

1 ROBERT G. DREHER
Acting Assistant Attorney General
2 Environment & Natural Resources Division
3 United States Department of Justice
LESLIE M. HILL (D.C. Bar No. 476008)
4 leslie.hill@usdoj.gov
Environmental Defense Section
5 601 D Street N.W., Suite 8000
6 Washington D.C. 20004
Telephone (202) 514-0375
7 Facsimile (202) 514-8865

8 Attorneys for Defendants

9
10 **IN THE UNITED STATES DISTRICT COURT**
11 **FOR THE NORTHERN DISTRICT OF CALIFORNIA**
12 **OAKLAND DIVISION**

13
14 SIERRA CLUB, *et al.*,
15 Plaintiffs,
16 v.
17 UNITED STATES ENVIRONMENTAL
18 PROTECTION AGENCY, *et al.*,
19 Defendants.
20

Case No.: 4:13-cv-2809-YGR

**EPA’S OPPOSITION TO PLAINTIFFS’
MOTION FOR SUMMARY JUDGMENT,
CROSS-MOTION FOR SUMMARY
JUDGMENT, AND [PROPOSED] ORDER**

Date: April 8, 2014
Time: 2:00 p.m.
Place: Courtroom 5, 2nd Floor

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

NOTICE OF CROSS-MOTION

Please take notice that on April 8, 2014 at 2:00 p.m. or as soon thereafter as counsel can be heard, Defendants, United States Environmental Protection Agency and Gina McCarthy, in her official capacity as Administrator of the Environmental Protection Agency (collectively, “EPA”), will move this Court, located in Courtroom 5, 2nd Floor, United States Court House located at 1301 Clay Street, Oakland, California, to grant summary judgment as to remedy and enter EPA’s Proposed Order.

RELIEF REQUESTED

The relief Defendants seek is summary judgment as to remedy and entry of EPA’s Proposed Order.

Table of Contents

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

I. BACKGROUND 3

 A. STATUTORY REQUIREMENTS FOR NAAQS AND THE FIVE-YEAR REVIEW 3

 B. REGULATORY AND LITIGATION BACKGROUND..... 5

 1. History of the Ozone NAAQS Review..... 5

 2. EPA’s Progress to Date in Its Review of the 2008 Ozone NAAQS..... 6

III. LEGAL STANDARD APPLICABLE TO PLAINTIFFS’ MOTION FOR SUMMARY JUDGMENT 10

IV. ARGUMENT 11

 A. THIS COURT HAS EQUITABLE DISCRETION TO DETERMINE A REASONABLE SCHEDULE FOR THE AGENCY TO TAKE WELL-REASONED, SCIENTIFICALLY SUPPORTED, AND DEFENSIBLE ACTION 11

 B. EPA’S ANTICIPATED DATE FOR BOTH PROPOSED AND FINAL ACTION IS THE MOST EXPEDITIOUS SCHEDULE IT REASONABLY CAN MEET UNDER THE CURRENT CIRCUMSTANCES 12

 1. Deadline for EPA Proposing Action..... 12

 2. Final Action Deadline 14

IV. PLAINTIFFS’ REQUESTED DEADLINES OF DECEMBER 1, 2014 FOR PROPOSAL AND OCTOBER 1, 2015 FOR FINAL ACTION ARE NOT REASONABLE 17

CONCLUSION..... 18

Table of Authorities

CASES:

Am. Farm Bureau Fed’n v. EPA,
559 F.3d 512 (D.C. Cir. 2009) 3, 14

Am. Lung Ass’n v. Browner,
884 F. Supp. 345 (D. Ariz. 1994) 11

Am. Petroleum Inst. v. Costle,
665 F.2d 1176 (D.C. Cir. 1981) 5

Am. Trucking Ass’ns v. EPA,
283 F.3d 355 (D.C. Cir. 2002) 5

Cronin v. Browner,
90 F. Supp. 2d 364 (S.D.N.Y. 2000) 12

Envtl. Def. Fund v. Thomas,
627 F. Supp. 566 (D.D.C. 1986) 11, 17

Lead Indus. Ass’n v. EPA,
647 F.2d 1130 (D.C. Cir. 1980) 2

Mississippi v. EPA,
-- F.3d --, 2013 WL 6486930 (D.C. Cir. Dec. 11, 2013) 5, 14

Mississippi v. EPA,
723 F.3d 246 (D.C. Cir. 2013) 6

Natural Res. Def. Council v. EPA,
902 F.2d 962 (D.C. Cir. 1990) 3, 6

Natural Res. Def. Council v. EPA,
921 F.2d 326 (D.C. Cir. 1991) 3

Natural Res. Def. Council v. Train,
510 F.2d 692 (D.C. Cir. 1975) 11, 17, 18

Sierra Club v. Johnson,
444 F. Supp. 2d 46 (D.D.C. 2006) 10, 12, 17

Sierra Club v. Thomas,
828 F.2d 783 (D.C. Cir. 1987) 12

1 Weinberger v. Carlos Romero-Barcelo,
 2 456 U.S. 305 (1982)..... 11

3 Whitman v. Am Trucking Ass’ns,
 4 531 U.S. 457 (2001)..... 5

5 **STATUTES:**

6 42 U.S.C. § 7408(a)(1)..... 2

7 42 U.S.C. § 7408(a)(2)..... 2, 3, 14

8 42 U.S.C. § 7409..... 2

9 42 U.S.C. § 7409(a) 2

10 42 U.S.C. § 7409(b) 2

11 42 U.S.C. § 7409(b)(1)-(2) 2

12 42 U.S.C. § 7409(d) 4

13 42 U.S.C. § 7409(d)(1) 1, 3, 5

14 42 U.S.C. § 7409(d)(2) 3

15 42 U.S.C. § 7409(d)(2)(B) 1

16 42 U.S.C. §7410..... 3

17 42 U.S.C. § 7602(h) 2

18 42 U.S.C. § 7607(d)(3) 1

19 42 U.S.C. § 7607(d)(3)(C)..... 3

20 42 U.S.C. § 7607(d)(5)(i)..... 14

21 42 U.S.C. § 7607(d)(5)(ii)..... 14

22 42 U.S.C. § 7607(d)(5)(iv)..... 14

23 42 U.S.C. § 7607(d)(6)(A)..... 16

24

25

26

27

28

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

RULES:

Civil L.R. 7-2 1
 Fed. R. Civ. P. 56(a) 1

FEDERAL REGISTER:

36 Fed. Reg. 8186 (Apr. 30, 1971) 5
 44 Fed. Reg. 8202 (Feb. 8, 1979) 5
 58 Fed. Reg. 13,008 (Mar. 9, 1993)..... 5
 58 Fed. Reg. 51,735 (Sept. 30, 1993) 13
 62 Fed. Reg. 38,856 (July 18, 1997)..... 5
 72 Fed. Reg. 37,818 (July 11, 2007)..... 15, 16
 73 Fed. Reg. 16,483 (Mar. 27, 2008)..... 5, 16
 73 Fed. Reg. 56,581 (Sept. 29, 2008) 7
 74 Fed. Reg. 54,562 (Oct. 22, 2009)..... 7
 76 Fed. Reg. 3821 (Jan. 18, 2011) 14
 76 Fed. Reg. 10,893 (Feb. 28, 2011) 7
 76 Fed. Reg. 23,755 (Apr. 28, 2011) 8
 76 Fed. Reg. 23,809 (Apr. 28, 2011) 7
 76 Fed. Reg. 60,820 (Sept. 30, 2011) 7
 77 Fed. Reg. 36,534 (June 19, 2012) 7
 77 Fed. Reg. 42,495 (July 19, 2012)..... 8, 9
 77 Fed. Reg. 46,755 (Aug. 6, 2012)..... 7
 78 Fed. Reg. 11,172 (Feb. 15, 2013) 8
 79 Fed. Reg. 4693 (Jan. 29, 2014)..... 10

1 79 Fed. Reg. 4694 (Jan. 29, 2014) 10

2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

1 Pursuant to Civil L.R. 7-2 and Fed. R. Civ. P. 56(a), Defendants, United States
2 Environmental Protection Agency and Gina McCarthy, in her official capacity as
3 Administrator of the Environmental Protection Agency (collectively, “EPA”), hereby file their
4 opposition to Plaintiffs Sierra Club’s, American Lung Association’s, Environmental Defense
5 Fund’s, and Natural Resources Defense Council’s Motion for Summary Judgment (“Pls.’
6 Mot.”) and concurrently cross-move for summary judgment as to remedy. Plaintiffs argue that
7 EPA has violated a non-discretionary duty under the Clean Air Act to complete a five-year
8 review of the national ambient air quality standards (“NAAQS”) for ozone and to “make
9 revisions or promulgate new standards as may be appropriate” in accordance with section
10 109(d) of the Act by March 12, 2013. Pls.’ Mot. at 2 (Dkt. No. 42); see 42 U.S.C. §
11 7409(d)(1). Plaintiffs ask the Court to impose a schedule on the Agency requiring EPA to
12 complete its review no later than October 1, 2015. Pls.’ Mot. at 2. Plaintiffs further request
13 that this Court require EPA to sign a proposed rule by December 1, 2014. Id. at 13.

14 EPA does not dispute that it has missed the statutory deadline for a final action
15 completing its review of the ozone NAAQS. See Answer ¶ 5 (Dkt. No. 33). Since the
16 completion of the last review in March 2008, the Agency has expended enormous effort in
17 conducting its review of the ozone NAAQS. However, the review has taken longer than the
18 statutory period due in part to the abundance of new scientific evidence concerning the
19 potential health and welfare effects of ozone pollution, the complexity of the issues raised in
20 the assessment of the new science, and the need to fully consider and address the comments the
21 Agency has received from the statutorily-mandated peer review body that participates in the
22 Agency’s development and review of NAAQS (the “Clean Air Scientific Advisory
23 Committee” or “CASAC”), and whose recommendations EPA is required to consider and
24 address, see 42 U.S.C. §§ 7409(d)(2)(B), 7607(d)(3). In particular, pursuant to CASAC’s
25 recommendation, EPA has utilized a different method of simulating atmospheric ozone levels,
26 and consequent human and environmental exposures, and has re-analyzed and re-interpreted all
27 of its health and exposure analyses to reflect this different methodology. The Agency is
28 working diligently to complete its remaining tasks, including finalization of human health and

1 public welfare risk assessments and the policy assessment, publication of a notice of proposed
2 rulemaking, and a subsequent final action. EPA now anticipates that it will take final action no
3 later than November 15, 2015. For reasons explained further below and in the accompanying
4 Declaration of EPA Acting Assistant Administrator Janet McCabe (“McCabe Decl.”) (Exh. A),
5 that date for final action is the most expeditious schedule EPA can reasonably meet under the
6 current circumstances. See, e.g., McCabe Decl. ¶¶ 20-37.

7 Conversely, the October 1, 2015 deadline for final action urged by Plaintiffs is not
8 reasonable for the Agency to meet. For reasons explained below and in the McCabe
9 Declaration, that deadline would not leave the Agency sufficient time to complete the
10 remaining tasks necessary for the NAAQS review, including, among other things: completion
11 of the health and welfare risk assessments; the policy assessment; the internal EPA process
12 involved in determining what action to propose; the preparation of a proposed regulation
13 package (a statement of basis and purpose, plus regulatory text if EPA proposes to amend the
14 NAAQS); the statutorily-required opportunities for public comment and hearing that must
15 follow EPA’s publication of a proposed decision; EPA’s preparation of an explanation for its
16 actions setting forth all factual data, methodology, legal interpretations and policy
17 considerations underlying its final action; and EPA’s preparation of responses to the significant
18 public comments. Accordingly, the Court should deny Plaintiffs’ motion for summary
19 judgment as to remedy, and should not order a deadline any earlier than November 15, 2015,
20 for EPA to take final action to complete its ozone NAAQS review.

21 Plaintiffs devote a significant portion of their motion to their belief that the ozone
22 NAAQS should be revised to be more stringent. See Pls.’ Mot. at 2, 5-7. The Court should
23 disregard that discussion because, as Plaintiffs themselves concede, see Pls.’ Opp. to Mot. to
24
25
26
27
28

1 Intervene at 1, 3-4 (Dkt. No. 22),¹ the only issue before the Court is the date by which EPA
2 shall complete its review.

3 **I. BACKGROUND**

4 **A. STATUTORY REQUIREMENTS FOR NAAQS AND THE FIVE-YEAR** 5 **REVIEW**

6 The Clean Air Act (“CAA”) establishes a comprehensive scheme to protect public
7 health and welfare from ubiquitous air pollutants. As part of this scheme, EPA must establish
8 NAAQS limiting concentrations of certain pollutants in the “ambient,” or outside, air. 42
9 U.S.C. §§ 7408 (a)(1), 7409 (a)-(b). These are generally referred to as “criteria pollutants.”
10 Specifically, EPA is tasked with developing “air quality criteria,” which must reflect the latest
11 scientific knowledge on “all identifiable effects on public health or welfare” that may result
12 from a criteria pollutant’s presence in the ambient air. *Id.* § 7408(a)(2).

13 Based on the air quality criteria, EPA must promulgate “primary” and “secondary”
14 NAAQS to protect against a criteria pollutant’s “adverse” effects on public health and public
15 welfare. *Id.* § 7409. Primary standards must, “in the judgment of the Administrator,” be
16 “requisite to protect the public health” with “an adequate margin of safety,” while secondary
17 standards must be “requisite to protect the public welfare from any known or anticipated
18 adverse effects.” *Id.* §§ 7409(b)(1)-(2), 7602(h). In establishing the primary standards, EPA
19 considers a number of factors, including the nature and severity of health effects, the types of
20 health evidence available, the kind and degree of uncertainty in the evidence, and the size and
21 nature of sensitive populations at risk. *Lead Indus. Ass’n v. EPA*, 647 F.2d 1130, 1161 (D.C.
22 Cir. 1980). The NAAQS apply everywhere in the United States, and are thus of fundamental
23 importance to public health and public welfare.

24
25
26 ¹ In arguing that proposed defendant-intervenors misconstrued the nature of this lawsuit,
27 Plaintiffs emphasize that they seek only “a finding that the [EPA] has failed to perform a
28 nondiscretionary duty to ‘complete a thorough review’ of ozone ambient air quality standards,
and a court-ordered deadline for completion of such review” and “do not, and cannot, ask for the
imposition of particular ozone air quality standards.” Pls.’ Opp. to Mot. to Intervene at 1 (Dkt.
No. 22).

1 The Act sets up a comprehensive program through a system of shared federal and state
2 responsibility. Thus, after EPA establishes a NAAQS, section 110 calls on the States to
3 establish State Implementation Plans, which impose controls on sources of air pollution as
4 necessary to attain the NAAQS. 42 U.S.C. § 7410.

5 To ensure that the NAAQS keeps pace with scientific advances, Congress required
6 EPA and an independent scientific review committee, the Clean Air Scientific Advisory
7 Committee (“CASAC”), to review air quality criteria and NAAQS at least once every five
8 years. Id. § 7409(d). CASAC is directed to make recommendations to EPA, and after
9 considering those recommendations, the Administrator must retain or revise the air quality
10 criteria and the NAAQS in accordance with section 7409(b). In revising or retaining the
11 NAAQS, the Administrator must explain any significant departures from CASAC’s
12 recommendations. Id. §§ 7409(d)(2), 7607(d)(3)(C). The final decision on whether and how
13 to revise the NAAQS is can only be made by the EPA Administrator. Id. § 7409(d)(1).

14 The NAAQS-setting process begins with the development of the “air quality criteria.”
15 Id. § 7408(a)(2). The scientific assessments constituting air quality criteria generally include
16 an “Integrated Science Assessment” (formerly termed an “Air Quality Criteria Document”) a
17 rigorous review of all pertinent scientific studies and related information. As part of the
18 NAAQS review, EPA staff also typically develop quantitative Risk and Exposure Assessments
19 (“REA”) estimating how variations in the ambient concentration of a criteria pollutant affect
20 exposures and the incidence of adverse effects on public health and welfare. In addition, EPA
21 staff typically develop a “Policy Assessment” (formerly termed a “Staff Paper”) to “bridge the
22 gap” between the scientific review and the public health and welfare policy judgments the
23 Administrator must make in determining whether to retain or revise the existing NAAQS for
24 ozone, and, if revision is considered, what revisions may be appropriate. See Natural Res. Def.
25 Council, Inc. v. EPA, 902 F.2d 962, 967 (D.C. Cir. 1990), vacated in part on other grounds,
26 921 F.2d 326 (D.C. Cir. 1991); Am. Farm Bureau Fed’n v. EPA, 559 F. 3d 512, 521 (D.C. Cir.
27 2009). These documents undergo extensive peer-review by CASAC and also undergo a
28 process of public notice and comment.

1 As noted, Congress required that EPA review the criteria and NAAQS for each criteria
2 pollutant at least once every five years, and revise them as “appropriate in accordance with
3 [sections 108 and 109(b)].” 42 U.S.C. § 7409(d)(1). In the case of the ozone NAAQS, EPA
4 completed its last statutory review cycle on March 12, 2008. *See Final Rule*, 73 Fed. Reg.
5 16,483 (Mar. 27, 2008). Accordingly, the statutory deadline to complete the current ozone
6 NAAQS review was March 12, 2013.

7 **B. REGULATORY AND LITIGATION BACKGROUND**

8 **1. History of the Ozone NAAQS Review**

9 EPA’s anticipated action completing the current ozone NAAQS review would represent
10 the Agency’s fifth review of the NAAQS for ozone since the enactment of the CAA and
11 setting of the original ozone NAAQS in 1971. *Final Rule*, 36 Fed. Reg. 8186 (Apr. 30, 1971)
12 (setting the primary and secondary standard at 0.08 ppm total photochemical oxidants as a 1-
13 hour average not to be exceeded more than one hour per year). EPA revised the primary and
14 secondary ozone NAAQS in 1979, *Final Rule*, 44 Fed. Reg. 8202 (Feb. 8, 1979) (lowering the
15 standard to 0.12 ppm ozone (instead of using total photochemical oxidants as the indicator);
16 *see American Petroleum Inst. v. Costle*, 665 F.2d 1176, 1184-87 (D.C. Cir. 1981) (rejecting
17 petitions for review of the 1979 standard filed by industry associations, states, cities, and
18 environmental groups). In 1993, EPA decided that revisions to the ozone NAAQS were not
19 necessary at that time. *Final Rule*, 58 Fed. Reg. 13,008 (Mar. 9, 1993). EPA next revised the
20 primary and secondary standards in 1997. *Final Rule*, 62 Fed. Reg. 38,856 (Jul. 18, 1997); *see*
21 *Am. Trucking Ass’ns v. EPA*, 283 F.3d 355, 375-80 (D.C. Cir. 2002), *on remand from*,
22 *Whitman v. Am. Trucking Ass’ns*, 531 U.S. 457 (2001) (rejecting petitions for review of
23 EPA’s revised ozone NAAQS from states, industry, and environmental groups).

24 EPA promulgated the most recent ozone NAAQS rule in March 2008, thus concluding
25 its review of the 1997 standards. 73 Fed. Reg. at 16,483. As in 1997, the 2008 ozone NAAQS
26 was challenged by various interests. The Court of Appeals for the D.C. Circuit upheld EPA’s
27 determination that the primary ozone NAAQS should be set below the 1997 level at 0.075 ppm
28 ozone. *Mississippi v. EPA*, -- F.3d --, 2013 WL 6486930, at *3-20, (D.C. Cir. Dec. 11, 2013),

1 reissuing, 723 F.3d 246 (D.C. Cir. 2013) (rejecting industry challenges that primary standard is
2 too stringent and state and environmental group challenges that primary standard is
3 insufficiently stringent). With respect to the secondary standard, however, the court held that
4 because EPA had failed to identify a level of air quality requisite to protect public welfare,
5 EPA’s comparison between the primary and secondary standards for determining if requisite
6 protection for public welfare was afforded by the primary standard was inherently arbitrary.
7 The court thus rejected EPA’s determination that the revised primary standard afforded
8 requisite protection of public welfare, and remanded the standard to EPA. Id. at *21-23. The
9 court of appeals issued its mandate on December 17, 2013.

10 **2. EPA’s Progress to Date in Its Review of the 2008 Ozone NAAQS**

11 Because of their extraordinary environmental, social, and economic importance, final
12 decisions on NAAQS, as discussed above, typically are vigorously contested by industry,
13 States, and environmental, public health, and other public interest groups. Making well-
14 reasoned decisions is especially challenging in the context of establishing or revising NAAQS,
15 because the key evidence on which EPA must rely often is drawn from emerging new research,
16 sometimes at the frontiers of science, and often raises complex new issues requiring careful
17 and thorough consideration as part of a comprehensive assessment of the entire body of
18 relevant scientific evidence. See, e.g., Natural Res. Def. Council, 902 F.2d at 968. Reflecting
19 the extraordinary importance of decisions on the NAAQS and the enormous volume of new
20 scientific research since the last ozone NAAQS review in 2008, EPA is undertaking a highly
21 rigorous review designed to address complex issues of science, policy, and law. See McCabe
22 Decl. ¶¶ 5-23.

23 As described more fully in the McCabe Declaration, following its promulgation of the
24 2008 ozone NAAQS, EPA announced a general call for information and hosted a “kick-off”
25 workshop to provide an opportunity for public discussion of the key policy issues around
26 which EPA would structure its next ozone NAAQS review and the most meaningful new
27 science that would be available to inform EPA’s understanding of these issues. McCabe Decl.
28 ¶ 5-6; see 73 Notice of Workshop and Call for Information on Integrated Science Assessment

1 for Ozone, 73 Fed. Reg. 56,581 (Sept. 29, 2008). EPA then drafted an “Integrated Review
2 Plan” outlining the schedule, process, and key policy questions that would guide the evaluation
3 of the air quality criteria for ozone and the review of the primary and secondary ozone
4 NAAQS. McCabe Decl. ¶ 8. EPA consulted with CASAC on its draft of the Plan, and the
5 final Plan addressed comments both from CASAC and the public, as well as input from senior
6 Agency managers. Id. ¶¶ 8, 12; see Science Advisory Board Staff Office Notification of a
7 Public Teleconference of the Clean Air Scientific Advisory Committee (CASAC) Ozone Review
8 Panel, 74 Fed. Reg. 54,562 (Oct. 22, 2009). EPA finalized its Integrated Review Plan in April
9 2011. McCabe Decl. ¶ 12.

10 EPA’s subsequent and continuing work includes developing the key foundational
11 documents that precede and inform the Agency’s rulemaking decisions for NAAQS -- the
12 Integrated Science Assessment (“ISA”) and the Health and Welfare Risk and Exposure
13 Assessments. Id. ¶¶ 7, 9-11, 13-18, 20-23. The ISA provides an evaluation and integration of
14 the available science information, including key science judgments upon which the risk and
15 exposure assessments build. Id. ¶¶ 7, 9.

16 EPA issued a first draft ISA in February 2011, and the CASAC reviewed the draft ISA
17 in May 2011. Id. ¶ 10, 13; Draft Integrated Science Assessment for Ozone and Related
18 Photochemical Oxidants, 76 Fed. Reg. 10,893 (Feb. 28, 2011); Science Advisory Board Staff
19 Office Notification of a Public Meeting of the Clean Air Scientific Advisory Committee
20 (CASAC) Ozone Review Panel, 76 Fed. Reg. 23,809 (Apr. 28, 2011). Based on comments
21 from CASAC and the public, EPA revised the ISA and released a second draft in September
22 2011. McCabe Decl. ¶ 14; Draft Integrated Science Assessment for Ozone and Related
23 Photochemical Oxidants, 76 Fed. Reg. 60,820 (Sept. 30, 2011). Again based on comments
24 from CASAC and the public, EPA revised the ISA and released a third draft in June 2012.
25 McCabe Decl. ¶ 15; see Third External Review Draft Integrated Science Assessment for Ozone
26 and Related Photochemical Oxidants, 77 Fed. Reg. 36,534 (June 19, 2012); Notification of a
27 Public Meeting of the Clean Air Scientific Advisory Committee (CASAC) Ozone Review Panel,
28 77 Fed. Reg. 46,755 (Aug. 6, 2012).

1 The final Integrated Science Assessment for this review, issued in February 2013,
2 comprises over 1,200 pages of material summarizing a wealth of scientific data and findings
3 and addressing a variety of issues. McCabe Decl. ¶ 18-19; see *Integrated Science Assessment*
4 *for Ozone and Related Photochemical Oxidants*, 78 Fed. Reg. 11,172 (Feb. 15, 2013). As
5 noted, the final version reflects multiple rounds of review by CASAC and the public. McCabe
6 Decl. ¶¶ 13-15, 17-18.

7 Building upon the information presented in the ISA, EPA prepared risk and exposure
8 assessments (“REA”) for both public health and welfare effects associated with ozone
9 pollution. The risk and exposure assessments draw upon information and conclusions
10 presented in the ISA to develop quantitative characterizations of exposures and associated risks
11 to human health or the environment associated with recent air quality conditions and with air
12 quality estimated to just meet the current or alternative standard(s) under consideration. This
13 assessment includes a characterization of the uncertainties associated with such estimates. Id.
14 ¶ 12. Preparation of the REAs begins with planning documents, called Scope and Methods
15 Plans, which outline the approaches that EPA staff intend to use in conducting the assessments
16 and seek input from CASAC and the public on these approaches. Id.; see *Release of Draft Risk*
17 *and Exposure Assessments and Final Integrated Review Plan for the National Ambient Air*
18 *Quality Standards for Ozone*, 76 Fed. Reg. 23,755 (Apr. 28, 2011).

19 EPA subsequently issued first draft public health and welfare risk and exposure
20 assessments for comments by CASAC and the public in July 2012. McCabe Decl. ¶ 16; see
21 *Release of Draft Documents Related to the Review of the National Ambient Air Quality*
22 *Standards for Ozone*, 77 Fed. Reg. 42,495 (July 19, 2012). CASAC provided comments on the
23 first draft REAs and advice for the next draft. CASAC sharply advised that the Health REA
24 and the Welfare REA needed substantial improvement because they did not “present an
25 adequate conceptual framework for the analyses.” McCabe Decl. ¶ 20. For both the Health
26 and Welfare REAs, CASAC advised EPA to adopt a new method for simulating air quality
27 resulting from (1) just meeting the current ozone standard or (2) meeting various alternative
28 standards. Id. Simulating air quality in some manner is necessary because both the human

1 health and the public welfare risk estimates include comparisons of exposures or risks
2 estimated for ozone associated with recent (*i.e.*, current) air quality conditions with the risks
3 for air quality adjusted to just meet the current standard or to meet alternative standards. EPA
4 agreed to use the model-based approach, called the Higher-order Direct Decoupled Method,
5 recommended by CASAC to develop the second draft health and welfare REAs. Id. ¶ 22.
6 However, this effort delayed EPA’s completion of second draft REAs and necessitated
7 considerably revised second drafts of the REAs, because EPA had to apply the new approach
8 to each of the 15 case study urban areas in the Health REA and at every monitor across the
9 nation for the Welfare REA and then redo all of the risk and exposure analyses in both the
10 REAs. Id. CASAC also made additional recommendations necessitating additional analyses.
11 Id. ¶ 21.

12 Based on the scientific and technical information assessed in the Integrated Science
13 Assessment and Risk and Exposure Assessments, EPA staff prepared a first draft Policy
14 Assessment. McCabe Decl. ¶ 16; see 77 Fed. Reg. at 42,495. As noted earlier, the Policy
15 Assessment is intended to help “bridge the gap” between the relevant scientific information
16 and assessments and the judgments required of the Administrator in reaching decisions on the
17 NAAQS. McCabe Decl. ¶ 16 The Policy Assessment is not a decision document; rather, it
18 presents EPA staff conclusions related to the broadest range of policy options that could be
19 supported by the currently available information. Id. ¶ 16. CASAC provided comments on the
20 first draft Policy Assessment and advice for EPA’s subsequent draft. CASAC pointedly
21 advised that “the [Policy Assessment] needs substantial improvement, reflecting the still very
22 preliminary first draft that was brought to the CASAC.” Id. ¶ 20.

23 Thus, given the complexity of these additional analyses in the second drafts of the
24 Health REA and Welfare REA, EPA needed additional time to complete, summarize and
25 synthesize the results of this work. These new analyses, in turn, informed the further analysis
26 and interpretations in the Policy Assessment, which EPA staff accordingly revised
27 substantially to reflect the new analyses and to respond to CASAC advice and critiques. EPA
28 had not anticipated the need for this change in approach when it announced its initial review

1 schedule, and thus the time necessary for conducting revised modeling, analyses, and
2 interpretation was not reflected in EPA's originally-announced schedule.

3 EPA issued second drafts of the REAs and Policy Assessment on February 3, 2014 and
4 is currently accepting public comment through March 24, 2014. McCabe Decl. ¶ 23; see
5 *Release of Draft Documents Related to the Review of the National Ambient Air Quality*
6 *Standards for Ozone*, 79 Fed. Reg. 4694 (Jan. 29, 2014).

7 CASAC and the public will review these assessments during a March 25-27, 2014
8 public meeting. McCabe Decl. ¶ 23; see *Notification of a Public Meeting of the Clean Air*
9 *Scientific Advisory Committee (CASAC) Ozone Review Panel*, 79 Fed. Reg. 4693 (Jan. 29,
10 2014). The upcoming CASAC meeting and resulting comments are pivotal to completion of
11 the review process. EPA's new modeling methodology for simulating ozone levels and
12 exposures could potentially lead to significant comments from CASAC. McCabe Decl. ¶ 25.
13 The impact of utilizing this new modeling methodology on the rulemaking schedule is
14 discussed more fully below in § IV.B. EPA expects to issue the final assessments after
15 considering public comments and CASAC's advice and recommendations resulting from its
16 March 2014 CASAC meeting. Id. ¶ 23.

17 **III. LEGAL STANDARD APPLICABLE TO PLAINTIFFS' MOTION FOR** 18 **SUMMARY JUDGMENT**

19 As noted above, EPA does not dispute that the CAA imposed a non-discretionary duty
20 on the Agency to complete the ozone NAAQS review by March 12, 2013, and that EPA failed
21 to do so; thus, the only dispute relates to remedy. Both parties agree that discovery is
22 unnecessary and that this matter can be resolved on motions for summary judgment with
23 declarations addressing remedy. See Joint Case Management Statement (Dkt. No. 31). Courts
24 adjudicating similar disputes concerning the remedy for an agency's failure to meet a statutory
25 deadline commonly have resolved such disputes through summary judgment. See, e.g., Sierra
26 Club v. Johnson, 444 F. Supp. 2d 46, 52 (D.D.C. 2006) ("Because defendant does not contest
27 the issue of liability, the entry of summary judgment is appropriate, and it remains only for the
28 Court to fashion an appropriate equitable remedy.") (citing cases). Accordingly, EPA has filed

1 a combined opposition to Plaintiffs' motion for summary judgment, a cross-motion seeking
2 entry of summary judgment as to remedy, and a proposed order that would require EPA to take
3 final action completing the ozone NAAQS review by no later than November 15, 2015.

4 Section III below discusses further the considerations typically applied by courts in resolving
5 remedy disputes such as this one.

6 **IV. ARGUMENT**

7 **A. THIS COURT HAS EQUITABLE DISCRETION TO DETERMINE A** 8 **REASONABLE SCHEDULE FOR THE AGENCY TO TAKE WELL-** 9 **REASONED, SCIENTIFICALLY SUPPORTED, AND DEFENSIBLE** 10 **ACTION.**

11 As stated above, the only question before this Court is what schedule the Court should
12 impose for EPA to take final action on its ozone NAAQS review. A district court has broad
13 discretion to fashion equitable remedies. Weinberger v. Carlos Romero-Barcelo, 456 U.S. 305,
14 311-13 (1982); Am. Lung Ass'n v. Browner, 884 F. Supp. 345, 347 (D. Ariz. 1994); see Envtl.
15 Def. Fund v. Thomas, 627 F. Supp. 566, 569-70 (D.D.C. 1986) (adopting compliance schedule
16 proposed by EPA in a case where the Agency had failed to comply with a nondiscretionary
17 statutory duty, after finding that the schedule was "reasonable"). The D.C. Circuit has held
18 that in a suit alleging violation of a Congressionally-mandated deadline for agency action,
19 "[t]he sound discretion of an equity court does not embrace enforcement through contempt of a
20 party's duty to comply with an order that calls him to do an impossibility." Natural Res. Def.
21 Council v. Train, 510 F.2d 692, 713 (D.C. Cir. 1975) (internal quotation marks omitted).
22 Moreover, "the court may forebear the issuance of an order in those cases where it is
23 convinced by the official involved that he has in good faith employed the utmost diligence in
24 discharging his statutory responsibilities." Id.

25 The D.C. Circuit also has recognized that the need for sufficient time to evaluate
26 complex scientific or technical issues is a relevant consideration in determining whether an
27 agency is making a "diligent" effort to comply with a statutory mandate. See id. at 712-13. As
28 other courts have noted, "[t]he public has a significant interest in ensuring that the government
does not promulgate rules via a process that emphasizes expediency over quality and

1 accuracy.” Cronin v. Browner, 90 F. Supp. 2d 364, 373 (S.D.N.Y. 2000); accord Sierra Club
 2 v. Thomas, 828 F.2d 783, 798-99 (D.C. Cir. 1987) (“Indeed, by decreasing the risk of later
 3 judicial invalidation and remand to the agency, additional time spent reviewing a rulemaking
 4 proposal before it is adopted may well ensure earlier, not later, implementation of any eventual
 5 regulatory scheme.”); see also Sierra Club v. Johnson, 444 F. Supp. 2d at 58 (“Nevertheless,
 6 since the purpose of this order is to protect the public interest and not to punish EPA, the Court
 7 would extend EPA’s time to compensate for its footdragging if it were convinced that doing so
 8 was necessary for the promulgation of workable regulations.”). It is difficult to imagine a
 9 circumstance where an agency could not sign some sort of a flawed rule by any particular date;
 10 but promulgating a flawed rule does nothing to advance the goals of Congress.

11 In short, when an agency has missed a statutory deadline, in ordering relief the court
 12 should examine the relevant facts and circumstances and evaluate the time needed by the
 13 agency to make a well-reasoned, scientifically supportable, and defensible decision.

14 **B. EPA’S ANTICIPATED DATE FOR BOTH PROPOSED AND FINAL**
 15 **ACTION IS THE MOST EXPEDITIOUS SCHEDULE IT REASONABLY**
 16 **CAN MEET UNDER THE CURRENT CIRCUMSTANCES.**

17 **1. Deadline for EPA Proposing Action**

18 As the McCabe Declaration explains in detail, significant activity is required between
 19 the present and EPA’s issuance of a proposal, and some of these actions -- notably the timing
 20 and substance of CASAC’s advice -- are not within EPA’s control. EPA believes that the
 21 earliest completion date for a proposed decision is January 15, 2015. This date takes into
 22 account the remaining activities, particularly consideration of CASAC and public comments on
 23 the second drafts of the REAs and Policy Assessment and addressing the impact of Mississippi
 24 v. EPA in evaluating the secondary NAAQS. As noted above, the CASAC will conduct its
 25 peer review of the second draft REAs and Policy Assessment during its upcoming meeting
 26 March 25-27, 2014 where review of these documents is the sole agenda item.

27 Both before and since completion of the second draft Policy Assessment in February
 28 2014, EPA has been working to determine whether to propose revisions to the ozone NAAQS.
 McCabe Decl. ¶¶ 5-25. As explained more fully in the McCabe Declaration, this is a time

1 consuming and complex undertaking, given the breadth of explanation and analysis that must
2 be presented in a proposed rulemaking package. Id. There is extensive new scientific
3 evidence and other information informing this review: more than 1,000 new health studies and
4 hundreds of new welfare studies. In addition, EPA seeks to assure sufficient time to assimilate
5 CASAC's input on the critical new analyses embodied in the second draft REAs and to
6 consider these analyses and the full evidence base in the draft PA. Further, the agency requires
7 sufficient time to make necessary changes in those documents based on the CASAC (and
8 public) comment and reflect that revised presentation in decision documents and briefings, as
9 well as in the proposed rulemaking package. Id. ¶ 34.

10 In addition, EPA is considering the possibility of a secondary standard that would differ
11 in basic ways from the primary standard, using a cumulative, seasonal exposure index for the
12 form of the standard, as opposed to using the concentration of ozone in the ambient air over an
13 8-hour period. CASAC has previously recommended that EPA consider such an index. EPA
14 must also identify a level of protection it considers "requisite" to protect the public welfare,
15 consistent with 42 U.S.C. § 7409(d) and the D.C. Circuit's recent remand of the secondary
16 standard in Mississippi v. EPA. EPA's proposed schedule takes these factors into account.

17 After the REA and PA are finalized, EPA staff will prepare decision documents and
18 briefings for EPA's senior agency staff and political managers, culminating in briefings and a
19 decision by EPA's Administrator as to whether to revise the current primary and secondary
20 standards, and if so, which options should be set forth in a notice of proposed rulemaking.
21 EPA staff will then prepare the notice of proposed rulemaking package (preamble and various
22 technical support documents). This is a time-consuming and involved undertaking, as the
23 rulemaking package needs to explain in detail EPA's reasoning concerning whether or not the
24 current primary and secondary standards for ozone are appropriate or should be revised. If
25 revisions are proposed, a rationale for each element of the NAAQS (averaging time, indicator,
26 form, and level) must be provided. EPA also intends to conduct interagency review pursuant
27 to Executive Orders No. 12,866, 58 Fed. Reg. 51,735 (Sept. 30, 1993), and No. 13,563, 76 Fed.
28 Reg. 3821 (Jan. 18, 2011). After completing interagency review, the next step would be for

1 EPA to sign the proposal and submit the proposal to the Office of the Federal Register for
2 publication.

3 EPA believes that it will take approximately ten months, until January 15, 2015, to
4 complete these tasks. McCabe Decl. ¶ 32. The determination whether or not to revise a
5 NAAQS is a science-driven process, and as such, the advice and recommendations of the
6 statutorily-mandated peer-review body -- CASAC -- are critical. See, e.g., Mississippi v. EPA,
7 2013 WL 6486930, at *1, 6, 15-20; Am. Farm Bureau, 559 F. 3d at 521-22. CASAC is not
8 bound by any statutory deadline, nor is its advice tailored by scheduling exigencies.
9 Consequently, the schedule EPA seeks (and in particular, EPA's estimate of the time needed to
10 prepare a proposed rulemaking package) reflects the agency's best estimate of the time
11 CASAC will need to complete its review and submit its advice and recommendations to EPA.
12 EPA's estimate further assumes that the nature of that advice and recommendations will allow
13 EPA to make appropriate revisions to these critical documents in the anticipated time-frame.
14 But CASAC might take more time than anticipated to provide its advice and recommendations,
15 and that substantive advice might require EPA to make more revisions over a longer time than
16 presently anticipated. Further, substantive revisions might necessitate additional review by
17 CASAC to assure that the revised analyses are "air quality criteria . . . reflect[ing] the latest
18 scientific knowledge" on which the NAAQS must be based. 42 U.S.C. § 7408 (a)(2). Should
19 CASAC take longer than anticipated to provide its advice and recommendations, or if its
20 advice and recommendations necessitate more comprehensive revisions by EPA (which might
21 necessitate further CASAC review), then EPA would need additional time to prepare the
22 proposed rulemaking package and ultimately to complete the review. In that case, EPA would
23 need to request an extension of the schedule imposed by this Court.

24 **2. Final Action Deadline**

25 After submitting the proposal for publication in the Federal Register, EPA is required
26 by statute to provide an opportunity for public comment and for public hearing(s), and to keep
27 the comment period open for a minimum of 30 days from completion of the public hearing(s).
28 42 U.S.C. § 7607(d)(5)(i)-(ii), (iv); McCabe Decl. ¶ 35. Because the ozone NAAQS proposal

1 will involve many complex scientific, technical, and policy issues of great public health
2 significance, EPA plans to allow a 90-day period for public comment. McCabe Decl. ¶ 28.
3 This is consistent with the past comment periods for ozone and other NAAQS proposals,
4 including the most recent ozone NAAQS review cycle. *Id.* ¶ 35; *see, e.g., National Ambient*
5 *Air Quality Standards for Ozone*, 72 Fed. Reg. 37,818 (July 11, 2007) (notice of proposed
6 ozone NAAQS rule). Since the last ozone NAAQS review, the depth and complexity of the
7 body of health science on ozone, and the corresponding complexity of the issues EPA must
8 consider have expanded. McCabe Decl. ¶ 20-22, 27. Thus, the public merits at least as much
9 opportunity to comment on EPA's proposal as it had during the last review. Based on its
10 experience with numerous NAAQS rulemakings, EPA believes that it needs somewhat more
11 than three months from the issuance of the proposed rule to have the rule published in the
12 Federal Register, hold public hearings, and complete the public comment period. *Id.* ¶ 35.

13 EPA expects, as in other proposed rulemakings for the ozone NAAQS, that there will
14 be a very large number of significant public comments submitted. *Id.* ¶ 28. For example, in
15 the last review, *Proposed Rule*, 72 Fed. Reg. 37, 818 (July 11, 2007), thousands of comments
16 were submitted by a broad variety of stakeholder groups, including representatives of
17 environmental, public health, and medical organizations, industry representatives, and state,
18 local, and tribal officials, in addition to comments by CASAC and EPA's Children Health
19 Protection Advisory Committee. McCabe Decl. ¶ 28. EPA then expended great effort to
20 review and evaluate those comments, to take them into consideration in deciding on the
21 content of the final rule, and to prepare a comprehensive response to the significant public
22 comments as required by 42 U.S.C. § 7607(d)(6)(B). EPA's Response to Comment document
23 for the 2008 rule comprised 210 pages of single-spaced text. McCabe Decl. ¶ 29. No less time
24 or effort will be needed to address comments in this rulemaking. *Id.* A period for interagency
25 review of a final rule is also called for under the Executive Orders cited above, although, as in
26 past reviews, EPA will continue to work substantively on aspects of the rulemaking during the
27 interagency review process (for example, drafting responses to public comments). *Id.* ¶ 36.
28

1 After the comment period closes, EPA must expend significant time and resources on
2 determining a final course of action. Id. ¶ 36. This will involve assessing all of the
3 information submitted by the public and briefing senior EPA management on the public
4 comments and on potential options for the final rule. Id. ¶ 37. Senior management will need
5 to consider and make decisions on the content of the final rule. Id. EPA will then develop a
6 final rulemaking package that embodies and explains these decisions, addresses the factual
7 data on which the final decisions are based and the methodology used in obtaining and
8 analyzing the data, and describes the major legal interpretations and policy considerations
9 involved in the decision. 42 U.S.C. § 7607(d)(6)(A).

10 Taking into account all of the above tasks, EPA believes that approximately ten months
11 from issuance of the proposal is an ambitious, but feasible period of time for completion of the
12 rulemaking process. McCabe Decl. ¶¶ 30-37. Under this schedule, EPA would then sign a
13 final action on November 15, 2015. Id. ¶ 32. As Assistant Administrator McCabe makes clear
14 in her declaration, this final action date reflects the most expeditious rulemaking schedule EPA
15 believes it reasonably can meet:

16 Given the importance and complexity of the issues involved in the review of the
17 ozone NAAQS, and the employment of significant agency resources to date and
18 in the future in this review, EPA believes that the time spent to date in developing
19 the supporting documents discussed above and the proposed regulatory package,
20 and the time projected for completion of the review -- especially time needed to
21 receive and react to comment from CASAC and the public on the second draft
22 REAs and PA, reflect the most expeditious schedule that EPA reasonably can
23 meet under the circumstances

24 Id. ¶ 33; see also id. ¶¶ 25-31 (explaining why the additional time is necessary).

25 This ten-month period from proposed to final action is the same amount of time
26 Plaintiffs consider to be reasonable. See Pls.' Mot. at 13-14. In addition, the ten-month period
27 is similar to the amount of time EPA took to complete the most recent ozone review after
28 proposal (9 months). See Final Rule, 73 Fed. Reg. at 16,511 (signed Mar. 12, 2008); Proposed Rule, 72 Fed. Reg. 37,818, 37,916 (July 11, 2007) (signed June 20, 2007). EPA believes that the additional month is warranted due to the first-time NAAQS review modeling methodology utilized in this review to estimate extent of exposure (and issues attendant in that use), which

1 are likely to be the subject of significant public scrutiny and comment. In addition, as noted
2 above, EPA may develop a secondary standard that differs fundamentally from the primary
3 standard, and expects that some additional time would be needed to deal with the issues posed
4 by a distinct secondary standard.

5 EPA's proposed schedule is essentially the same as Plaintiffs'-- just shifted six weeks
6 later (proposal on January 15, 2015 versus December 1, 2014). For the reasons explained
7 above and in the McCabe Declaration, the Court should find that EPA has made a diligent
8 effort to complete its review of the ozone NAAQS and that the anticipated final action date of
9 November 15, 2015 represents the most expeditious timetable for final action under the
10 circumstances.

11 **IV. PLAINTIFFS' REQUESTED DEADLINES OF DECEMBER 1, 2014 FOR**
12 **PROPOSAL AND OCTOBER 1, 2015 FOR FINAL ACTION ARE NOT**
13 **REASONABLE.**

14 Because the schedule sought by Plaintiffs "is simply too compressed at this stage to
15 afford any reasonable possibility of compliance," the Court should decline to enter the
16 Plaintiffs' requested injunction. Sierra Club v. Johnson, 444 F. Supp. 2d at 58-59 (declining to
17 adopt plaintiff's proposed schedule and instead ordering a schedule that allowed EPA some
18 additional time for compliance); see Natural Res. Def. Council v. Train, 510 F.2d at 712
19 (courts "cannot responsibly mandate" a proposed deadline when "the Administrator
20 demonstrates that additional time is necessary"). Moreover, the Court need not address
21 Plaintiffs' contention that the schedule should not allow for interagency review, since the
22 deadline they request fails to adequately account even for the time that is reasonably necessary
23 to complete the other tasks EPA must accomplish before taking final action. Cf. Envtl. Def.
24 Fund v. Thomas, 627 F. Supp. 566, 571 (D.D.C. 1986) ("In the case at bar, enjoining OMB
25 from interacting at all with EPA simply because OMB *might* cause delay past the new judicial
26 deadline is premature and an unwarranted intrusion into discretionary executive
27 consultations.") (emphasis in original); see also McCabe Decl. ¶ 29 (EPA continues to work
28 substantively on the rulemaking during the interagency review process, for example, drafting
responses to public comments).

1 As the D.C. Circuit has explained, “[a] federal equity court may exercise its discretion
2 to give or withhold its mandate in furtherance of the public interest, including specifically the
3 interest in effectuating the congressional objective incorporated in regulatory legislation.”
4 Natural Res. Def. Council v. Train, 510 F.2d at 713. Further, “the court may forbear the
5 issuance of an order in those cases where it is convinced by the official involved that he has in
6 good faith employed the utmost diligence in discharging his statutory responsibilities.” Id. It
7 is of the utmost importance for the agency to have sufficient time to conclude the NAAQS
8 review in a manner most likely to yield a well-reasoned, scientifically supportable, and
9 defensible decision that will survive the nearly inevitable challenge to that decision. Here,
10 Acting Assistant Administrator McCabe’s Declaration establishes that the Agency has indeed
11 acted with reasonable dispatch under the circumstances and that the schedule it plans to meet is
12 the most reasonably expeditious schedule possible. Thus, for the reasons explained above and
13 in the McCabe Declaration, the Court should not enter a proposed action deadline any earlier
14 than January 15, 2015 or a final action deadline any earlier than November 15, 2015. EPA’s
15 accompanying Cross-Motion for Summary Judgment as to Remedy includes a Proposed Order
16 requiring proposed and final action by those dates.

17 CONCLUSION

18 For the foregoing reasons, the Court should deny Plaintiffs’ Motion for Summary
19 Judgment as to remedy, and grant EPA’s Cross-Motion for Summary Judgment as to Remedy.

20 //

21 //

22 //

23 //

24 //

25 //

26 //

27 //

28 //

1 Respectfully submitted,

2 Date: February 25, 2014

3 ROBERT G. DREHER
4 Acting Assistant Attorney General
5 Environment and Natural Resources Division

6 /s/ Leslie M. Hill

7 LESLIE M. HILL (D.C. Bar No. 476008)
8 U.S. Department of Justice
9 Environment & Natural Resources Division
10 Environmental Defense Section
11 601 D Street N.W., Suite 8000
12 Washington D.C. 20004
13 leslie.hill@usdoj.gov
14 Telephone (202) 514-0375
15 Facsimile (202) 514 8865

16 *Attorneys for Defendants*

17 Of counsel:

18 Steven Silverman
19 Office of General Counsel
20 U.S. Environmental Protection Agency
21
22
23
24
25
26
27
28