

1 RONALD J. TENPAS
Acting Assistant Attorney General
2 Environment and Natural Resources Division

3 MARTIN F. McDERMOTT
Environment and Natural Resources Division
4 Environmental Defense Section
U.S. Department of Justice
5 P.O. Box 23986
Washington, D.C. 20026-3986
6 tel: (202) 514-4122
Attorneys for Defendants
7
8
9

10 UNITED STATES DISTRICT COURT
11 FOR THE CENTRAL DISTRICT OF CALIFORNIA

12 NATURAL RESOURCES DEFENSE
13 COUNCIL,

14 Plaintiff,

15 COUNTY OF LOS ANGELES and LOS
16 ANGELES COUNTY FLOOD CONTROL
DISTRICT,

17 Plaintiff-Intervenors,

18 NATIONAL ASSOCIATION OF CLEAN
WATER AGENCIES,

19 Plaintiff-Intervenor,

20 v.

21 STEPHEN L. JOHNSON, Administrator,
United States Environmental Protection
22 Agency, and UNITED STATES
ENVIRONMENTAL PROTECTION
23 AGENCY,

24 Defendants.
25
26
27
28

No. CV06-4843 PSG (JTLx)

**MEMORANDUM IN SUPPORT OF
DEFENDANTS' CROSS-MOTION
FOR SUMMARY JUDGMENT ON
REMEDY AND IN OPPOSITION TO
MOTIONS FOR SUMMARY
JUDGMENT FILED BY PLAINTIFF
AND PLAINTIFF-INTERVENORS**

HEARING: FEB. 11, 2008
TIME: 1:30 p.m.
JUDGE: Hon. Philip S. Gutierrez

TABLE OF CONTENTS

1		
2		
3	STATUTORY AND REGULATORY BACKGROUND	1
4	A. Water Quality Standards and Criteria	1
5	B. The BEACH Act	2
6	C. CWA Citizen Suits	4
7		
8	BACKGROUND	4
9	A. Overview	4
10	B. EPA's Research Efforts to Support New or Revised Water Quality Criteria	
11	From 1998-2007	6
12	C. EPA's Development of a Critical Path Science Plan and Criteria Development	
13	Plan (2006-2007)	9
14	1. EPA Convenes Scientific Workshop	9
15	2. EPA Develops 2007 Critical Path Science Plan	11
16	3. EPA Develops 2007 Criteria Development Plan	15
17	D. The Present Litigation	16
18	1. The Complaints	16
19	2. The Court's March 23, 2007 Order	18
20	3. The Present Motions	19
21	a. Plaintiffs' Motions For Partial Summary Judgment	19
22	b. EPA's Cross Motion for Summary Judgment on Remedy	21
23		
24	STANDARD OF REVIEW	21
25		
26	DISCUSSION	22
27		
28		

I.	INJUNCTIVE RELIEF IN THIS CASE SHOULD BE LIMITED TO AN ORDER REQUIRING EPA TO PUBLISH BY DECEMBER 15, 2012 THE NEW OR REVISED WATER QUALITY CRITERIA REQUIRED BY CWA SECTION 304(a)(9)	22
A.	Under The CWA Citizen Suit Provision, The Court's Authority To Remedy Any Failure By EPA To Comply With A Non-Discretionary Duty Is Limited To Imposing A Deadline For EPA To Discharge That Duty	23
B.	Courts Routinely Prescribe, Without Trial, Deadlines For The Completion Of Agency Action Following An Agency's Failure To Perform A Non- Discretionary Duty And There Is No Reason To Divert From That Practice Here	26
C.	Any Injunctive Relief Should Be Limited To The Imposition Of A Date For EPA To Publish New Or Revised Water Quality Criteria Pursuant To CWA Section 304(a)(9)	29
D.	EPA Should Be Afforded Until December 15, 2012 To Publish The Criteria Under Section 304(a)(9) And To Complete The Studies It Deems Appropriate To Accomplish That Task	36
1.	This Court Has Equitable Discretion To Determine A Reasonable Deadline For Agency Action Where Compliance With Statutory Deadline Is Impossible Or Infeasible	37
2.	EPA's Proposed Schedule Represents The Reasonable Minimum Time Necessary For EPA To Complete The Required Action	38
a.	EPA's Science Plan Schedule	40
b.	EPA's Criteria Development Schedule	42
	CONCLUSION	45

TABLE OF AUTHORITIES

FEDERAL CASES

<i>Alaska Center for the Environment v. Browner</i> , 20 F.3d 981 (9th Cir. 1994)	26
<i>Alvidres-Reyes v. Reno</i> , 981 F. Supp. 1008, 1009 W.D. Tex. 1997) (vacated on other grounds, 180 F.3d 199 (5th Cir. 1999)	35
<i>American Lung Association v. Browner</i> , 884 F. Supp. 345 (D. Ariz. 1994)	27, 37
<i>Anderson v. Liberty Lobby, Inc.</i> , 477 U.S. 242 (1986)	21
<i>Army & Air Force Exch. Serv. v. Sheehan</i> , 456 U.S. 728 (1982)	23
<i>Atlantic Terminal Urban Renewal Area Coal. v. New York City Department of Environmental Prot.</i> , 740 F. Supp. 989 (S.D.N.Y. 1990)	38
<i>Celotex Corp. v. Catrett</i> , 477 U.S. 317 (1986)	21
<i>City of Highland Park v. Train</i> , 374 F. Supp. 758 (D.C. Ill. 1974)	30
<i>City of Waukesha v. EPA</i> , 320 F.3d 228 (D.C. Cir. 2003)	35
<i>Conservation Law Foundation v. Mineta</i> , 131 F. Supp. 2d 19 (D.D.C. 2001)	34
<i>Cronin v. Browner</i> , 90 F. Supp. 2d 364 (S.D.N.Y. 2000)	37
<i>First Virginia Bank v. Randolph</i> , 110 F.3d 75 (D.C. Cir. 1997)	23

1		
2	<i>Flast v. Cohen</i> ,	
3	392 U.S. 83 (1968)	34
4	<i>Government of Guam v. America President Lines</i> ,	
5	28 F.3d 142 (D.C. Cir. 1994)	25
6	<i>Hallstrom v. Tillamook County</i> ,	
7	493 U.S. 20 (1989)	23
8	<i>In Re Barr Laboratories</i> ,	
9	930 F.2d 72 (D.C. Cir. 1991)	35, 36
10	<i>Kennecott Copper Corp. v. Costle</i> ,	
11	572 F.2d 1349 (9th Cir. 1978)	31
12	<i>Lane v. Pena</i> ,	
13	518 U.S. 187 (1996)	23, 25, 26
14	<i>Middlesex County Sewerage Authority v. National Sea Clammers Association</i> ,	
15	453 U.S. 1 (1981)	24
16	<i>Mountain States Legal Foundation v. Costle</i> ,	
17	630 F.2d 754 (10th Cir. 1980)	31
18	<i>NRDC v. EPA</i> ,	
19	797 F. Supp. 194 (E.D.N.Y. 1992)	28
20	<i>NRDC v. New York State Department of Environmental Conservation</i> ,	
21	700 F. Supp. 173 (S.D.N.Y. 1988)	38
22	<i>NRDC v. Train</i> ,	
23	510 F.2d 692 (D.C. Cir. 1975)	37
24	<i>National Coal Association v. Marshall</i> ,	
25	510 F. Supp. 803 (D.D.C. 1981)	34
26	<i>National Petrochemical & Refiners Association v. EPA</i> ,	
27	287 F.3d 1130 (D.C. Cir. 2002)	35
28	<i>Sierra Club v. Johnson</i> ,	
	444 F. Supp. 2d 46 (D.D.C. 2006)	28, 37

1		
2	<i>Sierra Club v. Ruckelshaus,</i>	
3	602 F. Supp. 892 (N.D. Cal. 1984)	27, 28
4	<i>Sierra Club v. Thomas,</i>	
5	658 F. Supp. 165 (N.D. Cal. 1987)	28, 37
6	<i>Sierra Club v. Thomas,</i>	
7	828 F.2d 783 (D.C. Cir. 1987)	31
8	<i>Transamerica Mortgage Advisors, Inc v. Lewis,</i>	
9	444 U.S. 11 (1979)	24
10	<i>United States Department of Energy v. Ohio,</i>	
11	503 U.S. 607 (1992)	23
12	<i>United States v. Testan,</i>	
13	424 U.S. 392 (1976)	23
14	<i>United Steelworkers of America v. Rubber Manufacturers Association,</i>	
15	783 F.2d 1117 (D.C. Cir. 1986)	38
16	<i>Weinberger v. Romero-Barcelo,</i>	
17	456 U.S. 305 (1982)	25
18	<i>Wisconsin's Environmental Decade, Inc. v. Wisconsin Power & Light Co.,</i>	
19	395 F. Supp. 313 (W.D. Wis. 1975)	31
20	FEDERAL STATUTES	
21	Rehabilitation Act of 1973, 29 U.S.C. § 791-794(e)	25
22	31 U.S.C. § 1314	40
23	The Federal Water Pollution Control Act, 33 U.S.C. § 1251-1387	1
24	33 U.S.C. § 1254(v)	1
25	33 U.S.C. § 1301(b)(1)	2
26	33 U.S.C. §1313(a)	1
27		
28		

1	33 U.S.C. §1313(b)	1
2	33 U.S.C. § 1313(c)	2
3		
4	33 U.S.C. § 1313(c)(1)	1
5	33 U.S.C. § 1313(c)(2)(A)	1
6	33 U.S.C. § 1313(c)(4)	4
7	33 U.S.C. § 1313(i)(1)(A)	4
8		
9	33 U.S.C. § 1313(i)(1)(B)	3, 15
10	33 U.S.C. § 1313(i)(3)	4
11	33 U.S.C. § 1314(a)(1)	2
12	33 U.S.C. § 1314(a)(9)	1
13		
14	33 U.S.C. § 1314(a)(9)(A)	2, 3
15	33 U.S.C. § 1346	2
16	33 U.S.C. § 1362(21)	3
17	33 U.S.C. § 1362(23)	3
18		
19	33 U.S.C. § 1365(a)(1)	25
20	33 U.S.C. § 1365(a)(2)	4, 24
21		
22	FEDERAL RULES OF CIVIL PROCEDURE	
23	Fed. R. Civ. P. 56(c)	21
24		
25	CODE OF FEDERAL REGULATIONS	
26	40 C.F.R. Pt. 131	1
27		
28		

1	40 C.F.R. § 131.2	2
2	40 C.F.R. § 131.5(b)	2
3		
4	40 C.F.R. § 131.11	2
5	40 C.F.R. § 131.11(b)	2
6	40 C.F.R. § 131.21(c)	4
7	40 C.F.R. 131.41	4
8		

FEDERAL REGISTER

10	69 Fed. Reg. 67,218 (Nov. 16, 2004)	4, 5
----	---	------

LEGISLATIVE HISTORY

13	H.R. Rep. No. 106-98 at 6 (1999)	5
14		
15	S. Rep. No. 106-366 at 2 (1999)	5

1 This Memorandum is filed in support of the cross-motion on remedy pursuant to Rule 56
2 of the Federal Rules of Civil Procedure filed by Defendants Stephen L. Johnson and the United
3 States Environmental Protection Agency (collectively, "EPA" or the "Agency"). It also responds
4 to the summary judgment motions filed on or about October 24, 2007 by Plaintiff Natural
5 Resources Defense Council ("NRDC") and by Plaintiff-Intervenors National Association of
6 Clean Water Agencies ("NACWA") and the County of Los Angeles, et al. ("the County"),
7 insofar as their motion papers argue for a trial in this case or otherwise suggest improper relief or
8 inefficient and unnecessary procedures to bring this matter to a close.^{1/} In this Memorandum,
9 EPA also explains why the Court should resolve this case by issuing a straightforward order
10 enjoining EPA to satisfy its non-discretionary duties under the BEACH Act by publishing, by
11 December 15, 2012, new or revised water quality criteria pursuant to section 304(a)(9), 33 U.S.C.
12 § 1314(a)(9).

13 STATUTORY AND REGULATORY BACKGROUND

14 A. Water Quality Standards and Criteria

15 The Federal Water Pollution Control Act ("Clean Water Act" or "CWA"), 33 U.S.C. §
16 1251-1387 establishes a State-federal partnership to restore and maintain the integrity of the
17 Nation's waters. CWA section 303 requires each State to adopt "water quality standards" for all
18 waters of the State and to review and, if appropriate, revise them every three years. 33 U.S.C. §
19 1313(a), (b) and (c)(1); 40 C.F.R. Pt. 131. A water quality standard is a method of expressing the
20 desired condition of a water body and consists of three main elements: (1) one or more
21 designated "uses" of each of the State's waters, such as recreation or propagation of fish; (2)
22 "criteria" expressed as pollutant concentration levels or narrative statements representing a
23 quality of water that supports a designated use; and (3) an anti-degradation policy to protect
24 existing uses and high quality waters. See generally 33 U.S.C. § 1313(c)(2)(A); 40 C.F.R. Pt.
25 131. Water quality standards serve as the regulatory basis for, among other things, the

26
27 ^{1/} EPA does not oppose entry of an order finding that EPA has not fully discharged its statutory
28 obligations under Clean Water Act section 104(v), 33 U.S.C. § 1254(v).

1 establishment of water quality-based effluent limitations in CWA National Pollutant Discharge
2 Elimination System ("NPDES") permits. 33 U.S.C. § 1301 (b)(1); 40 C.F.R. § 131.2. In
3 addition, water quality standards to protect swimming are used by States in beach monitoring and
4 notifications programs. See 33 U.S.C. § 1346.

5 When a State develops new standards or revises existing ones it must submit the
6 standards to EPA for review and approval or disapproval. 33 U.S.C. § 1313(c). EPA regulations
7 provide that States should establish: (1) numerical criteria based on (i) EPA's criteria guidance
8 developed under CWA section 304(a), (ii) EPA's criteria guidance modified to reflect site-
9 specific conditions, or (iii) other scientifically defensible methods; and (2) narrative criteria or
10 criteria based on biomonitoring methods where numerical criteria cannot be established or to
11 supplement numerical criteria. 40 C.F.R. § 131.11(b)

12 Section 304(a)(1) directs EPA to publish water quality criteria "reflecting the latest
13 scientific knowledge" on the effects of the presence of pollutants in water on health and welfare.
14 33 U.S.C. § 1314(a)(1). The criteria guidance documents that EPA publishes under section
15 304(a), including section 304(a)(9)(A), are intended to provide EPA's technical and scientific
16 recommendations for establishing the criteria components of State water quality standards, but
17 EPA's criteria are recommendations and not binding on States. EPA will approve different
18 criteria adopted by a State as long as the criteria are scientifically defensible and protective of the
19 designated uses of the State's waters. 40 C.F.R. §§ 131.5(b), 131.11.^{2/} Section 304(a) does not
20 specify the procedures EPA should follow in developing the criteria guidance.

21 **B. The BEACH Act**

22 On October 10, 2000, Congress enacted the Beaches Environmental Assessment and
23 Coastal Health ("BEACH") Act, which amended the CWA by, among other things, adding
24 section 304(a)(9)(A). That section, which is the focal point of this litigation, provides:
25

26
27 ^{2/} The term "criteria" thus refers to two distinct things: (1) EPA's non-binding technical and
28 scientific recommendations to States; and (2) the criteria components of water quality
"standards," which are used for regulatory purposes such as issuing discharge permits and
identifying impaired waters.

1 Not later than 5 years after [the date of the enactment of this
2 paragraph], after consultation and cooperation with appropriate
3 Federal, State, tribal, and local officials (including local health
4 officials), the Administrator shall publish new or revised water
5 quality criteria for pathogens and pathogen indicators (including a
6 revised list of testing methods, as appropriate), based on the results
7 of the studies conducted under [section 104(v)], for the purpose of
8 protecting human health in coastal recreation waters.

9 33 U.S.C. § 1314(a)(9)(A). As with the section 304(a) criteria described above, the section
10 304(a)(9)(A) criteria for pathogens and pathogen indicators – when published by EPA – will not
11 be binding on States. Section 104(v), referred to in the text of section 304(a)(9), is also relevant.
12 It provides that EPA “shall initiate, and not later than 3 years after [the date of enactment of this
13 subsection], shall complete . . . studies to provide additional information for use in developing –

14 (1) an assessment of potential human health risks, resulting
15 from exposure to pathogens in coastal recreation waters, including
16 nongastrointestinal effects;

17 (2) appropriate and effective indicators for improving
18 detection in a timely manner . . . of the presence of pathogens
19 harmful to human health;

20 (3) appropriate, accurate, expeditions, and cost-effective
21 methods . . . for detecting in a timely manner . . . the presence of
22 pathogens harmful to human health; and

23 (4) guidance for State application of criteria for pathogens
24 and pathogen indicators to be published under [section 304(a)(9)]
25 to account for the diversity of geographic and aquatic conditions.

26 The BEACH Act directs States with “coastal recreation waters” to adopt new or revised
27 water quality standards for all pathogens and “pathogen indicators” to which the new or revised
28 water quality criteria under section 304(a)(9)(A) are applicable. 33 U.S.C. 1313(i)(1)(B).^{3/}
States are directed to submit these new or revised standards to EPA 36 months after EPA

26 ^{3/} “Coastal recreation waters” is defined in the BEACH Act to include the Great Lakes and
27 marine coastal waters that are designated under CWA section 303(c) for swimming, bathing,
28 surfing, or similar water contact activities. 33 U.S.C. § 1362(21). While the BEACH Act does
not include a definition of “pathogen,” the term “pathogen indicator” is defined as “a substance
that indicates the potential for human infectious disease.” *Id.* § 1362(23).

1 publishes new or revised criteria under section 304(a)(9). Id.^{4/}

2 C. CWA Citizen Suits

3 The CWA includes a citizen suit provision, section 505(a)(2), 33 U.S.C. § 1365(a)(2),
4 which provides in pertinent part that “any citizen may commence a civil action on his own
5 behalf” against EPA “where there is alleged a failure of the Administrator to perform any act or
6 duty under this chapter which is not discretionary with the Administrator.” It specifies that the
7 district courts have jurisdiction “to order the Administrator to perform such act or duty.”

8 BACKGROUND

9 A. Overview

10 In 1986, EPA published “Ambient Water Quality Criteria for Bacteria –1986” (“1986
11 criteria”). That document contains EPA’s current recommended water quality criteria to protect
12 people from illnesses associated with fecal contamination in recreational waters, i.e., waters
13 designated for primary contact recreation or similar full body contact uses. Fourteen years later,
14 the BEACH Act directed States with coastal recreation waters to adopt by April 2004 water
15 quality standards that are as protective of human health as EPA’s 1986 criteria. 33 U.S.C. §
16 1313(i)(1)(A). The BEACH Act also required EPA to promulgate criteria applicable to coastal
17 recreation waters in States that did not adopt protective criteria. Id. § 1313(i)(2)(A). EPA
18 promulgated a rule establishing such criteria based on EPA’s 1986 criteria for coastal recreation
19 waters in 14 States and two territories. 69 Fed. Reg. 67,218 (Nov. 16, 2004); 40 C.F.R. 131.41.

20 EPA’s 1986 criteria are expressed as concentration levels for enterococci and E. coli,
21 which are both indicators of fecal contamination (“fecal indicators”). As EPA explained in the
22 April 2004 Rule, these fecal indicators, when present in recreational waters, “indicate” the
23 possible presence of pathogens that cause illness in humans. Public health agencies in the United
24 States and internationally have long used such indicator organisms to protect people from

25
26
27 ^{4/} If EPA determines that a State’s water quality standards do not meet CWA requirements, EPA
28 is required to promulgate such standards. 33 U.S.C. §§ 1313(i)(3) and 1313(c)(4). Standards
adopted by a State after May 20, 2000, are not effective for CWA purposes unless and until EPA
approves them. 40 C.F.R. § 131.21(c).

1 illnesses that they may contract from engaging in recreational activities in surface waters
2 contaminated by fecal pollution. These indicator organisms generally do not cause illness
3 directly, but have demonstrated characteristics that make them good indicators of fecal
4 contamination and thus the potential presence of pathogens capable of causing human illnesses
5 such as gastroenteritis. See 69 Fed. Reg. at 67,220.

6 EPA's 1986 recommended bacteria criteria were based on epidemiological studies^{5/}
7 conducted beginning in 1972 of the relationship between the presence and levels of fecal
8 indicators in waters and swimming-related health effects. 1986 Criteria at 3. As Congress
9 recognized when it enacted the BEACH Act, the state of the science had changed enough since
10 1986 to warrant EPA undertaking a process for revising or replacing those criteria
11 recommendations, leading to the requirement at issue in this case: that EPA publish new or
12 revised criteria recommendations "for pathogens and pathogen indicators" by October 10, 2005.
13 H.R. Rep. No. 106-98 at 6 (1999) and S. Rep. No. 106-366 at 2.

14 The task of conducting research on and developing criteria recommendations for
15 pathogens and pathogen indicators and associated rapid methods is technically complex and
16 challenging. Declarations of Ephraim S. King ("King Decl.") ¶ 7 and Charles I. Noss ("Noss
17 Decl.") ¶ 7. EPA is developing revised criteria recommendations for national application within
18 the next five years by continuing to study fecal indicators and the relationship between the
19 occurrence of these indicators and the occurrence of illness in humans, rather than focusing on
20 individual pathogens.^{6/} Id. ¶ 8. Waters with fecal contamination contain many microbes, only a

22 ^{5/} An epidemiology study measures the strength of associations between indicators and the
23 distributions and frequencies of health effects in a population.

24 ^{6/} Measuring all possible enteric pathogens rapidly and directly in recreational waters presents
25 both scientific limitations and practical challenges. First, the number of potential human
26 pathogens associated with fecal contamination is large (there are dozens of enteric viruses alone).
27 Second, in many cases the amount of a pathogenic microbe in water that could cause illness if
28 ingested is small (e.g., for cryptosporidium, a single spore) and they are found at much lower
concentrations than indicator organisms; accurately and reliably measuring such pathogens in
recreational water would require large water samples for accurate detection and quantification.

(continued...)

1 subset of which may be pathogenic (i.e. cause disease). Noss Decl. ¶ 11. Such indicators are
2 evaluated in terms of their relationship to human illness, which is indicative of co-occurrence
3 with pathogenic microbes. Id. However, the use of fecal indicators to predict swimming-related
4 risk is an inexact science. Fecal indicators may behave differently in a variety of waters and most
5 indicators are not for a specific source of fecal contamination even though there may be
6 significant differences in the risks associated with those different sources. Id. These are just
7 some of the variables that make it difficult for EPA to select a fecal indicator (and associated test
8 method) that is effective for accurately predicting human health risk to support national criteria
9 recommendations for a variety of waterbody types that may also differ in other significant
10 respects (e.g., size or flow of waterbody).

11 Accordingly, EPA's development of new or revised criteria recommendations will
12 involve the continued study of fecal indicators and methods that can be used in a range of CWA
13 programs (such as NPDES permitting, beach monitoring, water quality assessment, and
14 development of total maximum daily loads("TMDLs")) to estimate – as accurately as possible
15 given the limitations in the state of the science – the risks of illness associated with swimming in
16 water with fecal contamination. King Decl. ¶ 9. The research EPA has conducted, is presently
17 conducting, and plans to conduct over the next three years, is designed to provide, within five
18 years, a scientifically sound basis for EPA to establish such risk-based water quality criteria
19 recommendations with the ultimate goal of advancing the protection of human health. Id.

20 **B. EPA's Research Efforts to Support New or Revised Water Quality Criteria**
21 **From 1998-2007**

22 After Congress enacted the BEACH Act, EPA initiated in May 2001 an extensive
23

24 6/(...continued)

25 Third, for some pathogens, the state of the science is such that culturing the organism is
26 necessary, making rapid results using molecular biology methods currently out of reach. Finally,
27 for a range of reasons relating to viability, infectivity, occurrence, exposure, and host
28 susceptibility, even a direct measure of pathogens may not be useful at this time in predicting the
risk of illness from swimming. Therefore, the direct measurement of pathogens cannot be the
basis of any new or revised national criteria recommendations to be published in the near future
(within the next five years). Noss Decl. ¶ 10.

1 research study, the “National Epidemiological and Environmental Assessment of Recreational
2 Waters” (“NEEAR” study).^{2/} The NEEAR study, which is ongoing, consists of multiple research
3 efforts, most importantly several large scale epidemiological studies at Great Lakes and coastal
4 beaches.^{8/} A primary goal of the epidemiological studies is to establish a health-based
5 relationship between indicators of fecal contamination, and swimming-associated illness as
6 measured by a variety of methods, including timely molecular methods. The study evaluates
7 human health outcomes associated with different levels of indicators of fecal contamination.^{2/}
8 See Report to Congress at 3-3.

9 Planning and executing these large scale epidemiological studies is extremely complex
10 and resource intensive. Noss Decl. ¶15. For example, EPA initially developed a study design and
11 submitted it to external scientists for peer review.^{10/} Id. Then, in the summer of 2002, EPA
12 conducted a pilot study of its study design before investing significant resources and time to
13

14 ^{2/} Even before the BEACH Act, EPA had initiated research studies that have been and continue
15 to be used to inform the development of new or revised water quality criteria recommendations
16 to protect swimming. For example, in November 1998 EPA initiated its “Environmental
17 Monitoring for Public Access and Community Tracking” (“EMPACT”) Beaches project to
18 identify the characteristics or factors that have a significant impact on the results of monitoring
19 for fecal indicators. The study, completed in August 2005, involved collecting water samples
20 and other data at five different beach environments (Atlantic Ocean bay, Pacific Ocean, estuary,
21 Great Lakes, and Great Lakes riverine). In August 2000, EPA initiated another study, this one to
22 evaluate “off-the- shelf” technologies for detecting fecal contamination rapidly using “molecular
23 methods” instead of the standard culture-based method. See “Implementing the BEACH Act of
24 2000: Report to Congress” (Oct. 2006) (“Report to Congress”) at 5-1; Critical Path Science Plan
25 at 2-2; and Noss Decl. ¶20.

26 ^{8/} In the NEEAR study, EPA monitors beachgoers’ exposure to recreational waters and follows
27 up with them over time to determine the occurrence of illness. In conducting this study, EPA has
28 worked with the Centers for Disease Control and Prevention (“CDC”) and U.S. Geological
Survey (“USGS”). Report to Congress 3-3 and 3-4.

^{2/} These human health outcomes include diarrhea and gastrointestinal illness as well as non-
enteric swimming related illnesses (e.g., skin, ear, eye, urinary tract, and respiratory infections).
Report to Congress at 3-3.

^{10/} Peer review is a process through which independent subject-matter experts provide EPA with
objective evaluations of EPA work products. Noss Decl. ¶ 13.

1 conduct full-scale studies using that design. Id. Also, EPA's aforementioned evaluation of "off-
2 the-shelf" method technologies for measuring indicator organisms, begun before passage of the
3 BEACH Act, was part of this effort; EPA conducted the method technology study to determine
4 which molecular methods^{11/} would be appropriate for inclusion in the first round of
5 epidemiological studies in the Great Lakes. Id. Then, in the summers of 2003 and 2004, EPA
6 conducted four epidemiological studies at four different beaches in the Great Lakes region. Id.^{12/}

7 EPA analyzed the data from the four Great Lakes epidemiologic studies to determine
8 whether swimmers in the Great Lakes who were exposed to higher levels of fecal indicators (as
9 measured by molecular methods such as quantitative Polymerase Chain Reaction ("qPCR"))
10 experience more illness than non-swimmers, or swimmers exposed to lower levels of fecal
11 indicators. These studies were the first to establish a relationship between the levels of such
12 contamination in water as measured by rapid molecular methods and swimming-associated
13 health effects occurring within 10-12 days after a beach visit. Critical Path Science Plan

14
15 ^{11/} Molecular test methods (often referred to as "rapid methods" or, more accurately, "timely
16 methods") differ from culture-based test methods for detecting fecal contamination in water with
17 respect to the amount of time it takes to get results. In general, molecular methods work by
18 extracting DNA from cells and replicating a sequence of nucleic acids in a reaction that amplifies
19 this indicator organism's DNA so it can be measured in the lab in less than two hours. Culture-
20 based methods work by counting how many indicator organisms replicate or grow over a set
period of time; for bacteria, it is usually 24 hours. Molecular methods differ from culture-based
methods in another important respect: they do not identify the viability of the indicator
organism. Noss Decl. ¶ 14.

21 ^{12/} The list of major technical steps that precede the data collection component of the
22 epidemiologic studies does not capture all of the planning, outreach, development and approval
23 measures that are involved. These measures include, among other things, consulting with
24 agencies such as the CDC and USGS and with local health officials, publishing two Information
25 Collection Requests in the Federal Register to comply with the Paperwork Reduction Act,
26 submitting the study protocols and questionnaires to the Institutional Review Board for the CDC
27 and EPA's Human Subjects Review Official and entering into contracts for outside assistance in
28 conducting the studies. Noss Decl. ¶ 16. Data collection alone in the Great Lakes
epidemiological studies required substantial efforts. EPA recruited 10,000 volunteer households
at freshwater beaches during the summers of 2003 and 2004, from Memorial Day through Labor
Day. Over three years, EPA interviewed more than 21,000 beachgoers about their activities and
health status after beach visits. EPA also collected more than 1,500 water samples and tested
them for fecal indicators. Report to Congress at 3-4.

1 (“CPSP”) at 2-1. The molecular methods showed great promise for allowing beach managers to
2 potentially make more timely decisions regarding the safety of Great Lakes beach waters on any
3 given day. Id. at 2-1. The ability to sample water quality and get timely results for beach
4 monitoring and notification programs is one important goal of EPA’s recreational water quality
5 criteria recommendations. King Decl. ¶ 10.

6 **C. EPA’s Development of a Critical Path Science Plan and Criteria**
7 **Development Plan (2006-2007)**

8 While the NEEAR study and other ongoing research ^{13/} provide valuable scientific
9 information for use in EPA’s development of revised criteria, events beginning in late 2004 led
10 EPA to initiate an evaluation to confirm whether its ongoing research efforts would provide all of
11 the data it needed in order to develop new or revised water quality criteria recommendations that
12 would be suitable for multiple CWA programs, in addition to beach monitoring and notification
13 programs. King Decl. ¶ 11. EPA had received comments raising concerns about EPA’s 1986
14 criteria during the Agency’s 2004 rulemaking. Id. During the same time period, EPA’s efforts to
15 develop implementation guidance for the 1986 criteria generated substantial stakeholder feedback
16 identifying a number of similar concerns. Id. Also, EPA’s ongoing assessment of the data from
17 its Great Lakes studies and other research data highlighted additional scientific uncertainties that
18 needed to be addressed. Noss Decl. ¶ 18 and King Decl. ¶ 12. ^{14/} These events and subsequent

19
20 ^{13/} This discussion of the research EPA conducted from 1998-2007 does not include other
21 research it conducted, such as an epidemiological study in Biloxi, Mississippi that was not
22 completed due to Hurricane Katrina; a study evaluating chemical substances as possible
23 indicators of human fecal contamination (June 2001-Nov. 2004); a method development study of
24 qPCR methods for Enterococcus and Bacteroides (Apr. 2002-Nov. 2004 and May 2003-Mar.
25 2007); a study to develop a “Virtual Beaches” predictive modeling tool (Apr. 2004-Jan. 2007);
26 and a matrices evaluation study testing the aquatic matrix effects on the performance of the
27 qPCR molecular method to determine the method’s applicability beyond the four Great Lakes
28 test sites (Oct. 2005-Mar. 2007). In the summer of 2000 EPA conducted epidemiologic studies
at marine beaches in Alabama and Rhode Island and provided financial and technical assistance
to an outside organization to conduct an epidemiologic study in California. Noss Decl. ¶20.

^{14/} Plaintiffs do not dispute the high quality of EPA’s research activities and, in fact, EPA’s
protocol for the conduct of beach epidemiology studies is highly respected and followed by
(continued...)

1 discussions with stakeholders led EPA to embark on an outreach process to inform its evaluation
2 of whether the substantial ongoing research activities would provide all of the scientific
3 information necessary to support revised criteria recommendations. King Decl. ¶ 13.

4 **1. EPA Convenes Scientific Workshop**

5 To ensure that its evaluation of its criteria and research goals had the benefit of a wide
6 variety of scientific viewpoints, EPA brought together a cross-section of key experts. King Decl.
7 ¶ 14. EPA's intent was to identify common ground on the state of the science and identify
8 outstanding questions related to the human health risks from pathogens in recreational waters. Id.
9 To facilitate this dialogue, EPA established a two-stage process for engaging outside partners and
10 scientists. Id.

11 First, EPA engaged a group of stakeholders representing the public, academia, public
12 interest groups, State and local governments, industry, and municipal wastewater treatment
13 professionals ("stakeholders") through conference calls and a meeting in late 2006. King Decl. ¶
14 15 and CPSP at 1-1. Next, EPA convened its "Experts Scientific Workshop on Critical Research
15 and Science Needs for the Development of New or Revised Recreational Water Quality Criteria"
16 ("Experts Workshop"), a five-day meeting of 43 U.S. and international experts from academia,
17 States, public interest groups, EPA, and other federal agencies. Id. Before convening the Experts
18 Workshop, EPA asked the stakeholders to suggest attendees for the Workshop so that it would
19 include experts in various scientific and technical disciplines (e.g., statistics, microbiology,
20 epidemiology, water quality management) and would be representative of the sectors in which these
21 experts work (academia, public interest organizations, and local, State, and federal governments).
22 King Decl. ¶ 17.^{15/} EPA also asked the stakeholders to provide input on the "charge" questions
23

24 ^{14/}(...continued)
25 others. Noss Decl. ¶ 19.

26 ^{15/} NRDC and NACWA were members of the stakeholders group and participated in conference
27 calls and the stakeholders meeting. Of the 21 experts that NRDC recommended that EPA invite
28 to the Workshop, EPA invited fifteen, nine of whom participated in the Workshop. An expert
recommended by NACWA also participated. Thus, out of 43 experts attending the Workshop,
(continued...)

1 the experts would address. Id. The charge question document articulates the complexity of the
2 scientific questions regarding recreational water quality criteria, and EPA wanted to ensure that it
3 developed a complete set of charge questions and presented them objectively. Id. See Appendix
4 A of the Report of the Experts Scientific Workshop on Critical Research Needs for the
5 Development of New or Revised Recreational Water Quality Criteria (“Experts Report”) found at
6 EPA’s website epa.gov/waterscience/criteria/recreation.

7 The Experts Workshop, held March 26-30, 2007, was similar in organization and form to
8 “Pellston-style” workshops, where technical experts in a particular subject area are invited to
9 participate. King Decl. ¶19. They are provided with a charge to develop scientific views or work
10 products, and are typically sequestered to facilitate focused discussions and individual and
11 collaborative writing of a draft summary report that is responsive to the charge. Id. Here, EPA
12 established sub-workgroups around seven key topics related to criteria development. Id.^{16/} The
13 charge questions EPA prepared with stakeholder input helped the sub-workgroups define the
14 scope of their discussions. Id. The experts were asked to provide insights on the existing state of
15 the science, information and research gaps, as well as critical path research that they believed
16 could be completed by EPA in the next two to three years to fill the highest priority information
17 needs. Experts Report at 1-2. The Workshop’s end product, a draft summary report, was
18 finalized and published as the Experts’ Report on June 15, 2007.

19 This style of workshop is unusual and is generally reserved for difficult and important
20 issues because of the intensity of the effort and focus involved. King Decl. ¶ 20. EPA’s initiative
21 and leadership in sponsoring this scientific Workshop is indicative of its commitment to establish
22 scientifically sound water quality criteria, and the speed with which EPA planned and executed
23

24 ^{15/}(...continued)

25 almost one-quarter were recommended by Plaintiffs. King Decl. ¶ 18.

26 ^{16/} The seven topics were: Approaches to Criteria Development; Pathogens, Pathogen Indicators,
27 and Indicators of Fecal Contamination; Methods Development; Comparing Risks to Humans
28 From Different Sources; Acceptable Risk; Modeling Applications to Criteria Development and
Implementation; and Implementation Realities. Experts Report pp. 3-4.

1 the Workshop and published its final report reflects EPA's appreciation of the national
2 significance of the criteria. Id.

3 2. EPA Develops 2007 Critical Path Science Plan

4 Following completion of the Experts Report on June 15, 2007, EPA developed its
5 "Critical Path Science Plan" ("Science Plan" or "CPSP"), which it released on August 31, 2007.
6 King Decl. ¶ 21.^{17/} The Science Plan, which was promptly provided to the litigants in this case,
7 describes the high priority research and science that EPA intends to conduct to establish the
8 scientific foundation for EPA's new or revised recreational criteria recommendations. King Decl.
9 ¶ 22. All of the research activities included by EPA in the Science Plan were identified in the
10 Experts Report as high priority. Id. ^{18/} The Science Plan describes the overall research goals, key
11 science questions associated with data gaps in the existing science, and the studies that EPA
12 intends to conduct or support to develop new or revised water quality criteria for pathogens and
13 pathogen indicators. See CPSP at 1-1.

14 There are four main goals of the scientific research described in the Science Plan: (1)
15 assessment of the potential human health risks from swimming-related exposure; (2) development
16 of indicators for measuring risk; (3) development of methods for measuring the indicators; and (4)
17 extrapolation of the research results to other geographic locations and aquatic conditions in order
18 to develop national recommendations for new or revised criteria. King Decl. ¶ 24 and CPSP at 1-
19 4 and 1-5. These goals are consistent with Congress's direction in section 104(v) and represent
20

21 ^{17/} Before finalizing the Science Plan, EPA submitted a draft of the plan to three outside
22 scientific experts for independent peer-review. The outside reviewers "confirmed that the studies
23 in EPA's Science Plan reflected a generally reasonable and effective approach to answering the
24 science questions" and "supported EPA's focus on research related to non-human sources of
fecal contamination." CPSP at 3-1.

25 ^{18/} EPA's Science Plan, however, does not include all of the research activities identified as
26 important by the Workshop experts. After considering and synthesizing that input and assessing
27 additional feedback from stakeholders, EPA further prioritized the research activities identified
28 by experts so as to focus on only the studies that EPA believes can be designed, conducted, and
effectively incorporated into the development and publication of new or revised criteria by the
end of 2012. King Decl. ¶ 23; Noss Decl. ¶ 23.

1 what EPA considers essential to develop water quality criteria recommendations “based on the
2 latest scientific knowledge” (as called for by section 304(a)(1)) to protect humans from illnesses
3 associated with the presence of fecal contamination in water. King Decl. ¶ 25. To advance these
4 goals, EPA needed to understand where the data gaps are, what the key science questions are that
5 need to be answered to fill those gaps, and whether there are studies that EPA or others can
6 conduct that will yield data EPA can use to develop new or revised criteria in the relatively near
7 term (by 2012). Id. ¶ 26. The Science Plan addresses each of these needs in Chapter Three,
8 where EPA describes the data gaps, the key science questions, and the projects and research
9 activities EPA is either in the process of carrying out or intends to carry out in the near future. Id.

10 To assure a clear focus and high likelihood of success, EPA decided to include in the
11 Science Plan only those research activities that it believes are most important to achieving its goal
12 of issuing new or revised criteria recommendations that represent an important advancement in
13 public health protection by 2012. King Decl. ¶ 25. By its nature, such a deadline imposes a limit
14 on the bounds of scientific inquiry. Id. The development and publication of criteria, like all such
15 decisions, will be undertaken without perfect knowledge, but EPA is committed to materially
16 improving the 1986 criteria to significantly advance public health protection and EPA believes
17 that conducting the additional studies contemplated by the Science Plan will accomplish this
18 result. Id. EPA is required to revisit the criteria recommendations every five years to determine
19 whether they should be revised, see section 304(a)(9)(B), and future criteria will reflect future
20 scientific research and technological advances. Id.

21 While there may be other related research on pathogens in recreational waters that may be
22 performed in the near term, EPA made an expert scientific judgment to include only those
23 targeted research activities that can be completed in the next two to three years and that are most
24 likely to answer a key research question in a time frame that would allow EPA to use the
25 information gained in criteria to be published by the end of 2012. King Decl. ¶ 28.^{19/} EPA’s

27 ^{19/} EPA selected 2012 as the date for publication of the criteria because EPA recognized the need
28 (continued...)

1 decision to not include additional research activities in its Science Plan at this time in no way
2 precludes such research activities in connection with subsequent reviews and revisions of the
3 criteria. King Decl. ¶ 30. As EPA explained in the Science Plan, “EPA recognizes that a number
4 of science issues will be deferred for future criteria efforts because the current state-of-the-science
5 does not support their inclusion in the shorter term effort, or because preliminary research must be
6 completed first before remaining science issues can be addressed.” CPSP at 4-1.

7 This alignment of goals, key science questions, and research activities – together with the
8 need to develop new or revised criteria by late 2012 – was critical to the development of the
9 Science Plan. King Decl. ¶ 31. It helped EPA ensure that the Science Plan includes the research
10 activities that EPA believes it can and should conduct (or support) in order to develop in the near
11 term new or revised water quality criteria that materially advance public health protection. Id.
12 While the Science Plan does not include every study or research area identified in the Experts
13 Report, it does represent an ambitious, comprehensive, and challenging research program
14 designed to support the near-term publication of new or revised water quality criteria for
15 pathogens and pathogen indicators in recreational waters. Id.

16 In developing the Science Plan, EPA recognized that as research activities are completed,
17 data collected and analyses are conducted, EPA may identify needs to adjust or refine the research
18 described in the Plan. Noss Decl. ¶ 24. The outcome of the individual research activities, as with
19 any other such research, is uncertain. Id. Science is not static. Id. It has changed in significant
20 ways in recent years, even as EPA was engaged in conducting the epidemiologic studies in the
21 Great Lakes, and it is expected to continue to change, possibly at a much greater pace than in the
22 past. Id. A certain amount of flexibility, therefore, is built into the Science Plan. EPA describes
23 in the Plan the research that it intends to conduct, while recognizing the potential that it may need
24
25

26
27 ¹⁹/(...continued)

28 for additional research but did not want to go beyond a five-year time frame contemplated by
Congress. King Decl. ¶ 29.

1 to adjust the Plan to ensure that its research is well-founded and economical^{20/} and furthers the
2 goals and responds to the key research questions described above. Noss Decl. ¶ 25. EPA's
3 recognition of the inherent need for such flexibility is fully consistent with its commitment to
4 carry out the Plan's research activities informed by the results of this research process. Id.

5 **3. EPA Develops 2007 Criteria Development Plan**

6 Finally, in connection with the Science Plan, EPA also developed (and promptly shared
7 with Plaintiffs) EPA's "Criteria Development Plan" ("CDP"), which describes the process and
8 two-year timeline for EPA to develop and publish new or revised water quality criteria for
9 pathogens and pathogen indicators pursuant to section 304(a)(9)(A). King. Decl. ¶ 33. EPA's
10 water quality criteria recommendations will be the basis for State adoption and submission of new
11 or revised water quality standards for their coastal recreation waters for the pathogens and
12 pathogen indicators for which EPA's criteria recommendations are applicable. Section
13 303(i)(1)(B), 33 U.S.C. § 1313(i)(1)(B).

14 EPA brings over 30 years of experience to the process of developing water quality criteria
15 recommendations. King Decl. ¶ 34. EPA has published criteria recommendations for 165
16 pollutants addressing protection of human health and aquatic life. U.S. EPA 2006, National
17 Recommended Water Quality Criteria, Office of Water, Office of Science and Technology (EPA-
18 822-F-04-010). Recognizing the critical importance of criteria recommendations, EPA has
19 established a process designed to ensure that such recommendations will secure the protection of
20 the public health and represent sound public policy. (CDP at 2). Achieving these goals involves
21 the following key steps, as summarized in the Criteria Development Plan: (1) conduct
22 scientifically sound research and studies (this goal will be met by EPA's Science Plan); (2)
23 thoroughly evaluate, analyze, synthesize, and obtain scientific review of the data generated by the
24 research, studies and analyses; (3) formulate options; (4) obtain input from a wide range of
25 stakeholders including other federal agencies and various levels of government (e.g., State and
26

27 ^{20/} For example, scientists outside of EPA may perform research that obviates the need for a
28 particular study in EPA's research plan. Noss Decl. ¶ 26.

1 local) on the policy options; (5) draft and publish the proposed criteria for broad public input and
2 review, and compile and make available to the public any supplementary information that
3 provides the scientific and policy bases for EPA's recommendations; (6) carefully consider all
4 comments and views on the proposed criteria and make revisions as needed; and (7) publish final
5 criteria. CDP at 2.

6 Consistent with these steps, EPA's Criteria Development Plan provides a timeline that
7 begins in January 2011 (upon completion of the Science Plan) and ends in December 2012 with
8 EPA's publication of final criteria recommendations. The Plan discusses in detail each of the key
9 steps in the criteria development process.

10 **D. The Present Litigation**

11 **1. The Complaints**

12 In August 2006, NRDC filed a four-Count Complaint for declaratory and injunctive relief
13 against EPA. Two of NRDC's claims are relevant here.^{21/} Its First Claim asserts that section
14 104(v) of the BEACH Act "requires EPA to initiate water quality studies by April 2002 and
15 complete those studies by October 2003"; that in "failing to initiate studies that satisfy the criteria
16 of the BEACH Act by April 2002 and complete these studies by October 2003," EPA "violated"
17 section 104(v) and failed to perform a "nondiscretionary duty"; and that EPA "should be
18 compelled to comply" with section 104(v) "without further delay." NRDC Compl. ¶¶ 31-34.

19 NRDC's Third Claim cites the BEACH Act requirement in section 304(a)(9) that EPA
20 "shall publish" by October 10, 2005 new or revised water quality criteria "for pathogens and
21 pathogen indicators (including a revised list of testing methods, as appropriate)," based on the
22 results of the studies conducted under section 104(v), to protect human health in coastal recreation
23 waters. Compl. ¶ 38. NRDC alleges that EPA failed to meet that deadline and therefore failed to
24 perform a "nondiscretionary duty," and "should be compelled to comply" with section 304(a)(9)
25 "without further delay." Compl. ¶¶ 39-40.

27 ^{21/} NRDC voluntarily dismissed its Second and Fourth claims under the Administrative
28 Procedure Act ("APA").

1 In its Request for Relief, NRDC asks the Court, among other things, to: (1) declare that
2 EPA has failed to meet statutory deadlines to initiate and complete “appropriate” water quality
3 studies and to publish revised water quality criteria; (2) compel EPA to “initiate and complete
4 appropriate studies that evaluate all types of illnesses, pathogens, coastal waters, and sources of
5 beachwater pollution by a court-ordered deadline”; and (3) compel EPA to publish “revised water
6 quality criteria (including a revised list of testing methods) for pathogens and pathogen indicators
7 for use in coastal recreation waters by a court-ordered deadline.”^{22/}

8 Intervenor-Plaintiff NACWA’s complaint asserts claims similar to NRDC’s. NACWA’s
9 First Claim alleges that EPA has failed to initiate and complete water quality studies in violation
10 of an alleged non-discretionary duty under section 104(v), and asks the Court to compel EPA to
11 comply with that provision “without further delay.” (NACWA Compl. ¶¶ 28-29.) NACWA’s
12 Third Claim also tracks NRDC’s, alleging that EPA has “failed to meet the October 10, 2005
13 deadline” in section 304(a)(9) to publish revised water quality criteria for pathogens and pathogen
14 indicators (including a revised list of test methods, as appropriate) based on the results of the
15 studies conducted under section 104(v), and thus “failed to perform a nondiscretionary duty.”
16 NACWA Compl. ¶¶ 35-36.^{23/} NACWA, too, asks that EPA be “compelled to comply” with
17 section 304(a)(9) “without further delay.” Compl. ¶ 37. For relief, NACWA asks the Court to
18 declare that EPA has failed to meet statutory deadlines to initiate and complete “appropriate”
19 water quality studies and to publish revised water quality criteria based on those studies, and asks
20 the Court to order EPA (1) to initiate and complete such “appropriate” studies, and (2) publish
21 “revised water quality criteria.” (Compl. at 8.) NACWA’s Complaint, like NRDC’s, does not
22 specify what new deadlines NACWA believes should be judicially imposed on EPA.

23 The County’s complaint asserts that EPA failed to initiate and complete studies allegedly
24

25 ^{22/} As discussed *infra*, NRDC uses, without any statutory basis, the word “appropriate” to
26 describe the studies that it believes EPA is required to conduct under section 104(v), but omits
27 words “as appropriate” when describing section 304(a)(9)(A)’s direction to EPA to publish a list
of testing methods “as appropriate.”

28 ^{23/} NACWA, too, has voluntarily dismissed its APA-based Second and Fourth claims.

1 required under section 104(v) (First Claim) and failed to satisfy its non-discretionary duty under
2 section 304(a)(9) to publish revised water quality criteria for pathogens and pathogen indicators
3 (including a revised list of test methods, as appropriate) based on the results of those studies
4 (Second Claim). County Compl. ¶¶ 12, 17.²⁴/ The County, like NRDC and NACWA, asks the
5 Court to compel EPA to initiate and complete studies under section 104(v) and criteria under
6 section 304(a)(9), Compl. at 5, but proposes no deadlines for such EPA actions.

7 **2. The Court's March 23, 2007 Order**

8 In February 2007 NRDC filed a Motion for Partial Judgment on the Pleadings, seeking a
9 declaratory judgment that EPA had violated a non-discretionary duty to publish new or revised
10 water quality criteria by October 10, 2005, as required by section 304(a)(9). The Court found in
11 its March 23, 2007 Order (at 6) that it did not need to go beyond the pleadings to find that EPA
12 had not complied with section 304(a)(9), since EPA had conceded that it had not yet published
13 new or revised water quality criteria for pathogens and pathogen indicators as required by that
14 provision.²⁵/ The Court noted that in response to NRDC's motion, EPA had explained that the
15 "task of studying the problem of pathogens and pathogen indicators – the first step in developing
16 EPA's water quality criteria recommendations – is time-consuming, resource intensive,
17 controversial, and technically complicated." (Order at 6). The Court also noted EPA's
18 explanation that an epidemiological study undertaken at a Biloxi, Mississippi beach could not be
19 completed due to severe weather conditions (including Hurricane Katrina), and that four
20 epidemiological studies that EPA had already conducted on the Great Lakes led EPA to conclude
21 in 2006 that "it needed to consider expanding and/or revising future studies." (Order at 6.) The
22 Court observed that EPA had advised that it was "actively engaged in soliciting input from a wide
23 range of external scientific experts to assist EPA in identifying any needed changes to its science
24 plan before completion of the section 304(a)(9) criteria." In response, the Court stated that it

26 ²⁴/ The County's Complaint commingled APA claims (¶¶ 13, 18) with CWA claims (¶¶ 12, 17),
27 but the County has voluntarily dismissed its APA-based claims.

28 ²⁵/ The Order is published at 2007 WL 1121799.

1 “acknowledges the complexities involved in researching, developing and revising water criteria.
2 However, the Court’s job is to determine whether the EPA has violated § 1314(a)(9) [304(a)(9)],
3 not to assess whether the EPA has good cause for delay.” (Order at 6.) The Court went on to hold
4 that that provision imposes a “categorical requirement” that EPA “publish new or revised water
5 quality criteria” by October 10, 2005 and, hence, “imposes a non-discretionary duty that the EPA
6 was obligated, but failed, to abide by.” (*Id.* at 7.) The parties were directed to be prepared to
7 discuss at the then-upcoming April 2007 scheduling conference “the issue of the appropriate
8 amount of time the EPA should have to complete publication of new or revised water quality
9 criteria for pathogens and pathogen indicators.” (*Id.* at 8.)

10 Although NRDC’s Complaint requested that EPA be compelled to comply with section
11 304(a)(9) “without further delay” (Compl. ¶ 40), NRDC did not propose at the April 2007
12 scheduling conference a timeline setting out the appropriate amount of time that NRDC believes
13 EPA should be afforded to publish new or revised water quality criteria for pathogens and
14 pathogen indicators. Even now, after NRDC has engaged in wide-ranging fact-discovery, NRDC
15 declines to propose such a timeline for the Court’s consideration.

16 3. The Present Motions

17 a. Plaintiffs’ Motions For Partial Summary Judgment

18 NRDC now has filed a second “partial” summary judgment motion, this time seeking a
19 ruling “that EPA has failed to initiate and complete the studies required by the BEACH Act”
20 (NRDC Mem. at 2) and therefore is in violation of section 104(v) as a matter of law. *Id.*^{26/} NRDC
21 contends that while EPA’s Critical Path Science Plan does outline the Agency’s plans to develop
22 and finalize water quality criteria that will discharge EPA’s obligations under section 304(a)(9),
23 “triable issues of fact remain regarding the adequacy of EPA’s intended plan to comply with the
24 study requirements of the BEACH Act.” (NRDC Mem. at 12, emphasis added .) NRDC refers to
25 a hearsay document (Ex. K, “Expert Report of Dr. Jennifer A. Jay”) submitted with its current
26

27 ^{26/} NRDC asserts (NRDC Mem. at 1-2) that EPA “concedes that it failed to comply with its
28 statutory obligation to initiate and complete the necessary studies.”

1 motion to assert that EPA's Science Plan has "significant deficiencies" that must be adjudicated at
2 a "trial on the appropriate remedy." (NRDC Mem. at 12-13) NRDC asserts that the Court, in its
3 March 23, 2007 Order, "previously ruled" that EPA had failed to meet the BEACH Act's section
4 304(a)(9) deadline to publish water quality criteria based on "appropriate studies." (NRDC Mem.
5 at 1.) NRDC argues that a trial is necessary so the Court can determine what studies are
6 "appropriate" for EPA to perform in order to publish the criteria. Id.

7 In its motion for partial summary judgment, the County seeks an order declaring that EPA
8 has failed to comply with allegedly non-discretionary duties to "initiate and complete all studies
9 required by" section 104(v). See County Proposed Order at 2.²⁷/ For its part, NACWA similarly
10 asserts that EPA has not "initiated or completed studies that satisfy the requirements of the
11 BEACH Act." NACWA Mem. at 3.²⁸/ NACWA and the County propose substantially different
12 orders to address EPA's failure to fully satisfy section 104(v). The County requests (County
13 Mem. at 12-13; Proposed Order at 2-3) that EPA be ordered to submit within 30 days (a) "a
14 description and schedule of studies to be performed by" EPA that meet the "requirements" of
15 section 104(v); (b) a schedule for publication of "guidance for State application" of the new or
16 revised water quality criteria required to be published by section 304(a)(9); and (c) a schedule for
17 publishing such water quality criteria, in addition to a "revised list of testing methods as
18 appropriate, that meet the requirements of" section 304(a)(9). The County states that, upon
19 finding that EPA has submitted "a description and schedule of studies" that meet the
20 "requirements" of section 104(v), a schedule for the "publication of guidance," and a schedule for
21 "publishing revised water quality criteria" and a "list of testing methods," the Court "should then
22 issue an injunction requiring defendants to perform those studies and comply with those
23
24

25 ²⁷/ The County states (County Mem. at 6) that EPA has admitted during discovery that it has
26 neither initiated nor completed all the studies "required by" section 104(v).

27 ²⁸/ The County and NACWA ask the Court to award them judgment on their section 304(a)(9)
28 claim, see March 23, 2007 Order, the County's and NACWA's requests are moot.

1 schedules.” (County Mem. at 13.)^{29/} Unlike NRDC, the County does not argue that a trial is
2 necessary for the Court to order a remedy.^{30/}

3 NACWA seeks partial summary judgment on its section 104(v) and 309(a)(9) claims, and
4 states that it “anticipates future briefing on the appropriate remedy for EPA’s failure to meet these
5 deadlines.” (NACWA Mem. at 4.) In its Proposed Order (at 1), NACWA asks the Court to rule
6 that the “only issue remaining for trial in this matter is the appropriate form of order requiring
7 EPA to initiate and complete the studies required by” section 104(v) and to “publish the criteria
8 required by” section 304(a)(9). Consistent with NRDC and the County, NACWA declines to
9 propose a timeline for EPA to accomplish the foregoing tasks. Like the County, NACWA does
10 not mention, let alone discuss, EPA’s Science Plan or Criteria Development Plan, which EPA
11 were provided to them in August 2007.

12 **b. EPA’s Cross Motion for Summary Judgment on Remedy**

13 EPA takes an entirely different approach from Plaintiffs. EPA submits that trial is
14 unnecessary, that the Court lacks authority to order EPA to perform particular studies under the
15 BEACH Act, and that the Court should bring this matter to an efficient and timely conclusion by
16 issuing a straightforward order enjoining EPA to publish the section 304(a)(9) criteria by
17 December 15, 2012.

18 **STANDARD OF REVIEW**

19 Rule 56(c) of the Federal Rules of Civil Procedure provides that summary judgment “shall
20 be rendered forthwith if the pleadings, . . . together with the affidavits, if any, show that there is
21 no genuine issue as to any material fact and that the moving party is entitled to a judgment as a
22 matter of law.” See Celotex Corp. v. Catrett, 477 U.S. 317, 323 n.4 (1986) (citing Anderson v.
23 Liberty Lobby, Inc., 477 U.S. 242, 247 (1986)).

24
25
26 ^{29/} The County does not acknowledge the existence of EPA’s Science Plan.

27 ^{30/} NACWA asserts (Mem. at 3) that EPA has admitted during discovery that it has neither
28 initiated nor completed all the studies required by” section 104(v).

DISCUSSION

I. INJUNCTIVE RELIEF IN THIS CASE SHOULD BE LIMITED TO AN ORDER REQUIRING EPA TO PUBLISH BY DECEMBER 15, 2012 THE NEW OR REVISED WATER QUALITY CRITERIA REQUIRED BY CWA SECTION 304(a)(9)

This Court has previously found that EPA failed to discharge its non-discretionary duty under section 304(a)(9) to publish new or revised water quality criteria for pathogens and pathogen indicators within five years of October 10, 2000. Given that finding, the Court has authority to set a new deadline for EPA to comply with that missed statutory obligation. EPA submits that the deadline for such EPA action should be December 15, 2012, and that no further relief is appropriate with respect to section 304(a)(9). With respect to the claim that EPA has not fully discharged its statutory obligations under section 104(v), EPA does not oppose entry of an order to that effect. However, the Court should not issue any injunctive relief beyond setting a deadline for EPA to publish the criteria mandated by section 304(a)(9).

Choosing to proceed in piecemeal fashion, Plaintiffs do not address the specifics of any remedy under section 304(a)(9). Nothing in their current papers, however, indicates that they would disagree that EPA should be afforded sufficient additional time to draft and publish the section 304(a)(9) criteria, given the undeniable complexity of that undertaking.

Any injunctive order that does more than impose a deadline for EPA to complete action under section 304(a)(9) would be ill-founded. Such an injunction would extend beyond the authority conferred by Congress on the Court for enforcing any failure by EPA to comply with a non-discretionary CWA duty, including the duty imposed by section 304(a)(9).

With respect to section 104(v), NRDC again chooses not to address the specifics of the remedy. NRDC does suggest, however, that it will seek a far-reaching order enjoining EPA to conduct specified studies in order to draft the section 304(a)(9) criteria. See, e.g., NRDC Mem. at 12, indicating that NRDC intends to ask the Court to order certain “epidemiological studies” in “tropical regions” and studies specifically addressing “waters impacted primarily by urban or agricultural run-off or animal sources.” NRDC declines to address (except obliquely, in its attached expert report), the timing of such studies. The injunction that NRDC (and perhaps

1 Plaintiff-Intervenors) apparently contemplates under section 104(v) would extend beyond the
2 authority conferred by Congress to enforce any EPA failure to comply with a non-discretionary
3 duty and is fundamentally flawed. The Court should not require EPA to conduct specified studies
4 in order to discharge its obligations under the BEACH Act and NRDC's demand for a trial should
5 be rejected.

6 **A. Under The CWA Citizen Suit Provision, The Court's Authority To Remedy**
7 **Any Failure By EPA To Comply With A Non-Discretionary Duty Is Limited**
8 **To Imposing A Deadline For EPA To Discharge That Duty.**

9 The United States can be sued only if it has consented to be sued and that consent must be
10 found in a clear, unequivocal, and specific statement in the text of the statute at issue. See, e.g.,
11 United States Dep't of Energy ("DOE") v. Ohio, 503 U.S. 607, 615 (1992). The waiver of
12 sovereign immunity "'cannot be implied but must be unequivocally expressed,'" Army & Air
13 Force Exch. Serv. v. Sheehan, 456 U.S. 728, 734 (1982) (quoting United States v. Testan, 424
14 U.S. 392, 399 (1976)), and may not be "enlarged beyond what the language requires." DOE v.
15 Ohio, 503 U.S. at 607 (internal citation omitted). Even when Congress enacts a statute that
16 waives the sovereign immunity of the United States in some circumstances, the statute must be
17 construed narrowly and strictly in the sovereign's favor. See, e.g., DOE v. Ohio, 503 U.S. at 615,
18 620-28. These requirements go directly to a court's jurisdiction to hear an action and award relief
19 against the United States. First Virginia Bank v. Randolph, 110 F.3d 75, 77 (D.C. Cir. 1997).

20 Like the waiver of immunity to suit itself, a waiver of immunity as to a particular remedy
21 also must be "unequivocally expressed" and "will not be implied." Lane v. Pena, 518 U.S. 187,
22 192, 196-97 (1996). These principles apply to the evaluation of available remedies against the
23 United States under the CWA citizen suit provision at issue. DOE v. Ohio, 503 U.S. at 615-19
24 (applying sovereign immunity principles in evaluating availability of civil penalty remedies under
25 citizen suit provisions of the CWA and Resource Conservation and Recovery Act ("RCRA")).^{31/}

26 ^{31/} The Supreme Court has consistently interpreted analogous citizen suit provisions of federal
27 environmental statutes similarly. DOE v. Ohio, 503 U.S. at 615; Hallstrom v. Tillamook County,
28 493 U.S. 20, 23 n.1 (1989) (noting that most of the citizen suit provisions, including the CWA's,
(continued...)

1 The only jurisdictional basis for NRDC's (and Plaintiff-Intervenors') claims regarding
2 EPA's failure to timely publish water quality criteria under section 304(a)(9) or EPA's duty to
3 initiate and complete studies under section 104(v) is the CWA's citizen suit provision, 33 U.S.C.
4 § 1365(a)(2), and the only remedy available for a breached non-discretionary duty under that
5 provision is a court order directing EPA to perform such duty. Specifically, the citizen suit
6 provision as a whole defines three separate rights of action, of which the non-discretionary duty
7 provision is one, each with an attendant remedial provision specifying the scope of the Court's
8 remedial authority and discretion for each specific action. The right of action relevant here allows
9 suit against the Administrator where there is alleged a failure to perform any non-discretionary act
10 or duty under the CWA. 33 U.S.C. § 1365(a)(2). The provision goes on to state that the "district
11 courts shall have jurisdiction, without regard to the amount in controversy or the citizenship of the
12 parties . . . to order the Administrator to perform any such act or duty." *Id.* (emphasis added).

13 Thus, for suits alleging an EPA failure to perform a non-discretionary duty in this context,
14 Congress limited the waiver of sovereign immunity to one remedy: ordering EPA to perform the
15 unsatisfied duty. An injunction providing additional relief falls outside this limited waiver.

16 Aside from the sovereign immunity issue, any suggestion that this Court should dictate the
17 content of the criteria to be published or should order EPA to conduct particular studies in order to
18 draft and publish those criteria would violate traditional statutory construction canons related to
19 remedy. It is an "elemental canon of statutory construction that where a statute expressly provides
20 a particular remedy or remedies, a court must be chary of reading others into it." Middlesex
21 County Sewerage Authority v. Nat'l Sea Clammers Ass'n, 453 U.S. 1, 15-16 (1981) (quoting
22 Transamerica Mortgage Advisors, Inc v. Lewis, 444 U.S. 11, 19 (1979). "In the absence of strong
23 indicia of a contrary congressional intent, we are compelled to conclude that Congress provided
24 precisely the remedies it considered appropriate." Middlesex County, 453 U.S. at 15. These
25 limiting principles apply fully to determining whether the express remedy provided by Congress is

26
27 ³¹/(...continued)

28 were modeled after similar provisions in the Clean Air Act ("CAA") citizen suit provision).
Thus, rulings under the CAA and RCRA citizen suit provisions generally apply to the CWA.

1 intended to be the exclusive remedy. See, e.g., Gov't of Guam v. Am. President Lines, 28 F.3d
2 142, 145-46 (D.C. Cir. 1994). Here, the citizen suit provision provides a specific remedy for a
3 failure to perform a non-discretionary duty, which is to order that duty to be performed. Any
4 additional remedy cannot be squared with the doctrine of sovereign immunity or with the
5 principle that courts generally are limited by the specific remedies legislated by Congress.

6 The County (Mem. at 14) cites Weinberger v. Romero-Barcelo, 456 U.S. 305, 318 (1982),
7 apparently for the proposition that the CWA confers discretion on district courts. However,
8 Weinberger is not helpful to Plaintiffs. That case involved claims against the Navy under section
9 505(a)(1) of the CWA's citizen suit provision, 33 U.S.C. 1365(a)(1), which provides for citizen
10 suit enforcement against any person who is "in violation" of the CWA. In such situations
11 Congress provided district courts with authority to enforce the underlying CWA standard. The
12 issue in Weinberger was actually whether a court could order less relief than authorized by
13 Congress, which the Supreme Court answered in the affirmative. Here, in contrast, Congress has
14 authorized only narrow relief for EPA's failure to perform a non-discretionary duty and the
15 Plaintiffs are seeking to broaden that authorization.

16 More applicable is the Supreme Court's decision in a more recent case, Lane v. Pena, 518
17 U.S. at 196-97, where the Court considered whether monetary damages were available against the
18 United States for a violation of the Rehabilitation Act of 1973, 29 U.S.C. § 791-794(e), even
19 though no such remedy was specifically identified in the statute. The plaintiff in Lane claimed
20 that the courts retained the authority to award money damages because Congress had provided for
21 "all appropriate remedies" in the statute. But the Court held that "where a cause of action is
22 authorized against the federal government, the available remedies are not those that are
23 'appropriate,' but only those for which sovereign immunity has been expressly waived." Lane,
24 518 U.S. at 197. The Court concluded that it would contravene sovereign immunity principles to
25 infer that Congress intended additional remedies against the government beyond those expressly
26 provided. Id. Similarly here, Congress provided that the remedy for an EPA failure to perform a
27 non-discretionary duty is "to order the Administrator to perform such act or duty." Any injunction
28

1 prescribing the content of the criteria to be published or the performance by EPA of specific
2 studies to support those criteria would exceed this express waiver of sovereign immunity.^{32/}

3 This is not to say that a district court lacks all equitable discretion to fashion an
4 appropriate remedy for a CWA deadline violation. A court may consider the complexity of the
5 task at hand, EPA's budget, resource constraints, and similar factors in developing a reasonable
6 deadline for the Administrator to perform a non-discretionary duty. Put another way, a district
7 court need not order EPA to act as soon as possible, or even to act at all, but retains discretion to
8 set an appropriate and reasonable time for the discharge of the specific duty mandated by the
9 statute. Contrary to NRDC's and Plaintiff-Intervenors' suggestions, however, the courts do not
10 have "equitable discretion" under the CWA citizen suit provision to issue an injunction against
11 EPA that would dictate the content of the water quality criteria to be published or dictate the
12 studies that EPA will perform in support of those criteria.

13 **B. Courts Routinely Prescribe, Without Trial, Deadlines For The Completion Of**
14 **Agency Action Following An Agency's Failure To Perform A Non-**
15 **Discretionary Duty And There Is No Reason To Divert From That Practice**
16 **Here**

17 In its March 23, 2007 Order, this Court held that CWA section 304(a)(9) imposes a
18 requirement that EPA "publish new or revised water quality criteria" by October 10, 2005, and,
19 hence, "imposes a non-discretionary duty that the EPA was obligated, but failed, to abide by."
20 (Order at 7.) The Court directed that the parties be prepared to discuss "the issue of the
21 appropriate amount of time the EPA should have to complete publication of new or revised water
22 quality criteria for pathogens and pathogen indicators." (Order at 8.) For the reasons set forth in
23 the King and Noss Declarations, and discussed more fully in Section D, infra, EPA respectfully
24 submits that such publication date should be December 15, 2012. By that time, EPA will have
25 completed: (1) scientific studies sufficient to discharge EPA's non-discretionary duty under
26 section 104(v); and (2) those additional studies that EPA, in its discretion, believes will be
27 sufficient to inform and support the new or revised water quality criteria. Most importantly, EPA

28 ^{32/} The County also cites Alaska Center for the Environment v. Browner, 20 F.3d 981 (9th Cir.
1994), but that case was decided prior to the Supreme Court's 1996 decision in Lane.

1 will by such date have completed the work that it considers necessary to finalize and publish those
2 criteria. The Court should not need a trial to arrive at an equitable decision imposing such a
3 deadline.

4 Despite the passage of more than eight months since the Court issued its March 23, 2007
5 Order, NRDC has declined to take a position on the core issue that the Court identified therein –
6 how much time EPA should be given to publish the criteria mandated by section 304(a)(9).^{33/}
7 Instead, NRDC argues that the Court should hold a trial next year in order to determine what
8 studies are “appropriate” for EPA to publish the criteria. Presumably, NRDC will at some point
9 after trial finally state its position on how long EPA should be given to complete NRDC’s suite of
10 favored studies and to publish the section 304(a)(9) criteria. The Court should reject NRDC’s
11 piecemeal and protracted approach to bringing this case to conclusion.

12 Contrary to NRDC’s suggestion that this matter can only be resolved through trial, the
13 case law demonstrates that district courts routinely prescribe – on summary judgment motion and
14 without resort to trial – deadlines for the completion of agency action following an EPA failure to
15 perform a statutory duty. For example, in American Lung Association v. Browner, 884 F. Supp.
16 345 (D. Ariz. 1994), it was established that EPA had failed to discharge its statutory obligation to
17 revise certain air quality standards. The court stated that summary judgment was appropriate
18 “where, as here, it remains only for the Court, acting in its discretion, to fashion an equitable
19 remedy.” Id. at 346. The court cited with approval Sierra Club v. Ruckelshaus, 602 F. Supp. 892
20 (N.D. Cal. 1984), an earlier case where EPA had failed to meet a statutory deadline. In imposing
21 a deadline, the Sierra Club court stated that summary judgment was appropriate regarding the
22 “purely equitable” issue of how the court “should exercise its power as a chancellor in fashioning
23 a remedy.” Id. at 898 n.9. That court rejected the suggestion that it needed to decide “material
24

25 ^{33/} NRDC also provided a manifestly unresponsive answer to EPA’s interrogatories specifically
26 directed at that issue, and then compounded that failure by refusing to attend a Rule 30(b)(6)
27 deposition noticed by the United States to obtain that information through deposition. See
28 NRDC’s response to EPA Interrogatory No. 5 (Ex. “A” to McDermott Declaration submitted
herewith).

1 issues of fact” before it could fashion that remedy. Id. The parties in American Lung advanced
2 competing schedules for EPA to accomplish the statutorily-mandated actions and, on motion, the
3 court determined an appropriate schedule for the Agency to act. In reaching its decision that EPA
4 be required to publish its regulations in several years, the court analyzed both parties’ proposals
5 before arriving at its own “revised timetable.” 884 F. Supp. at 348.

6 The court in NRDC v. EPA, 797 F. Supp. 194 (E.D.N.Y. 1992), proceeded in similar
7 fashion. Because it was undisputed that EPA had failed to satisfy a non-discretionary duty to
8 issue certain guidance by a statutory deadline, the court stated that the only issue for resolution
9 was “what remedy it should order to address EPA’s failure to heed the Congressional directive
10 enunciated in the Act.” Id. at 196. On summary judgment, NRDC requested that EPA be ordered
11 to publish final regulations in four months; EPA countered that it required seven months. After
12 reviewing “evidentiary material” in the form of declarations submitted by the parties in support of
13 their proposed schedules, the Court resolved the motions (and the case) by imposing a date for
14 EPA action that was later than that proffered by NRDC but earlier than EPA had proposed. 797
15 F. Supp. at 198-99.

16 Sierra Club v. Thomas, 658 F. Supp. 165 (N.D. Cal. 1987), is also instructive. There, the
17 court determined that EPA had failed to meet a deadline to issue certain regulations. After
18 considering the parties’ submission of “evidence supporting their positions as to the length of time
19 to be allowed” for EPA to promulgate the regulations, the district court – again on motion and
20 without trial – set a date for EPA to publish the mandated regulations. Id. at 170, 174-75. The
21 evidence before the court in Sierra Club v. Thomas consisted of the parties’ declarations.

22 More recently, in Sierra Club v. Johnson, 444 F. Supp. 2d 46 (D.D.C. 2006), a district
23 court took the same efficient approach to resolving a deadline suit. The parties cross-moved for
24 summary judgment on remedy for EPA’s conceded non-compliance with statutory deadlines to
25 promulgate certain regulations. In describing the motions, the court stated that “the only dispute
26 concerns the schedule under which the Court should order EPA to discharge its statutory duty.”
27 Id. at 47-48. After considering declarations addressing that narrow question and weighing the
28

1 parties' justifications for their proffered schedules, the court established a deadline for EPA to
2 promulgate the regulations. *Id.* at 60. Trial was not deemed necessary to reach that result.

3 In sum, courts routinely determine and impose, on summary judgment and without trial,
4 equitable schedules for EPA to come into compliance when it fails to discharge a non-
5 discretionary mandate. This Court should do the same. Under the CWA's citizen suit provision,
6 the Court is empowered to set a new date for EPA to publish criteria under section 304(a)(9) and
7 through the current briefing and declarations will be in a position to do so without resort to
8 resource-intensive and distracting trial proceedings. In addition to being wasteful, NRDC's
9 approach – through which the Court would adjudicate what studies EPA will perform – would
10 improperly interject the Court into EPA's decisionmaking on matters involving scientific,
11 technical and policy matters.

12 **C. Any Injunctive Relief Should Be Limited To The Imposition Of A Date For**
13 **EPA To Publish New Or Revised Water Quality Criteria Pursuant To CWA**
Section 304(a)(9)

14 NRDC seeks a ruling that EPA has failed to initiate and complete “the studies required by
15 the BEACH Act” and is therefore in violation of section 104(v) “as a matter of law.” (NRDC
16 Mem. at 2.) Relatedly, NRDC contends that the Court's March 23, 2007 Order ruled that EPA
17 had failed to meet section 304(a)(9)'s deadline to publish water quality criteria based on
18 “appropriate studies.” (NRDC Mem. at 1.) While NRDC acknowledges that EPA has issued a
19 Science Plan setting out EPA's plans to conduct studies and develop the water quality criteria,
20 NRDC maintains that “triable issues of fact remain regarding the adequacy of EPA's intended
21 plan to comply with the study requirements of the BEACH Act.” (Mem. at 12, emphasis added.)
22 NRDC argues that the Science Plan has “significant deficiencies” and that a trial must be held so
23 the Court can determine the “appropriate” studies that EPA would be required to perform in order
24 for the Agency to draft and publish the section 304(a)(9) criteria. (Mem. at 12-13.) We disagree.

25 First, it makes no sense to force EPA to expend its limited resources on protracted
26 litigation and trial when those resources can better be spent on developing the section 304(a)(9)
27 criteria. The Agency scientists and administrators who would be involved in preparing for and
28

1 testifying at trial are the same personnel who are working to accomplish the drafting and
2 publication of the new or revised section 304(a)(9) criteria. Their attention has already been
3 partially diverted from that task by this litigation, as they responded to discovery and sat for
4 depositions. See City of Highland Park v. Train, 374 F. Supp. 758, 767 (D.C. Ill. 1974) (litigation
5 “interrupts the on-going process of regulation development and other substantive EPA
6 concerns.”). Continuing this diversion of agency resources through a trial would only serve to
7 undermine EPA’s ability to complete the important regulatory task at hand. A simple and
8 straightforward order imposing a reasonable deadline for EPA to publish the criteria is the best
9 way to realize the objectives of the CWA.

10 Second, contrary to NRDC’s suggestion, in its March 23, 2007 Order this Court did not
11 find that EPA had failed to meet the BEACH Act’s section 304(a)(9) deadline to publish water
12 quality criteria based on “appropriate studies.” (NRDC Mem. at 1.) The Court merely found that
13 the BEACH Act imposes a non-discretionary duty on EPA to “publish new or revised water
14 quality criteria” by October 10, 2005 and that EPA had failed to “abide by” that duty. (Order at
15 7.) NRDC’s argument that the Court should hold a trial to determine what studies are
16 “appropriate” for EPA to conduct so that the Agency will be in position to publish the section
17 304(a)(9) criteria is traceable to NRDC’s misapprehension that the BEACH Act imposes a non-
18 discretionary duty on EPA to perform “appropriate” studies. Section 104(v) merely directs EPA
19 to “initiate” (within 18 months of the statute’s enactment) and “complete” (within three years
20 after enactment) studies “to provide additional information” for EPA to use in accomplishing
21 various tasks related to criteria development: an assessment of human health risks from exposure
22 to pathogens in coastal recreation waters; indicators for improving the timely detection of such
23 harmful pathogens; improved methods for detecting such pathogens; and guidance for State
24 application of the section 304(a)(9) criteria to account for the diversity of geographic and aquatic
25 conditions. Section 104(v) does not specify any precise studies that EPA must perform.
26 Understandably, section 104(v) leaves the selection, design and conduct of those studies to the
27 discretion of EPA, the agency charged with carrying out the CWA.

1 The CWA citizen suit provision, section 505(a)(2), was “intended to provide relief only
2 in a narrowly-defined class of situations in which the Administrator failed to perform a mandatory
3 function.” Kennecott Copper Corp. v. Costle, 572 F.2d 1349, 1355 (9th Cir. 1978). It was not
4 intended to “permit the court to direct the manner in which any discretion given the Administrator
5 in the performance of those functions should be exercised.” Id. (quoting Wisconsin's Envtl.
6 Decade, Inc. v. Wisconsin Power & Light Co., 395 F. Supp. 313, 321 (W.D. Wis. 1975). While
7 section 104(v) does impose an obligation on EPA to initiate and complete studies to provide EPA
8 with additional information bearing on the matters enumerated in that section, the language and
9 structure of section 104(v) differ from that found in a typical non-discretionary duty provision,
10 such as section 304(a)(9). In a typical non-discretionary duty provision, the statute will
11 “‘categorically mandate’ that all specified action be taken by a date-certain deadline.” Sierra Club
12 v. Thomas, 828 F.2d 783, 791 (D.C. Cir. 1987) (emphasis in original). See also Mountain States
13 Legal Found. v. Costle, 630 F.2d 754, 766 (10th Cir. 1980) (citizen suit jurisdiction proper only in
14 actions to enforce “specific nondiscretionary clear-cut requirements”). Here, section 304(a)(9) not
15 only sets a firm date for agency action (Oct. 10, 2005), it also unambiguously defines the precise
16 nature of the duty – publication of new or revised criteria – that is enforceable in a citizen suit.

17 In contrast, section 104(v) only directs EPA to initiate and complete studies that will allow
18 EPA to obtain “additional information” on various topics related to criteria development. Such a
19 direction to perform studies is too general to provide the basis for an injunction mandating, for
20 example, that EPA perform any specific studies, such as a study of “tropical” waters. Unlike
21 section 304(a)(9), which has a clear objective and stopping point – the publication of new or
22 revised water quality criteria – section 104(v) lacks precision that would enable a court to examine
23 the Agency’s conduct and determine whether the duty had been fully discharged. In other words,
24 while section 104(v) does direct the Agency to perform “studies” (more than one, but not
25 necessarily more than two) to acquire additional information, at bottom the specific activities and
26 research that EPA conducts to fulfill section 104(v) are inherently discretionary. It is for the
27 Agency – not Plaintiff or even the Court – to decide whether EPA has gathered sufficient
28

1 information to accomplish the mandatory action that is clear-cut – publication of water quality
2 criteria under section 304(a)(9). Section 104(v) is simply not sufficiently clear-cut to form the
3 basis for the type of detailed injunctive relief apparently contemplated by Plaintiffs.

4 Further, although section 104(v) has several features typically found in non-discretionary
5 duty provisions – EPA “shall” initiate and complete an action (studies) by a date-certain (October
6 10, 2005) – the section provides only general directions to EPA to obtain new information on
7 various topics. It does not indicate, let alone dictate in mandatory terms, how many studies should
8 be conducted or how they should be designed. Nor does the section define a clear cut stopping
9 point for a court to discern when EPA would have completed all of the supposedly “correct”
10 studies under the section. Is the duty to study a problem discharged only when perfect
11 information is in hand, such that all scientists with expertise in the fields of study would agree that
12 nothing remains to be studied? Or is that duty discharged when an expert witness testifying on
13 NRDC’s behalf deems the studies sufficient? Neither seems correct, particularly since the
14 BEACH Act, as written, allocated EPA a very narrow 18-month window to conduct studies (i.e.,
15 only until October 2003 to “complete” studies that the Agency was to have “initiated” by April
16 2002).

17 The Court need not resolve the question of when EPA will have discharged its duty to
18 obtain “additional information” through studies under section 104(v). Given the absence of a
19 clear-cut benchmark that would demarcate when sufficient studies have been performed, the
20 prudent course is for the Court to exercise its equitable discretion and simply impose an end date
21 for EPA’s publication of the criteria, while allowing time for EPA to complete the research it
22 deems necessary. This is particularly true in this instance, where EPA has not only already
23 conducted various studies that have provided additional information consistent with section
24 104(v) but also plans to conduct additional studies that will furnish information relevant to the
25 specifically mandated task of publishing the mandated new or revised water quality criteria. EPA
26 understands that to be effective, such criteria must be based on sound science, and EPA intends to

1 expeditiously acquire the information that EPA's expert staff believes will accomplish that task.^{34/}

2 Moreover, an order requiring EPA to publish new or revised water quality criteria for
3 pathogens and pathogen indicators will satisfy any outstanding obligations EPA has under section
4 104(v) because of the relationship between sections 104(v) and 304(a)(9). The studies described
5 in section 104(v) are subsumed within the research activities that EPA has conducted and will
6 continue to conduct to publish criteria under section 304(a)(9). Under section 304(a)(9)(A), the
7 Administrator is to publish new or revised water quality criteria for pathogens and pathogen
8 indicators "based on the results of the studies conducted under section 104(v)," for the purpose of
9 protecting human health in coastal recreation waters. Conversely, section 104(v) directs EPA to
10 complete studies "to provide additional information" for EPA to use in activities that are involved
11 in developing water quality criteria for pathogens and pathogen indicators: (1) developing an
12 assessment of human health risks from exposure to pathogens in coastal recreation waters; (2)
13 developing indicators for improving the timely detection of such harmful pathogens; (3)
14 developing improved methods for detecting such pathogens; and (4) developing guidance for
15 State application of the section 304(a)(9) criteria to account for the diversity of geographic and
16 aquatic conditions. These four items are the interim, preparatory activities involved in
17 developing new or revised criteria. They are consistent with the goals and research activities in
18 EPA's Science Plan.^{35/} Thus, when EPA publishes the section 304(a)(9)(A) criteria, the Agency

20 ^{34/} As discussed in the Noss Declaration (§ 20), EPA has already initiated various studies to
21 acquire additional information as contemplated by section 104(v)(1) - (4), and has completed
22 some of those studies. Also, as discussed in EPA's Science Plan, EPA intends to conduct a
23 number of additional studies to inform and support its drafting of water quality criteria under
24 section 304(a)(9). While the multiple additional studies to be undertaken pursuant to the Science
25 Plan are of the type contemplated under section 104(v) and would certainly discharge EPA's
general section 104(v) obligations, EPA designed that Science Plan with the ultimate goal of
publishing sound criteria under section 304(a)(9).

26 ^{35/} This view of the section 104(v) requirements as part and parcel of the section 304(a)(9)
27 requirements is consistent with NRDC's arguments regarding standing. NRDC does not argue
28 that its members are injured by EPA's lack of research alone, but rather by EPA's failure to
publish criteria based on the studies.

1 will have completed the studies contemplated under section 104(v).

2 Any claim by Plaintiffs that this Court has jurisdiction to order EPA to conduct particular
3 studies is flawed for another reason – such a claim for relief is not justiciable. “Justiciability is a
4 threshold requirement arising out of the Article III ‘case or controversy’ clause.” Nat’l Coal Ass’n
5 v. Marshall, 510 F. Supp. 803, 805 (D.D.C. 1981) (citing Flast v. Cohen, 392 U.S. 83, 95 (1968)).
6 Claims are deemed non-justiciable where (1) their resolution requires a court to make a
7 determination that is not a matter of judicial expertise but of “management, public policy, or
8 technical expertise”; (2) the requested relief “usurps the functions of a coordinate branch of
9 government”; or (3) the requested relief “is not judicially manageable.” Nat’l Coal, 510 F. Supp.
10 at 805. Any request that this Court adjudicate and dictate the studies that EPA should
11 “appropriately” conduct under the BEACH Act runs afoul of all three of these factors. The
12 decision on which studies to conduct undoubtedly implicates policy and managerial decisions and
13 involves the Agency’s exercise of its technical expertise. Further, an injunction ordering EPA to
14 conduct particular studies would usurp an Executive Branch agency’s functions and potentially
15 mire the Court in future disputes on whether EPA has “completed” a study and whether that study
16 was an “appropriate” one. See, e.g., Conservation Law Foundation v. Mineta, 131 F. Supp.2d 19,
17 28 n.20 (D.D.C. 2001) (in refusing to second-guess agency’s choice of which studies to rely on,
18 court stated: “It is simply not the Court’s role to interject itself into this extremely technical
19 scientific debate; indeed, this is precisely the type of issue in which the Court should properly
20 defer to Defendants’ expertise.”).

21 By way of example, as EPA previously advised the Court, extreme weather disrupted a
22 earlier BEACH Act study in Mississippi. In the event a comparable disruption were to occur in
23 the future when EPA is performing what NRDC submits is a “non-discretionary study,” the Court
24 might be asked to second-guess EPA’s decision to abandon that study and rely on data obtained
25 from other sources. In such a situation, who decides whether a study is “completed”? In the same
26 vein, if EPA decides that adequate information is available through extrapolation from existing
27 data and that performing a further study would be unproductive or too costly given its expected
28

1 outcome, NRDC's approach would involve the Court in micro-managing EPA's decisions on
2 these inherently discretionary matters.

3 The acquisition of scientific information is a dynamic and unpredictable process. There
4 may be instances where a single study furnishes a sufficient basis for agency action and other
5 situations where an agency requires many years and a host of studies to reach the point where it
6 believes it is able to take a action. In still other cases, an agency may be able to gain sufficient
7 knowledge entirely from studies undertaken in foreign countries or by other entities in the United
8 States, such as universities and research institutes. Whereas the BEACH Act includes a clear
9 benchmark in section 304(a)(9) that allows a court to determine whether EPA has discharged its
10 statutory duty (publication of the criteria), section 104(v) has no such clear benchmark. There is
11 no objective standard in section 104(v) that allows a court to determine the point at which EPA
12 has fully discharged an obligation to study a problem. Further, while section 304(a)(9) instructs
13 EPA to utilize the information obtained through studies conducted pursuant to section 104(v),
14 nothing in section 304(a)(9) mandates that EPA perform any particular studies in order to draft the
15 criteria.

16 The courts accord EPA a high degree of deference when it is evaluating "scientific data
17 within its technical expertise." City of Waukesha v. EPA, 320 F.3d 228, 247 (D.C. Cir. 2003).
18 See also Nat'l Petrochemical & Refiners Ass'n v. EPA, 287 F.3d 1130, 1135 (D.C. Cir. 2002) (per
19 curiam) ("[d]eference is particularly great where EPA's decision is based on complex scientific or
20 technical analysis."). EPA deserves such deference in this context, where the duty at issue centers
21 on the study of a problem in order to make the operative decision, here issuance of criteria.
22 Moreover, under the doctrine of separation of powers, "courts must be careful not to interfere in
23 the workings of the other two branches of government." Alvidres-Reyes v. Reno, 981 F. Supp.
24 1008, 1009 W.D. Tex. 1997) (vacated on other grounds, 180 F.3d 199 (5th Cir. 1999). "Courts do
25 not have the inherent right or the necessary expertise to micromanage the actions of either
26 branch." Id. at 1009. See also In re Barr Laboratories, 930 F.2d 72, 76 (D.C. Cir. 1991) (agency
27 is in "a unique and authoritative position to view its projects as a whole, estimate the prospects for
28

each, and allocate its resources in the optimal way.”).

Even where a court finds that an agency has violated a statutory deadline, “equitable relief does not necessarily follow.” Barr Laboratoriess, 930 F.2d at 76 (stating that courts should generally refrain from “reordering agency priorities.”). Given that EPA has already initiated and completed various studies under section 104(v), and given that EPA intends to perform additional studies pursuant to its Science Plan in the interest of crafting sound water quality criteria, the Court should limit its remedial order to setting a deadline for EPA to publish the water quality criteria mandated by section 304(a)(9).^{36/}

In the following section, EPA details the additional studies it plans to conduct, how long those studies will take, and how much time EPA requires to draft and publish water quality criteria that take those studies (and any other information deemed relevant by EPA) into account.

D. EPA Should Be Afforded Until December 15, 2012 To Publish The Criteria Under Section 304(a)(9) And To Complete The Studies It Deems Appropriate To Accomplish That Task

EPA has not yet discharged its non-discretionary duty under CWA section 304(a)(9) to publish new or revised water quality criteria for pathogens and pathogen indicators (including a revised list of testing methods, as appropriate) in order to protect human health in coastal recreation waters. For the reasons stated above, the appropriate remedy is an order requiring EPA to publish such criteria by a new, court-imposed deadline. That deadline should be calculated to ensure that EPA has sufficient time to consider the complex technical and policy questions involved. The public interest would be poorly served by the publication of inadequate or unsupported criteria. Such criteria could result in communities closing beaches that are safe for swimming or keeping beaches open when they are unsafe. King Decl. ¶ 36.

The schedule proposed by EPA is straightforward. EPA requests that it be afforded approximately five years – until December 15, 2012 – to publish the criteria at issue. King Decl. ¶

^{36/} In the event that the Court decides that some relief directed at future compliance with section 104(v)(4) is necessary, EPA submits that the Court should merely direct EPA in general terms to “comply” with that section while the Agency works to discharge its statutory duty to publish the new or revised water quality criteria under section 304(a)(9).

1 37. Such a deadline represents the reasonable minimum time in which EPA can develop and
2 obtain the scientific information that it believes is critical, and then draft and finalize criteria that
3 represent a significant advancement in public health protection. Id. Taking procedural or
4 analytical shortcuts in order to expedite this schedule could seriously jeopardize the soundness of
5 the action. Id.

6 **1. This Court Has Equitable Discretion To Determine A Reasonable**
7 **Deadline For Agency Action Where Compliance With Statutory**
8 **Deadline Is Impossible Or Infeasible**

9 When EPA has failed to meet a CWA statutory deadline, a court has jurisdiction to compel
10 EPA to fulfill it and may exercise its equitable powers to set an enforceable deadline for that task.
11 Am. Lung Ass'n v. Browner, 884 F. Supp. at 347. In a suit alleging violation of a congressionally
12 mandated duty, "[t]he sound discretion of [a] . . . court does not embrace enforcement . . . of a
13 party's duty to comply with an order that calls [on] him to do an impossibility." NRDC v. Train,
14 510 F.2d 692, 713 (D.C. Cir. 1975) ("Train"). A statutory deadline should not be enforced to the
15 extent it is impossible or infeasible to comply with such a deadline. American Lung Ass'n, 884 F.
16 Supp. at 347. As recently stated in Sierra Club v. Johnson, 444 F. Supp. 2d at 56, the court's
17 "primary concern" in a deadline suit should be "not what EPA has (or has not) achieved in the
18 past, but what it can reasonably be expected to accomplish going forward."

19 In Train, a leading case on the subject of an agency's failure to meet statutory deadlines,
20 the D.C. Circuit recognized two types of circumstances that might necessarily delay agency action
21 and make it infeasible to comply with a particular deadline: (1) budgetary and manpower
22 constraints, and (2) the need for an agency to have more time to sufficiently evaluate complex
23 technical issues. 510 F.2d at 712-13. The courts recognize that the public has "a significant
24 interest" in ensuring that the government does not take a regulatory action "via a process that
25 emphasizes expediency over quality and accuracy." Cronin v. Browner, 90 F. Supp. 2d 364, 373
26 (S.D.N.Y. 2000). Because the public interest in sound agency action "is of paramount
27 importance," Sierra Club v. Thomas, 658 F. Supp. 165, 172 (N.D. Cal. 1987), "it would be
28 inappropriate to set an infeasible schedule in order to punish a delinquent agency." Id. See also

1 United Steelworkers of America v. Rubber Mfrs. Ass'n, 783 F.2d 1117, 1120 (D.C. Cir. 1986)
2 (holding judicial imposition of overly hasty timetable on agency would ill serve the public
3 interest); Atlantic Terminal Urban Renewal Area Coal. v. New York City Dep't of Env'tl. Prot.,
4 740 F. Supp. 989, 997 (S.D.N.Y. 1990) (Many courts, when "faced with violations of . . .
5 seemingly absolute deadlines have concluded that the only practical response . . . is to require
6 compliance within a reasonable time."); NRDC v. New York State Dept. of Env'tl. Conservation,
7 700 F. Supp. 173, 181 (S.D.N.Y. 1988) (in evaluating a remedy, the court must consider the
8 complexity of the subject and "the necessity of dealing with the issues on a pragmatic basis.").

9 In short, when an agency has missed a statutory deadline, a court should examine the
10 relevant facts and circumstances and evaluate the time frame needed by the agency to make well-
11 reasoned, scientifically supportable and defensible decisions.

12 **2. EPA's Proposed Schedule Represents The Reasonable Minimum Time**
13 **Necessary For EPA To Complete The Required Action**

14 Neither NRDC nor Plaintiff-Intervenors have yet taken a clear position on the critical
15 question before the Court – how long EPA should be given to publish the criteria at issue.
16 However, NRDC's proffered expert, Dr. Jennifer A. Jay, and presumably NRDC as well, believes
17 that a significant amount of additional scientific study should be undertaken by EPA over the next
18 three years to support the crafting of new or revised criteria. See Jay Report at 11, Ex. "K" to
19 Colangelo Decl., submitted in support of NRDC's Motion for Partial Summary Judgment. NRDC
20 devotes no attention to how long EPA should have to actually draft and publish the criteria
21 themselves once studies are finished.

22 The County asks that the Court order EPA to identify the studies it will conduct and
23 schedules for conducting those studies and for publishing the section 304(a)(9) criteria. (County
24 Mem. at 12.) The County urges that EPA undertake a thorough course of additional scientific
25 study to inform those criteria..^{37/} Id. at 13. Plaintiff-Intervenor NACWA is silent both on the

26
27 ^{37/} The County also asks for an order imposing a schedule on EPA for the publication of
28 "guidance for state application" of the criteria for pathogens and pathogen indicators to be

(continued...)

1 extent and type of research it believes EPA should conduct in support of the criteria and how
2 much time the Court should give EPA to complete such studies. Thus, in contrast to NRDC, the
3 County and NACWA both decline to offer even a hint as to how long such studies will take.
4 Further, like NRDC, neither the County nor NACWA discusses how long EPA should be given,
5 once the Agency has completed its scientific studies, to draft and publish the criteria document.
6 NACWA (Mem. at 5) merely asserts that it “anticipates future briefing” on remedy. In contrast to
7 the NRDC and the Plaintiff-Intervenors, EPA believes it makes little sense to prolong this
8 litigation in order to arrive at an appropriate remedy that allows the Agency adequate time to
9 finish its work on the matters at hand. In this Section, EPA explains the basis for the deadline that
10 it believes is appropriate to resolve this case.

11 As noted above, the courts have recognized that practical circumstances, including
12 “budgetary and manpower constraints,” can affect the amount of time needed for agency action.
13 Train, 510 F.2d at 712-13. EPA, like all agencies, has finite resources based on congressional
14 appropriations and many competing priorities.^{38/} The approximately five-year period proposed in
15

16 ^{37/}(...continued)

17 published under section 304(a)(9). See County Proposed Order at 2. To the extent that amounts
18 to a request that the Court order EPA to publish the guidance required by section 304(a)(9)(A) by
19 a date certain, EPA does not contest it because CWA section 304(a) criteria recommendations are
20 a form of “guidance.” However, elsewhere the County suggests that EPA is required to publish
21 “guidance required by 33 U.S.C. 1254(v) while the criteria identification process goes forward so
22 that the states will know whether they should be requiring the expenditure of funds to meet the
23 1986 water quality criteria through programs such as the TMDL program while the new criteria
24 are being adopted, and how the new criteria are going to correlate with the 1986 criteria.”
25 (County Mem. at 10.) There is no statutory basis for the suggestion that EPA is required to
26 publish any guidance other than the section 304(a)(9)(A) criteria recommendations, either while
27 EPA is in the process of developing criteria under section 304(a)(9)(A) or after EPA publishes
28 that guidance. Such an injunction would be outside the Court’s authority. Further, it is unclear
whether any Plaintiff is also requesting an order enjoining EPA to publish a “revised list of
testing methods,” see County Proposed Order at 3, but any such request would also be outside the
Court’s jurisdiction. Moreover, the words “as appropriate” in section 104(v) make clear that the
decision as to whether EPA should publish a revised list of test methods is discretionary.

^{38/} As described in the King and Noss Declarations (¶¶ 44 and 35, respectively), EPA is
(continued...)

1 this case by EPA is the reasonable minimum time necessary for EPA to complete the studies that
2 EPA believes are important and to develop and publish the water quality criteria required by
3 section 304(a)(9)(A). The Science Plan and the Criteria Development Plan set forth detailed
4 descriptions of the work necessary for EPA to accomplish those objectives. The most salient
5 components of that work are discussed below.

6 **a. EPA's Science Plan Schedule**

7 EPA's Science Plan includes a three-year period for initiating and completing a
8 comprehensive set of studies which, in combination with substantial research already completed,
9 will provide EPA with the scientific foundation for the new or revised criteria for pathogens and
10 pathogen indicators required by section 304(a)(9)(A). This is an ambitious, yet achievable,
11 research plan. Noss Decl. ¶ 35 and King Decl. ¶ 43. The Science Plan includes 32 studies to be
12 carried out between 2007 and 2010, which "will yield the largest data set of its kind related to the
13 problem of fecal contamination." CPSP Table 3-1 and CDP at 5.^{39/} While this is a massive
14 research effort, it does not include additional research that EPA believes is unnecessary to the
15 development of the criteria that EPA would publish by the end of 2012. As discussed above, the
16 Science Plan includes only those studies that can be completed by the end of 2010, and that are
17 most likely to answer a key research question in a time frame that would allow EPA to use the
18 information gained in developing the criteria to be published by the end of 2012. King Decl. ¶ 23;
19 Noss Decl. ¶ 23.

20
21 ^{38/}(...continued)

22 committed to carry out the Science Plan and the Criteria Development Plan. (EPA's
23 commitment to carry out the Plans is made subject to the restrictions on all federal government
24 agencies that they not obligate or pay funds in contravention of the Anti-Deficiency Act. 31
25 U.S.C. § 1314.) EPA is in the process of developing accountability systems, milestones, and
deadlines for carrying out the Science Plan and the Criteria Development Plan over the next five
years. King Decl. ¶44; Noss Decl. ¶36.

26 ^{39/}EPA estimates that it has already expended approximately \$14 million on extramural funding
27 alone on BEACH Act research activities carried out between 2000 and the summer of 2007.
28 This figure does not include the significant expense of salaries for all of the EPA personnel who
worked on the studies. Noss Decl. ¶ 21.

1 There are three main reasons why the research activities in the Science Plan cannot be
2 completed before the end of 2010. Noss Decl. ¶ 29. First, there are several sequential steps
3 involved in completing a study; second, the studies in the research plan build on each other such
4 that certain studies cannot be initiated or completed until other studies have been completed; and
5 third, EPA needs to plan for the possibility that adjustments will need to be made in the research
6 in the event some studies yield unexpected results or findings. Id.

7 With respect to the first factor, conducting a study often includes several steps. For
8 example, the epidemiological studies described in the plan include study design, data collection,
9 data analysis, peer review, preparation of a draft report, and publication of a final report. See CDP
10 3-20, footnote 1 and Noss Decl. ¶ 30. The data collection alone is a major effort that involves
11 interviewing thousands of swimmers at beaches and taking thousands of water quality samples. Id.
12 Moreover, because EPA is studying the health effects of swimming, the data collection for these
13 studies can only be carried out during the summer swimming season when most people go to the
14 beach. Id. Once the data are collected, there are several more steps that must be taken before the
15 study is completed. EPA first conducts a quality assurance and quality control review of the raw
16 data. Next, EPA runs statistical analyses of the data and prepares a draft report of the results,
17 analyses, and conclusions. Id. Only then does EPA submit the draft report for independent peer
18 review and comment, and prepare a final report of the study. Id.

19 With respect to the second factor, the two epidemiological or QMRA studies that EPA is
20 scheduled to begin in 2009 (epidemiologic or QMRA studies of agricultural animal sources and
21 urban runoff) involve significant efforts before EPA can even initiate them. Noss Decl. ¶ 31. For
22 example, EPA must develop a new or modified design for the epidemiology studies as compared
23 to the studies EPA has conducted at beaches affected by treated human sewage (referred to in the
24 Science Plan as “POTW-impacted” beaches”). Id. These new or modified study designs will need
25 to be peer-reviewed if they are significantly different than the previous study design. Id. In
26 addition, if conducting an epidemiological study, EPA must conduct a comprehensive site
27 characterization study of numerous locations before selecting an individual beach and beginning
28

1 data collection. Id.

2 These two key studies for 2009-2010 are good examples of how EPA's Science Plan
3 includes studies which build on each other. Noss Decl. ¶ 32. EPA cannot conduct an
4 epidemiologic or QMRA study of health effects from nonhuman sources of fecal contamination
5 until it conducts appropriate site and source characterization studies. Id. Further, the site selection
6 process itself is complex. EPA must find a beach with enough swimmers and enough fecal
7 contamination from non-human sources to provide meaningful results. Id. Thus, because the
8 Science Plan includes a series of studies which must be carried out in a sequence over multiple
9 beach seasons rather than simultaneously or in a compressed amount of time, it necessarily
10 extends to the end of 2010. Id.

11 The third reason that the research activities in the Science Plan cannot be completed before
12 the end of 2010 is that, in developing the schedule for the Science Plan, EPA needed to account
13 for the possibility that as research activities are completed, data collected and analyses conducted,
14 modifications to the research program laid out in the Science Plan may become appropriate. Noss
15 Decl. ¶ 33. This is because the outcome of the research activities in the plan is uncertain. Id.
16 Moreover, the state of the science is not static; it has changed in significant ways in recent years
17 (even as EPA was engaged in conducting epidemiologic studies in the Great Lakes) and it is
18 expected to continue to change, possibly at a much greater rate than in the past. Id. Some
19 flexibility and contingencies, then, needed to be built into the Science Plan. Id.

20 In sum, EPA requires three years to complete the research activities it believes are critical
21 to preparing sound criteria under section 304(a)(9).

22 **b. EPA's Criteria Development Schedule**

23 In conjunction with its development of the Science Plan, EPA developed a Criteria
24 Development Plan, which outlines and describes the process and two-year timeline for EPA to
25 develop and publish new or revised water quality criteria for pathogens and pathogen indicators
26 by December 15, 2012. King Decl. ¶ 33. As described in the Criteria Development Plan, "long
27 experience at EPA in producing significant regulations and guidance such as new or revised
28

1 recreational criteria has resulted in EPA's establishment of a formal process to ensure that EPA
2 produces scientifically sound and technically rigorous regulations and guidance in the shortest
3 amount of time feasible." CDP at 2. In the BEACH Act amendments, Congress provided that
4 EPA was to issue revised criteria two years after completion of scientific studies called for in
5 section 104(v). EPA's proposed timetable for the criteria tracks that two-year period, once the
6 research is finished.

7 The Criteria Development Plan explains the steps that are required and how long each
8 takes. After completion of the scientific studies outlined in the Science Plan, the first stage in
9 EPA's development of the criteria will be to analyze and synthesize the study results. CDP at 5.
10 Due to the magnitude of the information and the complexity of the problem, this will be a
11 significant exercise. Id. at 5. This critical step (including independent scientific peer review) is
12 expected to produce information to provide a "reliable basis for estimating the level of human
13 health risks associated with various indicator organisms and levels of indicator organisms in
14 water." Id. EPA has scheduled 90 days to complete this work. Id.

15 EPA's Criteria Development Plan then schedules five and one-half months for EPA to
16 develop options for the criteria and draft the initial criteria document. CDP at 5-6. This process
17 will involve the identification and resolution of many scientific and public policy issues
18 associated with developing the revised criteria recommendations. Id. The criteria document that
19 EPA will ultimately publish is expected to be a stand-alone document that not only communicates
20 what EPA's revised criteria recommendations are, but also, the complete scientific and policy
21 rationale for EPA's recommendations. Id. As with other criteria documents, EPA expects that
22 States will use and rely on the important supplementary information in EPA's criteria document to
23 support their adoption of scientifically defensible criteria into State law. CDP at 6.

24 Once EPA has completed this work, the Plan allocates six weeks for scientific peer review
25 of EPA's draft criteria document and eight weeks for EPA to analyze the peer review comments
26 and make any necessary modifications to the draft criteria document. EPA considers external
27 independent expert peer review as essential to ensuring that EPA's new or revised criteria are
28 "scientifically sound and understandable." CDP at 7. EPA believes that six weeks is the

1 minimum time needed to permit a thoughtful, thorough evaluation of the information presented.
2 Id. After peer review, the Plan allocates two months for EPA to analyze the comments, propose
3 any changes to the draft criteria for consideration by EPA management, and modify the draft
4 criteria as appropriate. Id.

5 Upon completion of EPA's revision of the draft criteria, the Plan allows three to four
6 months for review by other federal agencies and by other offices within EPA. Review by other
7 federal agencies accords with Executive Order 12866 and ensures that senior management and
8 policymaking levels in other federal agencies (for example the CDC and the National Institute for
9 Environmental Health Studies) review important policy documents for issues and technical rigor
10 before EPA releases a document for public review and comment. CDP at 8.

11 The Criteria Development Plan then allocates two to three months for public review and
12 comment on the draft criteria document. This phase provides an opportunity for the full range of
13 interested persons and organizations to identify issues that may still need to be addressed and/or to
14 provide comment on the draft criteria. Such public review and comment generally ensures better
15 Agency actions and, for criteria that may ultimately affect thousands of communities and millions
16 of beachgoers, is essential here. CDP at 9.

17 Following the public review process, the final stages for criteria development provide time
18 for EPA to analyze, consider and address the public comments and make appropriate revisions to
19 the criteria document. EPA expects an unusually large number of comments and giving careful
20 consideration to them will be time-consuming. Id. The Criteria Development Plan allows up to
21 three months to complete this process. After EPA's Office of Water has completed a final criteria
22 document, the Plan provides an opportunity for internal EPA review and review by other federal
23 agencies of the final criteria document. This review process would take 60 to 90 days. Id. at 10.

24 The final 60 days in EPA's schedule provides time for any final revisions to the criteria
25 document in response to internal and external agency review and for publication in the Federal
26 Register of a notice of availability of the final criteria recommendations. Id. at 10.

27 Each of the steps outlined above is necessary and the time frames were established based
28 on EPA's experience in publishing water quality criteria and similar documents. King Decl. ¶41.

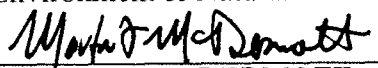
1 As stated in the Criteria Development Plan, the schedule "reflects decades of EPA experience
2 with the steps that are necessary and the time that is needed to produce scientifically sound water
3 quality criteria recommendations and other significant national environmental policy and guidance
4 documents." CDP at 2. These steps are especially important to the development of these
5 particular water quality criteria recommendations because once the criteria are developed and
6 published, States are expected to revise their water quality standards taking into account EPA's
7 recommendations. The new State standards will impact thousands of communities and millions
8 of beachgoers nationwide. Id. The importance of EPA's criteria recommendations, together with
9 the magnitude of the information and the complexity of the problem of fecal contamination justify
10 the two-year post-research timeline for ensuring that its criteria are based on sound science and
11 developed with input from the public (including these litigants), States, other federal agencies, and
12 scientific experts.

13 CONCLUSION

14 The Court should grant EPA's cross-motion for summary judgment on remedy. The
15 appropriate remedy for EPA's failure to fully satisfy its obligations under sections 304(a)(9) and
16 104(v) is an order requiring EPA to publish new or revised water quality criteria by December 15,
17 2012. The Court should reject any suggestion by Plaintiffs that a trial is necessary to resolve this
18 case, as well as any suggestion that the Court should impose requirements on the Agency in
19 addition to the December 15, 2012 deadline for publication of the criteria.

20 Respectfully submitted, this 4th day of December, 2007.

21 RONALD J. TENPAS
22 Acting Assistant Attorney General
23 Environment & Natural Resources Division

24 
25 MARTIN F. McDERMOTT
26 U.S. Department of Justice
Environmental Defense Section
P.O. Box 23986
Washington, D.C. 20026-3986
ATTORNEYS FOR DEFENDANTS

27 Of Counsel:
28 LESLIE J. DARMAN
U.S. Environmental Protection Agency
Office of General Counsel

CERTIFICATE OF SERVICE

On December 4th, 2007, I caused a true and correct copy of the foregoing to be served by first class mail on counsel at the following addresses:

Counsel for Plaintiff NRDC:

DAVID S. BECKMAN
Natural Resources Defense Council
1314 Second Street
Santa Monica, CA 90401
(310) 434-2300


MARTIN F. McDERMOTT

AARON COLANGELO*
BEN LONGSTRETH
Natural Resources Defense Council
1200 New York Ave NW, Suite 400
Washington, D.C. 20005
(202) 289-2376

* Also served by Federal Express overnight.

AARON BLOOM
Natural Resources Defense Council
40 W. 20th St.
New York, NY 10011

Counsel for Intervenor-Plaintiffs:

RAYMOND G. FORTNER, JR.
JUDITH A. FRIES
Kenneth Hahn Hall of Admin.
500 W. Temple St., Rm. 653
Los Angeles, California 90012
(213) 974-1923

HOWARD GEST*
DAVID W. BURHENN
BURHENN & GEST LLP
624 S. Grand Ave., Suite 2200
Los Angeles, California 90017
(213) 688-7715

**Counsel for Intervenor-Plaintiff
NACWA:**

DAVID W. BURCHMORE
Squire, Sanders & Dempsey L.L.P.
4900 Key Tower, 127 Public Square
Cleveland, OH 44114
(216) 479-8779

ALEXANDRA DAPOLITO DUNN
General Counsel
National Association of Clean Water
Agencies
1816 Jefferson Place, N.W.
Washington, D.C. 20036-2505
(202) 533-1803