect an agency to respond to each and every statement made in papers attached to comments, when such statements are not offered to support anything stated in comment. Moreover, EPA has provided an adequate explanation as to the inapplicability of MDLs in biological test methods. *See*, *e.g.*, RTC at 224-25, J.A. at XX-XX. Accordingly, EPA's response was sufficient and should be upheld.

IV. WET TEST METHODS ARE NOT A *DE FACTO* WATER QUALITY STANDARD.

Petitioners claim that EPA's WET test methods constitute a *de facto* water quality standard that EPA has imposed on States. *See* Pet. Br. at 12, 52, 61-62.[54/] Petitioners apparently base this claim on the fact that EPA has *recommended* that permit authorities utilize 1.0 toxicity units ("TUc") as the level protective against

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[53/] The Risk Sciences Paper suggests two – not three – ways to calculate an MDL for biological test methods.

[54/] Petitioners' claim is less than clear, as they refer to CWA Section 303(c) (regarding the development of mandatory water quality *standards*) *and* CWA Section 304(a) (regarding the development of recommended water quality *criteria guidance*). Pet. Br. at 61. The distinction is immaterial, however, because EPA has developed neither with regard to whole effluent toxicity.

chronic toxicity. *See* TSD at 35, J.A. XX. This recommendation, however, appears *nowhere* in EPA's NPDES regulations and EPA did not even reference this level in the preambles to the 1995 or 2002 WET Rules. In short, the 2002 WET Rule does not recommend or establish 1.0 TUc as the water quality standard for WET.

EPA ratified the WET test methods at issue in this rule pursuant to completely distinct CWA authority, specifically CWA Section 304(h), which directs EPA to "promulgate guidelines establishing test procedures for the analysis of pollutants." 33 U.S.C. § 1314(h). Petitioners concede as much. Pet. Br. at 1. EPA has never characterized its action as anything other than the promulgation of test *procedures* pursuant to Section 304(h); basically, the "measurement tools" States are to use to determine the level of toxicity present. 66 Fed. Reg. 49,796. The authorities for the rulemaking identified in the preamble to the 2002 WET Rule do *not* include CWA Sections 304(a) or 303(c). 67 Fed. Reg. 69,953. Though not dispositive, courts will consider an "agency's characterization of an administrative action" in determining its nature. *American Portland Cement Alliance v. EPA,* 101 F.3d 772, 776 (D.C. Cir. 1996).

EPA also explicitly stated that the above-mentioned toxicity levels are merely "recommended" and are *not* published under the authority of CWA Section

304(a), 33 U.S.C. § 1314(a). TSD at xiv, 35, J.A. XX, XX; RTC at 333, J.A. XX. Similarly, EPA did not promulgate its own water quality standard for WET pursuant to CWA Section 303(c) or impose one upon the States.[55/]

Moreover, although EPA is authorized to establish and publish national water quality criteria guidance pursuant to CWA Section 304(a), 33 U.S.C. § 1314(a), EPA has *never* established criteria guidance for whole effluent toxicity pursuant to CWA Section 304(a).[56/] Even assuming *arguendo* that EPA's recommendations regarding WET limits could be construed

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[55/] Petitioners' only alleged support for this notion is a December 23, 2002 letter from EPA Region 4 to a State environmental official. Pet. Br. at 62, n.52 citing "Region 4 Letter." This letter should be disregarded because it was generated *after* the rule challenged here and, therefore, is not in the record. Moreover, the letter merely states, consistent with EPA's regulations, *see* 40 C.F.R. § 136.1, that the approved WET test methods must be used to assess compliance with WET requirements. Region 4 Letter at 5. Petitioners also erroneously aver that EPA has directed States to ignore the results of field studies indicative of a healthy ecosystem. Pet. Br. at 62. Instead, EPA has merely reminded states that EPA *recommends* that they not rely on a single approach (such as a field study) to assess impact. RTC at 344, J.A. XX. EPA has consistently recommended a water quality-based toxics control strategy that considers "chemical specific, whole effluent, and bioassessment approaches." TSD at 22, J.A. XX. The regulation Petitioners cite merely indicates that in developing water quality standards, "site-specific information should be used," which would include any or all of the above approaches. 40 C.F.R. § 130.7(c)(1)(i).

[56/] Irrelevant to Petitioners' claims here, pursuant to 33 U.S.C. §§ 1313(c) and 1268, EPA established WET criteria for application exclusively in the Great Lakes basin. 60 Fed. Reg. 15,366 (Mar. 23, 1995) (40 C.F.R. pt. 132, App. F, Procedure 6).

as Section 304(a) criteria guidance, Petitioners are still in error. EPA's issuance of Section 304(a) criteria does not even constitute reviewable final agency action under the APA because:

> EPA's [Section 304(a)] criteria document is neither a 'definitive' statement of its position nor does it have the status of law, compelling immediate compliance with its terms. Although this document does serve as an important reference manual to states . . . we note that it does not purport to create or establish rights or responsibilities for any party, nor does it mandate legal action.

Natural Resources Defense Council, Inc. v. EPA, 16 F.3d 1395, 1407 (4th Cir. 1993); *see also* 48 Fed. Reg. 51,400, 51,411 (1983) (States "are equally free to use any other criteria for which they have sound scientific support.").

Finally, EPA's regulations confirm the advisory nature of Section 304(a) guidance by allowing States that develop numeric water quality standards to base their standards on such guidance or "other scientifically defensible methods." 40 C.F.R. § 131.11(b)(1). In sum, the Court should reject Petitioners' argument that the WET tests are a *de facto* water quality standard along with Petitioners' claim that EPA failed to follow related notice-and-comment requirements. *See* Pet. Br. at 61.

V. API CANNOT CHALLENGE EPA'S DECISION NOT TO RATIFY THE MARINE ACUTE METHODS FOR USE IN THE PACIFIC OCEAN, AND, IN ANY EVENT, EPA'S DECISION WAS REASONABLE.

In a separate brief, Intervenor API challenges EPA's decision not to ratify for use in the Pacific Ocean three WET test methods that measure acute toxicity to marine and estuarine organisms.[57/] The lone issue that API raises was not raised in or adopted by Petitioners' brief. Thus, API cannot raise this issue because an intervening party "may join issue only on a matter that has been brought before the court by another party." *Illinois Bell Telephone Co. v. F.C.C.,* 911 F.2d 776, 786 (D.C. Cir. 1990) (citing *Vinson v. Washington Gas Light Co.*, 321 U.S. 489, 498 (1944) ("an intervenor is admitted to the proceeding as it stands, and in respect of the pending issues, but is not permitted to enlarge those issues")); *see also* D.C. Cir. R. 28(e)(2).

Second, an intervenor must satisfy the same standing requirements imposed on the parties to the action. *City of Cleveland v. NRC*, 17 F.3d 1515, 1517-18 (D.C. Cir. 1994). Here, API cannot and does not attempt to show the necessary injury-in-fact because EPA's decision not to ratify use of the Marine Acute Methods for the Pacific Ocean does not harm API. *Lujan v. Defenders of Wildlife*,

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[57/] The WET methods at issue are the sheepshead minnow acute, the mysid acute, and the inland silverside acute (hereinafter "Marine Acute Methods").

504 U.S. 555, 560 (1992) (party must show invasion of a legally protected interest which is "concrete and particularized" and "actual or imminent, not 'conjectural' or 'hypothetical.'"). The preamble to the 2002 WET Rule, states explicitly that permit writers retain the discretion, on a permit-by-permit basis, to apply the Marine Acute Methods in addressing marine and estuarine waters of the Pacific Ocean. 67 Fed. Reg. 69,962; *see also* 40 C.F.R. §§ 122.41(j)(4); 122.44(i)(1)(iv). Though not mandatory, the Marine Acute Methods remain available for inclusion as a permit requirement in NPDES permits.

Finally, by ratifying, and making mandatory, certain test methods for use in the Pacific Ocean, EPA would have foreclosed the application of test methods being developed, tested and validated by the California State Water Resources Control Board. The methods being developed are specific to West coast species, and EPA reasonably determined that the work was valuable and should not be displaced for use in California or elsewhere by requiring the use of the Marine Acute Methods. *See* 67 Fed. Reg. 69,962; RTC at 321, J.A. XX. Thus, EPA tailored its ratification of the Marine Acute Methods to address this specific situation. API's challenge should, therefore, be dismissed or denied.

CONCLUSION

For the foregoing reasons the petitions should be denied.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE WITH WORD LIMITATIONS

Pursuant to Fed. R. App. P. 32(a)(7)(C), I hereby certify that the foregoing brief contains 20,791 words, in 14 point Times New Roman typeface as counted by the word court feature of Corel WordPerfect 9.0, and thus complies with the 21,250 word limitation imposed by the Court's November 25, 2003, Order.

Dated: June 8, 2004

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David S. Gualtieri
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CERTIFICATE OF SERVICE

I hereby certify that I caused a true and correct copy of the foregoing BRIEF OF RESPONDENTS UNITED STATES ENVIRONMENTAL PROTECTION AGENCY, *et al.* to be served this 8th day of June 2004, by first class mail, on the following:

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