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

AMERICAN FARM BUREAU FEDERATION, et al., Petitioners, v. UNITED STATES ENVIRONMENTAL PROTECTION AGENCY, Respondent.	No. 06-1410 (and consolidated cases)

EPA'S RESPONSE IN OPPOSITION TO PETITIONS FOR WRIT OF MANDAMUS

TABLE OF CONTENTS

TABLE OF AUTHORITIES

FEDERAL CASES

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[*] Cases upon which EPA chiefly relies are marked with an asterix.

FEDERAL STATUTES

CODE OF FEDERAL REGULATIONS

FEDERAL REGISTER

EXECUTIVE ORDERS

INTRODUCTION

Respondent United States Environmental Protection Agency ("EPA") hereby files its opposition to the two separate Petitions for a Writ of Mandamus submitted in this case by American Lung Association, Environmental Defense Fund, and National Parks Conservation Association ("Environmental Petitioners"), and by the States of New York, Connecticut, Delaware, Maryland, Massachusetts, New Hampshire, New Mexico, Oregon, Rhode Island, and Vermont ("State Petitioners"). Both groups of Petitioners argue that EPA has unreasonably delayed responding to the mandate issued by this Court on April 17, 2009, which remanded (but did not vacate) EPA's 2006 national ambient air quality standards ("NAAQS" or "standards") for fine particulate matter pollution. See American Farm Bureau Fed'n v. EPA, 559 F.3d 512 (D.C. Cir. 2009). As discussed further below, the time taken and the approach selected by EPA to address the scientific issues that were the subject of the Court's remand is reasonable under the circumstances and in line with past cases in which the Court has concluded that agency delay is not so "egregious" that it warrants the drastic sanction of granting a writ of mandamus. Moreover, in the accompanying Declaration of EPA Assistant Administrator Regina McCarthy ("McCarthy Decl.") (submitted as Attachment 1 to this brief), EPA has identified a clear and expeditious timetable for completing its response to the Court's remand and has carefully explained why it needs the additional time. For these reasons, the Court should deny the mandamus petitions.

I. BACKGROUND

A. Statutory Requirements for NAAQS

The NAAQS provisions of the CAA establish a comprehensive scheme to protect public health and welfare from ubiquitous air pollutants. Sections 108 and 109 of the Act require EPA to establish, review and revise air quality criteria and standards. 42 U.S.C. §§ 7408, 7409. Section 110 then calls on the States to establish State Implementation Plans, which impose controls on sources of air pollution as necessary to attain the NAAQS. Id. § 7410.

The NAAQS process begins with the development of "air quality criteria," which must reflect the latest scientific knowledge on "all identifiable effects on public health or welfare" that may result from a pollutant's presence in the ambient air. Id. § 7408(a)(2). The scientific assessments constituting air quality criteria generally take the form of a "Criteria Document" or "Integrated Science Assessment," a rigorous review of all pertinent scientific studies and related information. As part of the NAAQS review, EPA staff also typically develops quantitative Risk Assessments estimating how variations in the ambient concentration of a criteria pollutant affect the incidence of adverse health and welfare effects. In addition, EPA staff typically develops a "Staff Paper" or "Policy Assessment" to "bridge the gap" between the scientific review and the policy judgments the Administrator must make to set standards. See Natural Res. Def. Council, Inc. v. EPA, 902 F.2d 962, 967 (D.C. Cir. 1990). All of these documents undergo extensive scientific peer-review by the statutorily mandated

peer review body (the "Clean Air Scientific Advisory Committee" or "CASAC") pursuant to 42 U.S.C. § 7409(d)(2)(B), as well as public notice and comment.

Based on the air quality criteria, EPA must promulgate "primary" and "secondary" NAAQS to protect against a pollutant's "adverse" health and welfare effects. 42 U.S.C. § 7409. "Primary" standards must be set at levels that, "in the judgment of the Administrator," are requisite to protect public health with "an adequate margin of safety," while "secondary" standards must protect public welfare. Id. §§ 7409(b)(1) & (2), 7602(h). In establishing the primary standards, EPA considers a number of factors, including the nature and severity of health effects, the types of health evidence available, the kind and degree of uncertainty in the evidence, and the size and nature of sensitive populations at risk. Lead Indus. Ass'n v. EPA, 647 F.2d 1130, 1161 (D.C. Cir. 1980).

To ensure that each NAAQS will keep pace with advances in scientific knowledge, Congress also required that EPA review the criteria and NAAQS at least once every five years, and revise them as "appropriate in accordance with [sections 108 and 109(b)]." 42 U.S.C. § 7409(d)(1). In this review, EPA must consider, and explain any significant departure from, the recommendations of CASAC, which, as noted above, is an independent committee established specifically to advise the Administrator on air quality criteria and NAAQS. Id. §§ 7409(d)(2)(B), 7607(d)(3).

B. Regulatory and Litigation Background

The NAAQS rulemaking reviewed by this Court in its 2009 opinion was the fourth in which EPA considered particulate matter. Particulate matter was among

six pollutants covered by the original NAAQS promulgated in 1971. 36 Fed. Reg. 8186 (Apr. 30, 1971). EPA subsequently revised the particulate matter NAAQS in 1987 to focus on smaller, "inhalable" particles with a diameter of 10 micrometers or less ("PM_{10}"), based on evidence that the health risks associated with such particles were "markedly greater" than those associated with larger particles. 52 Fed. Reg. 24,634, 24,639 (July 1, 1987). In 1997, EPA again revised the particulate matter NAAQS, and for the first time established separate standards for "fine" particles (those with a diameter of 2.5 micrometers or less, i.e., "$PM_{2.5}$"), and coarse particles ("PM_{10}"). The Agency's decision to modify the standards was based on evidence that serious health effects were associated with short- and long-term exposure to fine particles in areas that met the existing PM_{10} standards. 62 Fed. Reg. 38,652, 38,665-68 (July 18, 1997). In American Trucking Ass'ns v. EPA, 283 F.3d 355 (D.C. Cir. 2002), this Court upheld both EPA's decision to create the $PM_{2.5}$ indicator and the levels EPA chose for the $PM_{2.5}$ standards.[1/] Finally, in October 2006, EPA completed its review of the 1997 standards; with respect to fine particles, EPA: (a) reduced the level of the 24-hour $PM_{2.5}$ standard from 65 to 35 micrograms per cubic meter; (b) left in place the level of the existing

[1/] In an earlier decision, the Court upheld EPA's determination to have separate standards for coarse particles, but held that EPA's use of PM_{10} as the indicator for coarse particles was arbitrary or capricious. It also upheld EPA's decision to establish secondary standards for fine particles (for the purpose of addressing adverse effects on visibility) which were identical to the primary $PM_{2.5}$ standards. American Trucking Ass'ns v. EPA, 175 F.3d 1027 (D.C. Cir.), modified on reh'g, 195 F.3d 4 (D.C. Cir. 1999), rev'd in part on other grounds, Whitman v. Am. Trucking Ass'ns, 531 U.S. 457 (2001).

annual $PM_{2.5}$ standard of 15 micrograms per cubic meter; and c) established secondary standards identical to the two primary $PM_{2.5}$ standards. 71 Fed. Reg. 61,144 (Oct. 17, 2006); see also American Farm Bureau, 559 F.3d at 516 (explaining the difference between the annual and the 24-hour or "daily" standards for $PM_{2.5}$).

The Petitioners challenged the 2006 annual $PM_{2.5}$ standard on four distinct grounds, two of which the Court found were without merit. Specifically, the Court concluded that EPA reasonably interpreted the evidence of adverse health effects obtained from studies of long-term exposure to particulate matter pollution, and that EPA acted reasonably in deciding not to rely upon a quantitative risk assessment when setting the levels for the $PM_{2.5}$ NAAQS. American Farm Bureau, 559 F.3d at 526-28. However, the Court found that EPA acted arbitrarily in two other respects: (1) by failing to adequately explain why it considered only long-term exposure studies, rather than also considering short-term exposure studies, in setting the level of the annual standard; and (2) by failing to adequately explain how the annual standard would protect against the risk of morbidity in children and other sensitive sub-populations. Id. at 520-26. The Court also found that EPA had not articulated a reasonable basis for the secondary $PM_{2.5}$ standards. Id. at 528-30. The Court remanded the annual standard and the secondary standards for $PM_{2.5}$ to EPA for reconsideration, but did not vacate the standards, first, because "the EPA's failure adequately to explain itself is in principle a curable defect," and second, because "vacating a standard [that] may be insufficiently protective would sacrifice

such protection as it now provides, making the best an enemy of the good." Id. at 528.[2/] The Court issued its mandate in the case on April 17, 2009.

C. EPA's Actions to Date in Response to the Court's Remand, and Its Anticipated Schedule for Completing the Remaining Tasks

At the time of the Court's remand, EPA already had taken a number of steps towards completing its statutory five-year review of the 2006 NAAQS, including public release of the first draft of the Integrated Science Assessment. McCarthy Decl. ¶ 14.[3/] Accordingly, the Administrator decided that the Agency should incorporate its reconsideration of the issues that were the subject of the Court's remand into the Agency's ongoing review of the 2006 standards. See McCarthy Decl. ¶ 15.

By 2009, it was already clear that there was an enormous body of new science on particulate matter since the 2004 PM Criteria Document, including hundreds of new epidemiologic studies. Id. ¶ 14. There were also significant additions to existing studies, including a continuation of the Gauderman study

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[2/] The Court also denied all petitions for review with respect to the NAAQS for coarse particulate matter. Id. at 531-39.

[3/] See also, e.g., 72 Fed. Reg. 34,004 (June 20, 2007) (announcing initial workshops to be held in July 2007 regarding the primary and secondary particulate matter NAAQS); 72 Fed. Reg. 63,177 (Nov. 8, 2007) (announcing forthcoming consultation with CASAC and opportunity for public comment regarding draft Integrated Review Plan); 73 Fed. Reg. 30,391 (May 27, 2008) (providing notice of June 2008 peer review workshop on preliminary draft chapters of Integrated Science Assessment); 74 Fed. Reg. 7688 (Feb. 19, 2009) (releasing first external review draft of the Integrated Science Assessment and providing notice of public meeting with CASAC on this review draft).

examining effects of long-term exposure to $PM_{2.5}$ on a cohort of southern California children, which had figured significantly in the Court's determination that EPA did not adequately explain how the annual standard was requisite to protect children from morbidity effects resulting from long-term exposure to $PM_{2.5}$. Id.; see American Farm Bureau, 559 F.3d at 524-25; supra at 5-6. Given this body of new information, and a recommended approach to consider both long-term and short-term exposure studies in assessing the level of the annual standard, EPA believed it made sense to respond to the Court's remand as part of the ongoing statutory review cycle, rather than attempting to explain or revise its prior NAAQS determination based solely on the record for the 2006 rulemaking. McCarthy Decl. ¶ 15. This assured that EPA's response would reflect all of the new science, including the continuation of the Gauderman study, and consideration of the entire body of short-term and long-term exposure studies. Id. This approach also assured that EPA's ongoing review would not be diverted or disrupted by committing resources to a separate re-evaluation of the 2006 rule based on a scientific record which had been partially superceded. Id.

Accordingly, following the Court's remand, EPA continued its ongoing work on the review of the 2006 standards. EPA held two public meetings with CASAC in April and October 2009 for the purpose of taking comments on drafts of its "Integrated Science Assessment for Particulate Matter," and then published the final Integrated Science Assessment in December 2009. 74 Fed. Reg. 7688 (Feb. 19, 2009) (notice of April 2009 public meeting); 74 Fed. Reg. 46,586 (Sept. 10, 2009) (notice of October 2009 public meeting); 74 Fed. Reg. 66,353 (Dec. 15,

2009) (notice of final Integrated Science Assessment).[4] EPA also prepared a draft health risk assessment and a draft visibility impact assessment, which similarly underwent two rounds of CASAC and public review at the above-noted October 2009 meeting and at a subsequent meeting in March 2010. 75 Fed. Reg. 8062 (Feb. 23, 2010) (notice of March 2010 public meeting). EPA released the final "Quantitative Health Risk Assessment for Particulate Matter" and "Particulate Matter Urban-Focused Visibility Assessment" in July 2010. 75 Fed. Reg. 39,252 (July 8, 2010).[5]

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[4] The Integrated Science Assessment was formerly termed the "Criteria Document." It reflects the latest knowledge on the kind and extent of effects of ambient particulate matter on public health and welfare. The December 2009 PM Integrated Assessment consists of nine chapters and six Annexes. Among other things, the Integrated Science Assessment: (1) evaluates and integrates epidemiologic, controlled human exposure, and animal toxicological information; (2) organizes that information by health outcome category; (3) evaluates this evidence related to populations potentially susceptible to PM-related effects (including children); and (4) evaluates data on direct welfare effects of particles in the ambient air (notably visibility impairment, damage to materials, and negative climate interactions. McCarthy Decl. ¶ 7.

[5] The Risk Assessment estimates risk for: (1) all-cause, ischemic heart disease-related, cardiopulmonary- and lung cancer-related mortality associated with long-term $PM_{2.5}$ exposure; (2) non-accidental, cardiovascular-related, and respiratory-related mortality associated with short-term $PM_{2.5}$ exposure; and (3) cardiovascular-related and respiratory-related hospital admissions and asthma-related emergency department visits associated with short-term $PM_{2.5}$ exposure. The Risk Assessment interprets the risk estimates associated with simulating just meeting the current suite of standards, as well as the risk estimates associated with meeting certain combinations of alternative standards, in various parts of the United States. McCarthy Decl. ¶ 10. The Urban Focused-Visibility Assessment includes: (1) a reanalysis of public preference studies providing information useful

(continued...)

Based on the scientific and technical information available in this NAAQS review as documented by the Integrated Science Assessment, Health Risk Assessment and Visibility Assessment, EPA staff prepared a Policy Assessment. As noted above, the Policy Assessment is intended to help bridge the gap between the relevant scientific information and assessments and the policy judgments that the Administrator must make to reach decisions on the NAAQS.[6/] This document includes the EPA staff's final conclusions on the adequacy of the current standards and on alternative standards for the Administrator to consider.

[5/](...continued)
for the selection of "target levels" for urban visibility protection; (2) analyses of the factors contributing to visibility impairment for selected urban areas, including PM species component contributions and variations in relative humidity, providing information useful for better characterizing regional differences; and (3) analyses of air quality simulated to just meet the current $PM_{2.5}$ standards as well as alternative standards using different combinations of the four elements of the NAAQS (indicator, averaging time, level and form). McCarthy Decl. ¶ 11.

[6/] The Policy Assessment was previously termed the "Staff Paper." See American Farm Bureau, 559 F.3d at 516, 521, 530. EPA initially released a preliminary draft of the Policy Assessment in September 2009 for informational purposes and to facilitate discussion with CASAC at the October 2009 meeting on the overall structure, areas of focus, and level of detail to be included in the Policy Assessment. CASAC's comments on this preliminary draft were considered in developing a first draft, which EPA released to the public in January 2010. 75 Fed. Reg. 4067 (Jan. 26, 2010). The first draft was then discussed at the March 2010 public meeting and at public teleconferences with CASAC in April and May 2010. 75 Fed. Reg. 8062 (Feb. 23, 2010) (notice of April teleconference); 75 Fed. Reg. 19,971 (Apr. 16, 2010) (notice of May teleconference). The Policy Assessment went through a second round of CASAC and public review before EPA published the final Policy Assessment on April 22, 2011. See 75 Fed. Reg. 32,763 (June 9, 2010) (notice of July 2010 public meeting); 76 Fed. Reg. 22,665 (Apr. 22, 2011) (notice of final Policy Assessment).

Since completion of the Policy Assessment in April 2011, multiple offices within EPA, as well as senior Agency officials, have continued their work on developing a proposed rulemaking package that addresses all relevant issues bearing on whether the PM NAAQS should be revised and, if so, how. See McCarthy Decl. ¶ 16. This is a massive undertaking. The proposed rulemaking package must explain whether the current primary and secondary standards for both fine and coarse particulate matter are appropriate or should be revised. Id. If revisions are to be proposed, EPA must provide a rationale for each element of the NAAQS (averaging time, indicator, form, and level). Id.; see American Farm Bureau, 559 F.3d at 515. In addition, the rulemaking package discusses intricate issues related to interpretation of the $PM_{2.5}$ NAAQS, including requirements for data use and reporting. McCarthy Decl. ¶ 16; see 40 C.F.R. Pt. 50, App. N. Consistent with other NAAQS proposals, EPA contemplates that the rulemaking package also will discuss highly technical issues relating to PM monitoring and the extent and location of the PM monitoring network. McCarthy Decl. ¶ 16.

EPA has committed significant Agency resources to all of the work performed to date in the review of the PM NAAQS. This work has involved large numbers of staff and managers at several different offices within EPA, including the Office of Air and Radiation, Office of Research and Development, Office of General Counsel, Office of Policy, and the Office of the Administrator. McCarthy Decl. ¶ 17. As discussed above, very significant progress has been made. EPA's next steps including finishing internal Agency review and completing interagency review pursuant to Executive Orders 12,866 and 13,563. McCarthy Decl. ¶ 17; see

58 Fed. Reg. 51,735 (Sept. 30, 1993) (Exec. Order 12,866); 76 Fed. Reg. 3821 (Jan. 18, 2011) (Exec. Order 13,563). EPA expects that these processes will be complete by June of this year.[7] Accordingly, EPA's current plan is to sign a proposed rule sometime in June 2012. McCarthy Decl. ¶ 17.

As discussed above, the PM NAAQS rulemaking proposal will involve many complicated issues of great public health and public welfare significance. Therefore, EPA believes the public should have ample time to comment on the proposal, as well as to participate in the public hearings provided by 42 U.S.C. § 7607(d)(5). EPA also needs time to prepare a final rulemaking package. Among other things, based on past PM NAAQS rulemakings, EPA anticipates receiving thousands of public comments which will require EPA's response. A reasonable period for interagency review of a final rule under the above-cited Executive Orders is also appropriate. EPA believes that one year is a reasonable period of time in which to complete these processes after signing the proposed rule. McCarthy Decl. ¶ 18. Taking all of the above into account, it is EPA's current intention to sign a final action setting forth its determination as to whether to revise the 2006 NAAQS and, if so, how, by June 2013. For the reasons previously explained, this final action would also serve as EPA's response to the Court's April 2009 remand.

[7] This estimate includes allowing up to 90 days for interagency review under Executive Order 12,866. Id. § 6(b)(2)(B); McCarthy Decl. ¶ 17 n.1.

II. STANDARD OF REVIEW

"Mandamus is an extraordinary remedy, warranted only when agency delay is egregious." In re Monroe Communications Corp., 840 F.2d 942, 945 (D.C. Cir. 1988) (citations omitted); see also, e.g., Kerr v. District Court, 426 U.S. 394, 402 (1976) ("The remedy of mandamus is a drastic one, to be invoked only in extraordinary situations."). The party seeking a writ of mandamus bears the burden of proving that its right to issuance of the writ is "clear and indisputable." In re Int'l Union, United Mine Workers of Am., 231 F.3d 51, 54 (D.C. Cir. 2000) (citations omitted).

In cases such as this, where a petitioner seeks a writ of mandamus based on a claim of unreasonable agency delay, this Court has articulated six factors as providing "useful" but "not ironclad" guidance. Telecommunications Research and Action Center ("TRAC") v. FCC, 750 F.2d 70, 79-80 (D.C. Cir. 1984). "The first and most important factor is that 'the time agencies take to make decisions must be governed by a rule of reason.'" In re Core Communications, Inc., 531 F.3d 849, 855 (D.C. Cir. 2008) (quoting TRAC, 750 F.2d at 80) (internal quotation marks omitted). The remaining five are:

> (2) where Congress has provided a timetable or other indication of the speed with which it expects the agency to proceed in the enabling statute, that statutory scheme may supply content for this rule of reason . . .; (3) delays that might be reasonable in the sphere of economic regulation are less tolerable when human health and welfare are at stake . . .; (4) the court should consider the effect of expediting delayed agency action on agency activities of a higher or competing priority . . .; (5) the court should also take into account the nature and extent of the interests prejudiced by delay . . .; and (6) the court need not "find any impropriety lurking behind agency lassitude in order to hold that agency action is 'unreasonably delayed.'"

TRAC, 750 F.2d at 80 (citations omitted); Core Communications, 531 F.3d at 855. As explained below, in this case Petitioners have failed to demonstrate their entitlement to the extraordinary relief of a writ of mandamus.

III. ARGUMENT

A. EPA's Actions to Date Are Within The "Rule of Reason."

Two years and nine months have passed since the Court issued its mandate in this case on April 17, 2009. As described above, during this time period EPA has made substantial progress towards completing its five-year review of the 2006 NAAQS, and in conjunction with that overall review effort it is reconsidering the specific issues that the Court held were not adequately explained in EPA's October 2006 rulemaking. EPA has provided a reasonable explanation for combining its response to the judicial remand with the global NAAQS review effort, rather than undertaking the remand response separately from the global review. Supra at 6-8; see Action on Smoking and Health v. Department of Labor, 100 F.3d 991, 995 (D.C. Cir. 1996) (deferring to Occupational Safety and Health Administration's ("OSHA's") decision to address a number of indoor air quality contaminants in one global rulemaking, rather than separately developing a regulation to address workplace exposure to second-hand tobacco smoke). The NAAQS review process necessarily has included extensive interaction with CASAC and multiple opportunities for public comment on the scientific, technical and policy analysis documents that will provide the foundation for the final decisions to be made by the Administrator. All of these tasks necessarily have required a substantial amount of time to complete, and as described above and in the attached

Declaration of EPA Assistant Administrator Regina McCarthy, the Agency has committed a tremendous amount of resources to this effort.

In short, EPA's actions since April 2009 do not represent an unreasonable delay of its response to the Court's remand. Furthermore – unlike many of the cases cited by Petitioners in which the Court has found it necessary to impose mandamus relief – the McCarthy Declaration identifies a clear timetable according to which the Agency will complete its response to the Court's remand, and explains in detail why EPA anticipates that this additional time will be necessary.[8/]

"While there is no absolute definition of what is a reasonable time," Community Nutrition Inst. v. Young, 773 F.2d 1356, 1361 (D.C. Cir. 1985), in past cases this Court generally has not found agency delays of less than three years sufficiently "egregious" so as to warrant the extraordinary relief of granting a writ of mandamus. See, e.g., Monroe Communications, 840 F.2d at 945-46 (three years' delay in a television license renewal proceeding was, "[t]o be sure, an undesirably large amount of time," but "[w]e cannot, however, call the delay

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[8/] Compare, e.g., In re American Rivers and Idaho Rivers United, 372 F.3d 413, 418, 420 (D.C. Cir. 2004) (FERC did not attempt "to demonstrate the reasonableness of its more than six-year delay, and "offer[ed] 'no plea of administrative error, administrative convenience, practical difficulty . . . or need to prioritize in the face of limited resources'") (quoting Cutler v. Hayes, 818 F.2d 879, 898 (D.C. Cir. 1987)), In re Bluewater Network, 234 F.3d 1305, 1315 (D.C. Cir. 2000) (Coast Guard disavowed any intention of taking further action, although the statute mandated establishment of compliance standards and use requirements), and Public Citizen Health Research Group v. Auchter, 702 F.2d 1150, 1158 (D.C. Cir. 1983) (as amended) (agency provided "no reasoned explanation" for rulemaking delay), with McCarthy Decl. ¶¶ 4-20 and supra at 6-11.

unreasonable on its face"). In Sierra Club v. Thomas, 828 F.2d 783 (D.C. Cir. 1987), the Court concluded that it should not grant mandamus relief in response to a nearly three-year delay in EPA's decision on whether to place strip mines on the list of pollutant sources subject to fugitive emissions regulation under the CAA's "Prevention of Significant Deterioration" program. Id. at 797-99. Thus, even in a case where – unlike Monroe – administrative delay had the potential to affect public health rather than primarily economic interests, the Court did not find a delay approaching three years in length to be so extraordinary that the Court should impose a deadline for the agency to complete its rulemaking. In other cases involving shorter delays the Court similarly has concluded that mandamus relief is not warranted. See, e.g., Public Citizen Health Research Group v. Brock, 823 F.2d 626, 628-29 (D.C. Cir. 1987) (a six-year schedule to complete a rulemaking addressing work-place exposure to the toxin ethylene oxide – including two years to respond to the Court's remand in an earlier opinion – met the rule of reason under the circumstances, though it treaded on "the abyss of unreasonable delay"); Action on Smoking and Health, 100 F.3d at 993-95 (sixteen months' delay of final action following close of administrative hearing did not constitute unreasonable delay).[9/]

[9/] Petitioners have cited one case in which the Court found a three-year delay unreasonable. See Auchter, 702 F.2d at 1158. But as noted above, in that case, unlike here, the agency offered the Court "no reasoned explanation" for the length of time it anticipated taking to complete the rulemaking at issue. Id. at 1158; supra at 14 & n.8.

Conversely, the Court has at times found imposition of mandamus relief to be justified where the administrative delay at issue significantly exceeds four years in length, especially where – unlike here – the agency has not manifested an intention to promptly complete a rulemaking proceeding or otherwise take action in the near future. See, e.g., MCI Telecomm. Corp. v. FCC, 627 F.2d 322, 340 (D.C. Cir. 1980) (almost four years' delay, from June 1976 to April 1980); Midwest Gas Users Ass'n v. FERC, 833 F.2d 341, 359 (D.C. Cir. 1987) (four years had passed already, and several additional years of delay were likely unless the Court intervened); Bluewater Network, 234 F.3d at 1315-16 (Coast Guard had missed by *nine* years a statutory deadline under the Oil Pollution Act to develop compliance standards and use requirements, and had no plans even to undertake such a rulemaking); American Rivers, 372 F.3d at 418-20 (more than six years to respond to a petition seeking formal consultation under the Endangered Species Act, and the agency offered no explanation for the delay); Core Communications, 531 F.3d at 855-57 (six years' delay in responding to the Court's remand warranted mandamus relief).[10/]

Potomac Electric Power Co. ("PEPCO") v. Interstate Commerce Comm'n, 702 F.2d 1026 (D.C. Cir. 1983), which the Environmental Petitioners cite as a "substantially similar" case, actually involved a much lengthier agency delay. There, the Interstate Commerce Commission had not responded to the Court's mandate in an earlier decision after *five* years. See id. at 1028, 1032. At that

[10/] Accord American Rivers, 372 F.3d at 419 n.12 (listing past decisions of the Court).

juncture, the Court found that "[h]owever justified a single delay in the course of [the Commission's] proceedings may have been, the limit has been reached." Id. at 1035. The present case, however, is more readily analogous to Sierra Club v. Thomas, in which the Court found that it should refrain from granting mandamus relief. See 828 F.2d at 797. Sierra Club represents an applicable precedent not only because of the similarity in the length of time (thirty-months in Sierra Club, thirty-three months here) and statute at issue, but because, as in Sierra Club, EPA here has made substantial progress towards completion of its rulemaking effort and has laid out a clear timetable for completing the rulemaking within the reasonably near future. Compare id. at 798-99 (describing the scientific and technical challenges associated with the rulemaking at issue and EPA's progress to date), with supra at 6-11 and McCarthy Decl. ¶¶ 4-20.

This Court should not grant mandamus as a means of "penalizing" EPA for failing to meet the expedited NAAQS review schedule it announced in October 2009. See Envt'l Pets.' Br. at 16-17; State Pets.' Br. at 15. EPA made its best efforts to meet this schedule but was unable to do so due chiefly to the time taken for preparation of the supporting documents for the rulemaking package (especially the Integrated Science Assessment, the Risk Assessment, the Visibility Assessment and the Policy Assessment), these documents' repeated reviews by CASAC and the public, and the significant revisions undertaken in light of CASAC's review and the public comments. See McCarthy Decl. ¶ 19. Additionally, in the first three months of 2011, EPA conducted a series of meetings with stakeholders, particularly those from the agricultural community, relating to the review of the

primary and secondary standards for coarse particulate matter. The Agency did not complete and release the Policy Assessment until those meetings were completed and the comments from the meetings had been assessed by EPA. Id. ¶ 13. Thus, while the schedule EPA envisioned in October 2009 was well-intentioned at the time, it ultimately proved "aspirational," and EPA was within its discretion to adjust that schedule for the reasons identified in the McCarthy Declaration, particularly since the overall length of the remand-response effort is still within what this Court has generally regarded as the "rule of reason." See Action on Smoking and Health, 100 F.3d at 993 (agreeing with OSHA that its self-imposed deadlines were merely aspirational and did not override the inherent statutory discretion OSHA had to order its priorities in a reasonable manner).

Finally, Petitioners' belief that EPA took too long between the 1997 and 2006 final NAAQS rules is not a valid basis to subject EPA's *current* response to the Court's 2009 remand to a judicially-imposed deadline. See Envt'l Pets' Br. at 11. This is an argument the Court has expressly rejected in the past. See United Steel Workers of Am. v. Rubber Mfrs. Ass'n, 783 F.2d 1117, 1120 (D.C. Cir. 1986) (noting that the reasonableness of time taken by the agency in the past was not before the court). Indeed, the Court observed in United Steel Workers that "judicial imposition of an overly hasty timetable . . . would ill serve the public interest" where the agency's prior rule has been invalidated by the Court, since the new rule "must be constructed carefully and thoroughly if the agency's action is to pass judicial scrutiny this time around." Id. That observation is equally apt here. Accord Sierra Club v. Thomas, 828 F.2d at 798 (in the Clean Air Act context,

"EPA must be afforded the time necessary to analyze such [complex scientific, technological, and policy] questions so that it can reach considered results in a final rulemaking that will not be arbitrary and capricious or an abuse of discretion").

In sum, when considered in the context of the Court's past decisions, the two years and nine months that have passed since the Court issued its remand in this case is not an "extraordinary" length of time, particularly given the complex scientific and technical analysis and statutorily-mandated peer review that must occur before reaching decisions concerning the $PM_{2.5}$ primary and secondary NAAQS. EPA's actions in this matter are within the "rule of reason" and do not warrant the judicial intervention sought by Petitioners.

B. There Is No Applicable Statutory Timetable.

The second TRAC factor states that "where Congress has provided a timetable or other indication of the speed with which it expects the agency to proceed in the enabling statute," that statutory scheme may supply content for the "rule of reason" inquiry. See TRAC, 750 F.2d at 80. However, "absent a precise statutory timetable or other factors counseling expeditious action, an agency's control over the timetable of a rulemaking proceeding is entitled to considerable deference." Sierra Club, 828 F.2d at 797 (citation omitted). This is true even where the agency initially set forth its own aspirational deadlines for action with "dates long gone." Action on Smoking and Health, 100 F.3d at 993. In this case, no statutory timetable governs the response to a judicial remand, and EPA's response activities to date and anticipated timetable for completing the response is within the rule of reason as shown above.

Environmental Petitioners argue that the Court should consider the failure to meet the five-year review deadline under section 109(d) of the CAA, 42 U.S.C. § 7409(d), as a basis for a writ of mandamus. See Envt'l Pets.' Br. at 12. However, the Agency's compliance with that statutory provision is not before this Court. See 42 U.S.C. § 7604(a) (investing the district courts with jurisdiction over citizen suits challenging the failure to perform nondiscretionary acts under the CAA); see also Attachment 2 (Oct. 18, 2011 notice of intent by American Lung Association and National Parks Conservation Association to file citizen suit).

C. EPA Has Discretion Reasonably to Prioritize and Coordinate Various Regulatory Activities Pertaining to Human Health and Welfare.

EPA's actions to date are also consistent with the third, fourth and fifth TRAC factors. The third TRAC factor is that "delays that might be reasonable in the sphere of economic regulation are less tolerable when human health and welfare are at stake," while the fourth factor is that "the court should consider the effect of expediting agency action on agency activities of a higher or competing priority." TRAC, 750 F.2d at 80. The fifth factor is that "the court should also take into account the nature and extent of the interests prejudiced by delay." Id.

This case does, of course, involve important questions of human health and welfare, and Petitioners argue that this renders the time EPA has taken to complete its rulemaking unreasonable. See Envt'l Pets.' Br. at 12-15. But as the Court has previously explained in the CAA context, "this factor alone can hardly be considered dispositive when, as in this case, virtually the entire docket of the agency involves issues of this type." Sierra Club, 828 F.2d at 798. Instead, "[i]n

such circumstances, whether the public health and welfare will benefit or suffer from accelerating this particular rulemaking depends crucially upon the competing priorities that consume EPA's time, since any acceleration here may come at the expense of delay of EPA action elsewhere." Id. Therefore, consideration of TRAC's third, fourth and fifth factors overlaps.

Of course, at a time of dwindling resources, EPA faces significant competing demands to implement its extensive responsibilities under the Clean Air Act relating to implementation of current NAAQS, controls on emissions of hazardous (toxic) air pollutants, control of emissions from mobile sources, control of acid deposition, and stratospheric ozone protection. Court-imposed deadlines with respect to the remand response likely would constrain, to some extent, the Agency's ability to allocate its resources where necessary to complete other pending rulemakings involving equally weighty public health considerations.

Moreover, the specific deadlines sought by Petitioners would not allow even a minimally adequate period of time to complete the remaining tasks that are necessary before EPA finalizes the rulemaking. For example, Petitioners urge the Court to require EPA to sign a proposed rule by February 15, 2012 (see Envt'l Pets.' Br. at 1), which would leave insufficient time to complete interagency review prior to issuing the proposal. See supra at 10-11 & n.7; McCarthy Decl. ¶ 17 & n.1. Petitioners also advocate a Court-imposed deadline of September 15, 2012 for a final rule, which would leave insufficient time for public comment and public hearings related to the proposal, and for EPA to adequately respond to the

public comments in conjunction with finalizing the rulemaking, as well as insufficient time for interagency review. See supra at 11; McCarthy Decl. ¶ 18.

For these reasons, the mere fact that this case involves public health and welfare issues does not justify the extraordinary relief sought by the Petitioners. Given the importance, difficulty, and sensitivity of the issues involved in determinations relating to the $PM_{2.5}$ NAAQS, the time EPA has spent in preparing the draft proposed rulemaking package and that it anticipates needing in order to complete the proposal and the subsequent final action is reasonable. Therefore, the third, fourth and fifth TRAC factors do not support imposition of a judicial order overriding EPA's discretion, given the explanation provided in the McCarthy Declaration and above.

D. EPA Has Acted In Good Faith In Responding To This Court's 2009 Decision.

The sixth and final TRAC factor states that "the court need not 'find any impropriety lurking behind agency lassitude in order to hold that agency action is 'unreasonable delayed.'" TRAC, 750 F.2d at 80. Petitioners do not suggest that any impropriety has occurred in this case, and the Agency's actions as described above and in the Declaration certainly do not manifest any bad faith on EPA's part.

IV. CONCLUSION

For all the foregoing reasons, the Court should deny the Mandamus Petitions, including the Petitioners' request that the Court exercise continuing

jurisdiction over EPA's administrative activities in response to the Court's remand.[11/]

Respectfully submitted,

IGNACIA S. MORENO
Assistant Attorney General
Environment and Natural Resources Division

Dated: January 17, 2012 By: /s/ Brian H. Lynk
BRIAN H. LYNK, D.C. Bar No. 459525
U.S. Department of Justice
Environmental Defense Section
P.O. Box 23986
Washington, D.C. 20026-3986
(202) 514-6187 (tel.)
Attorneys for Respondent

OF COUNSEL:

STEVEN SILVERMAN
JOHN HANNON
Office of General Counsel (2344A)
U.S. Environmental Protection Agency
1200 Pennsylvania Ave., NW
Washington, DC 20460

[11/] In Monroe Communications, the Court explained that a three-year delay in a television license renewal proceeding "f[e]ll so short of egregious delay that we would withhold relief altogether," but that due to the "unusual circumstance" of an unrebutted allegation of bad faith, the Court would retain jurisdiction until the conclusion of the proceeding. 840 F.2d at 946-47. As previously noted, Petitioners do not allege bad faith in this case.

CERTIFICATE OF SERVICE

I hereby certify that the foregoing EPA's Response in Opposition to Petitions for Writ of Mandamus has been filed with the Clerk of the Court this 17th day of January 2012, using the CM/ECF System, through which true and correct copies will be served electronically on all counsel of record that are registered to use CM/ECF. In addition, hard copies of this filing were sent by first-class mail, postage prepaid, to each of the following counsel that do not presently appear on the list of CM/ECF users for this case:

Julia Anna Potts
American Farm Bureau Federation
600 Maryland Ave., SW
Suite 1000W
Washington, DC 20024

Carl C. Danberg
Valerie S. Csizmadia
Attorney General Office
102 W. Water Street, 3rd Floor
Dover, DE 19904

Michael C. Formica
National Pork Producers' Council
122 C Street, NW
Suite 875
Washington, DC 20001

Lisa Madigan
Matthew J. Dunn
Environmental Enforcement and
Asbestos Litigation Division
Thomas Davis
Environmental Bureau
500 South Second Street
Springfield, IL 62706

Gary H. Baise
John J. Zimmerman
Kilpatrick Stockton, LLP
607 14th Street, NW
Suite 900
Washington, DC 20005

Kelly A. Ayotte
Maureen D. Smith
Office of the Attorney General
33 Capitol Street
Concord, NH 03301-6397

Tamara Thies
National Cattlemen's Beef Association
1301 Pennsylvania Ave., NW
Suite 300
Washington, DC 20004-1701

Patricia A. Madrid
Ron Curry
Stephen R. Farris
Tracy M. Hughes
William G. Grantham
P.O. Box Drawer 1508
Sante FE, NM 87504-1508

Richard Blumenthal
Kimberly Massicotte
Scott Koshwitz
P.O. Box 122, 55 Elm Street
Hartford, CT 06141-0120

Hardy Myers
Philip Schradle
Richard M. Whitman
1162 Court Street, NE
Salem, OR 97301

William H. Sorrell,
Kevin O. Leske
Office of the Attorney General
109 State Street
Montpelier, VT 05609-1001

Harold P. Quinn, Jr.
National Mining Association
101 Constitution Avenue, NW
Washington, DC 20001

Richard Gupton
Agricultural Retailers Association
1156 15th Street, NW
Suite 302
Washington, DC 20005

Gary H. Baise
John Zimmerman
Kilpatrick Stockton, LLP
607 14th Street, NW
Suite 900
Washington, DC 20005

Kathy M. Kinsey
Office of The State of Maryland
Department of the Environment
1800 Washington Boulevard
Suite 6048
Baltimore, MD 21230

Dated: January 17, 2012

/s/ Brian H. Lynk

BRIAN H. LYNK
U.S. Department of Justice
Environmental Defense Section
P.O. Box 23986
Washington, D.C. 20026-3986
(202) 514-6187 (tel.)
Attorney for Respondent

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

AMERICAN FARM BUREAU FEDERATION, et al.,	)	
Petitioners,	)	
v.	)	No. 06-1410 (and consolidated cases)
UNITED STATES ENVIRONMENTAL PROTECTION AGENCY,	)	
Respondent.	)	

DECLARATION OF REGINA MCCARTHY

I, Regina McCarthy, declare under penalty of perjury under the laws of the United States of America that the following is true and correct to the best of my knowledge, information, and belief, and is based on my own personal knowledge or on information contained in the records of the United States Environmental Protection Agency (EPA) or supplied to me by EPA employees under my supervision.

1. I am the Assistant Administrator for the Office of Air and Radiation at

EPA, a position that I have held since June 2009. The Office of Air and Radiation (OAR) is the EPA office that develops national programs, technical policies, and regulations for controlling air pollution. OAR's assignments include the protection of public health and welfare, pollution prevention and energy efficiency, air quality, industrial air pollution, pollution from vehicles and engines, acid rain, stratospheric ozone depletion, and climate change.

2. OAR is responsible for conducting rulemakings to adopt or revise National Ambient Air Quality Standards (NAAQS) under section 109 of the Clean Air Act (CAA). 42 U.S.C. § 7409. My office also is responsible for either preparing or assisting in the preparation of the scientific and technical documents that the Administrator reviews in determining whether revisions to the NAAQS are appropriate. OAR provides assistance to the Administrator as she assesses the body of evidence and proposes and takes final actions concerning decisions to retain or revise the NAAQS in light of the CAA's requirements.

3. Under 42 U.S.C. section 7409 (d), EPA must conduct review of each NAAQS, and the air quality criteria on which the NAAQS are based, at five year intervals. Accordingly, after promulgating the PM NAAQS in October 2006, EPA commenced the five year review cycle.

4. EPA has expended enormous effort in conducting this review. EPA initiated the current review of the air quality criteria for PM in June 2007 with a

general call for information (72 FR 35462, June 28, 2007). In July 2007, EPA held two "kick-off" workshops on the primary (health-based) and secondary (welfare-based) PM NAAQS, respectively (72 FR 34003 to 34004, June 20, 2007). These workshops provided an opportunity for a public discussion of the key policy-relevant issues around which EPA would structure this PM NAAQS review and the most meaningful new science that would be available to inform our understanding of these issues.

5. Based in part on the workshop discussions, EPA developed a draft Integrated Review Plan outlining the schedule, process, and key policy-relevant questions that would guide the evaluation of the air quality criteria for PM and the review of the primary and secondary PM NAAQS. On November 30, 2007, EPA held a consultation with Clean Air Scientific Advisory Committee (CASAC) on the draft Integrated Review Plan (72 FR 63177, November 8, 2007), which included the opportunity for public comment. The final Integrated Review Plan incorporated comments from CASAC and from the public on the draft plan as well as input from senior Agency managers.

6. A major element in the process for reviewing the NAAQS is the development of an Integrated Science Assessment (previously termed a "Criteria Document"). This document provides an evaluation and integration of the policy-relevant science, including key science judgments upon which the risk and

exposure assessments build. As part of the process of preparing the PM Integrated Science Assessment, EPA's National Center for Environmental Assessment (NCEA) hosted a peer review workshop in June 2008 on preliminary drafts of key Integrated Science Assessment chapters (73 FR 30391, May 27, 2008). The first external review draft Integrated Science Assessment (73 FR 77686, December 19, 2008) was reviewed by CASAC and the public at a meeting held in April 2009 (74 FR 2688, February 19, 2009). Based on comments of CASAC and the public, NCEA prepared a second draft Integrated Science Assessment (74 FR 38185, July 31, 2009), which was reviewed by CASAC and the public at a meeting held on October 5 and 6, 2009 (74 FR 46586, September 10, 2009). Based on CASAC and public comments, NCEA prepared the final Integrated Science Assessment titled Integrated Science Assessment for Particulate Matter, December 2009 (4 FR 66353, December 15, 2009).

7. The final Integrated Science Assessment consists of nine chapters and six annexes and comprises thousands of pages of material. Key chapters deal with issues of atmospheric chemistry, sources, and exposure of and to PM; dosimetry (deposition, translocation, clearance, and retention of particles and their constituents within the respiratory tract and extrapulmonary tissues) of PM; pathways and mode of action of PM; and evidence related to populations potentially susceptible to PM-related effects. Separate chapters are devoted to

studies of short- and long-term exposure to PM, subdivided by health outcome, where for each health outcome category, summary sections integrate the findings. Welfare effects related to particle-phase gases in the ambient air – primarily visibility impairment, effects on materials, and negative climate interactions, are discussed in the final chapter of the Integrated Science Assessment. Annexes provide detailed descriptions of the key studies discussed in the Integrated Science Assessment chapters.

8. Building upon the information presented in the PM Integrated Science Assessment, EPA prepared Risk and Exposure Assessments for both public health and welfare effects. In developing the Risk and Exposure Assessments for this PM NAAQS review, OAQPS released two planning documents: Particulate Matter National Ambient Air Quality Standards: Scope and Methods Plan for Health Risk and Exposure Assessment and Particulate Matter National Ambient Air Quality Standards: Scope and Methods Plan for Urban Visibility Impact Assessment (; 74 FR 11580, March 18, 2009). These planning documents outlined the scope and approaches that EPA staff planned to use in conducting quantitative assessments as well as key issues that would be addressed as part of the assessments. In designing and conducting the initial health risk and visibility impact assessments, the Agency considered CASAC comments on the Scope and Methods Plans made during an April 2009 consultation (74 FR 7688, February 19, 2009) as well as public

comments.

9. Two draft assessment documents, Risk Assessment to Support the Review of the $PM_{2.5}$ Primary National Ambient Air Quality Standards: External Review Draft, September 2009 and Particulate Matter Urban-Focused Visibility Assessment - External Review Draft, September 2009 (US EPA, 2009f) were reviewed by CASAC and the public at a meeting held on October 5 and 6, 2009 (74 FR 46586, September 10, 2009). Based on CASAC and public comments, OAQPS staff revised these draft documents and released second draft assessment documents in January and February 2010 (75 FR 4067, January 26, 2010) for CASAC and public review at a meeting held on March 10 and 11, 2010 (75 FR 8062, February 23, 2010). Based on CASAC and public comments on the second draft assessment documents, EPA revised these documents and released final assessment documents titled Quantitative Health Risk Assessment for Particulate Matter, June 2010 ("Risk Assessment,") and Particulate Matter Urban-Focused Visibility Assessment – Final Document, July 2010 ("Visibility Assessment") (75 FR 39252, July 8, 2010).

10. The Risk Assessment (RA) estimates risk for: (1) all-cause, ischemic heart disease - related, cardiopulmonary- and lung cancer-related mortality associated with long-term $PM_{2.5}$ exposure; (2) non-accidental, cardiovascular-related, and respiratory-related mortality associated with short-term $PM_{2.5}$

exposure, and (3) cardiovascular-related and respiratory-related hospital admissions and asthma-related emergency department visits associated with short-term $PM_{2.5}$ exposure. The RA interprets the risk estimates associated with simulating just meeting the current suite of standards and alternative standards, considering especially (1) the importance of changes in annual mean $PM_{2.5}$ concentrations for a specific study area in estimating changes in risks related to both long- and short-term exposures associated with recent air quality conditions and air quality simulated to just meet the current suite of $PM_{2.5}$ standards and alternative suites of standards; (2) the ratio of peak-to-mean ambient $PM_{2.5}$ concentrations in a study area; and (3) the spatial pattern of ambient $PM_{2.5}$ reductions that result from using different approaches to simulate just meeting the current standard levels and alternative standard levels (i.e., rollback approaches).

11. The Visibility Assessment includes: (1) analyses of the factors contributing to visibility impairment for selected urban areas, including PM species component contributions and variations in relative humidity, providing information useful for better characterizing regional differences; and (2) analyses of air quality simulated to just meet the current $PM_{2.5}$ standards as well as alternative standards using different combinations of the four elements of the NAAQS (indicator, averaging time, level and form); (3) a reanalysis of public preference studies providing

information useful for the selection of "target levels" for urban visibility protection.

12. Based on the scientific and technical information assessed in the Integrated Science Assessment and Risk and Exposure Assessments, EPA staff prepared a Policy Assessment. The Policy Assessment is intended to help 'bridge the gap' between the relevant scientific information and assessments and the judgments required of the Administrator in reaching decisions on the NAAQS. American Farm Bureau v. EPA, 559 F. 3d at 516. The Policy Assessment is not a decision document; rather it presents EPA staff conclusions related to the broadest range of policy options that could be supported by the currently available information. A preliminary draft Policy Assessment was released in September 2009 for informational purposes and to facilitate discussion with CASAC at the October 5 and 6, 2009 meeting on the overall structure, areas of focus, and level of detail to be included in the Policy Assessment. CASAC's comments on this preliminary draft were considered in developing a first draft Policy Assessment (75 FR 4067, January 26, 2010) that built upon the information presented and assessed in the final Integrated Science Assessment and second draft Risk and Exposure Assessments. The EPA presented an overview of the first draft Policy Assessment at a CASAC meeting on March 10, 2010 (75 FR 8062, February 23, 2010) and it was discussed during public CASAC teleconferences on April 8 and

9, 2010 (75 FR 8062, February 23, 2010) and May 7, 2010 (75 FR 19971, April 16, 2010).

13. The EPA developed a second draft Policy Assessment (75 FR 39253, July 8, 2010) reflecting CASAC and public comments on the first draft Policy Assessment. The second draft Policy Assessment was reviewed by CASAC at a meeting on July 26 and 27, 2010 (75 FR 32763, June 9, 2010). CASAC and public comments on the second draft Policy Assessment were considered by EPA staff in preparing a final Policy Assessment titled Policy Assessment for the Review of the Particulate Matter National Ambient Air Quality Standards, (76 FR 22665, April 22, 2011). In addition, in the first three months of 2011, EPA conducted a series of meetings with stakeholders, especially those from the agricultural community, relating to the review of the primary and secondary standards for coarse PM and did not complete and release the Policy Assessment until those meetings were completed and the comments from the meetings assessed by EPA. The final Policy Assessment includes final staff conclusions on the adequacy of the current PM standards and alternative standards for consideration by senior EPA officials.

14.. EPA's current PM NAAQS review was well underway when the Court of Appeals for the District of Columbia Circuit issued its mandate in American Farm Bureau v. EPA, 559 F. 3d 512 on April 18, 2009. By that time, as explained in paragraphs 6 and 8 above, EPA had issued the first external draft of the

Integrated Science Assessment which CASAC and the public were reviewing. EPA had also already issued Scope and Method Plans for conducting both the Risk Assessment and the Urban-Focused Visibility Assessment. It was already clear that there was an enormous body of new science on PM since the 2004 PM Criteria Document, including hundreds of new epidemiologic studies, including extended follow-up to important long-term exposure studies. The new science includes a continuation of the Gauderman study examining effects of long-term $PM_{2.5}$ exposure in a cohort of southern California children, a study that figured significantly in the court's decision to remand the primary annual $PM_{2.5}$ standard (see 559 F. 3d at 524-25).

15. Given the body of new scientific information, EPA decided to respond to the remand as part of the on-going statutory periodic review and related rulemaking, rather than attempting to explain or revise its prior decision based on the already outdated scientific record for the 2006 PM NAAQS. This assured that EPA's response would reflect consideration of all of the new science, including the continuation of the Gauderman study, and consideration of the entire body of short-term and long-term exposure studies. This approach also assured that EPA's on-going periodic review would not be diverted or disrupted by a separate action reevaluating the 2006 rule based on a scientific record which had been partially superseded.

16. Both before and since completion of the Policy Assessment in April 2011, EPA has been working to develop a comprehensive proposed rulemaking package that addresses all relevant issues involving whether, and if so how, the PM NAAQS should be revised. This is a time consuming and involved undertaking, as the rulemaking package needs to explain in detail EPA's reasoning concerning whether or not the current primary and secondary standards for both fine and coarse PM are appropriate or should be revised. If revisions are proposed, a rationale for each element of the NAAQS (averaging time, indicator, form, and level; see 559 F. 3d at 515) must be provided. In addition, the package discusses the intricate issues related to interpretation of the NAAQS for $PM_{2.5}$, including requirements for data use and reporting for comparison with the $PM_{2.5}$ NAAQS. (see 40 CFR Part 50 Appendix N). Consistent with other NAAQS proposals, EPA contemplates discussing issues relating to monitoring PM in the package, including issues relating to the Federal Reference method and equivalent monitoring methods for PM, as well as issues regarding the size and location of the PM monitoring network.

17. EPA has committed enormous agency resources to all of the work performed to date in the review of the PM NAAQS. This work has involved large numbers of staff and managers within several different offices within EPA, including the Office of Air and Radiation, Office of Research and Development,

Office of General Counsel, Office of Policy, and the Office of the Administrator. As discussed above, very significant progress has been made to date. EPA's next steps include finishing internal agency review and completing interagency review pursuant to Executive Orders 12866 and 13563.[1] The schedule proposed by Petitioners, however, would not allow sufficient time for completing the steps necessary to prepare and issue the proposed rule, especially the interagency review process under the Executive Orders. EPA expects that these steps can be completed by June 2012. Accordingly, EPA's current plans are to sign a proposal in June of 2012.

18. The PM NAAQS proposal will involve many complex scientific, technical, and policy issues of great public health significance. As noted, the proposal will address both primary and secondary standards for not only fine PM but coarse PM as well. Accordingly, EPA believes the public should have ample time to comment on the proposal, as well as to participate in the public hearings provided by 42 U.S.C. section 7607 (d)(5). As in other proposed NAAQS rulemakings, EPA expects there will be very significant public comments submitted. It will take a significant period of time to review and evaluate the comments, make decisions on the content of the final action in light of the comments, and then develop a rulemaking package embodying and explaining the

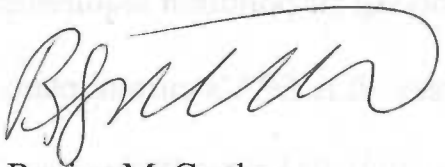
[1] Executive Order 12866 provides for 90 days for interagency review. EO section 6(b)(2)(B).

final decision(s). EPA will also develop a comprehensive response to public comments. A period for interagency review of a final rule is also required under the Executive Orders cited above. EPA currently believes approximately one year from issuance of the proposal is reasonable for completion of the rulemaking process. This is based both on the complexity and the importance of the issues. The rulemaking deals with primary and secondary standards for both fine and coarse particulate matter, a large body of new science, and highly significant public health and welfare considerations. While in some NAAQS rulemakings the time between proposing and taking final action has been somewhat less, EPA believes that this rulemaking warrants this amount of time given the complexity and importance of the issues. This amount of time also takes into account the fact that during the same time period EPA's Office of Air and Radiation will be working on many other major rulemakings, involving air pollution requirements for a wide variety of stationary and mobile sources. It is EPA's current plan, therefore, to take final action on its review of the 2006 PM NAAQS by June 2013. This action would also serve as EPA's response to the D.C. Circuit's remand of the primary annual $PM_{2.5}$ standard and secondary $PM_{2.5}$ standard from the PM NAAQS completed in 2006.

19. EPA had earlier indicated publicly that EPA planned to propose and take final action on the review of the 2006 PM NAAQS on a more aggressive

schedule. Notwithstanding these plans, EPA was unable to do so due chiefly to the time needed for the preparation of the complex and comprehensive supporting documents discussed in paragraphs 5 to 13 above, the multiple reviews by CASAC and the public, and the significant revisions undertaken in light of CASAC's review and the public comments.

20. Given the importance and complexity of the issues involved in the review of the PM NAAQS, and the employment of significant agency resources to date and in the future in this review, EPA believes that the time spent to date in developing the supporting documents discussed above and the proposed regulatory package, and the time projected for completion of the review, reflect a reasonable and appropriate period of time for this review.



Regina McCarthy

Assistant Administrator for the Office of Air and Radiation

January 13, 2012

EARTHJUSTICE

ALASKA CALIFORNIA FLORIDA MID-PACIFIC NORTHEAST NORTHERN ROCKIES
NORTHWEST ROCKY MOUNTAIN WASHINGTON, DC INTERNATIONAL

October 18, 2011

Via Certified and Electronic Mail

Ms. Lisa P. Jackson
Administrator
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20460

Re: 60-Day Notice of Intent to File Clean Air Act Citizen Suit

Dear Administrator Jackson:

This letter is submitted on behalf of the American Lung Association[1] and National Parks Conservation Association[2] to notify you, pursuant to section 304(b) of the Clean Air Act ("CAA" or "Act"), that they intend to sue the U.S. Environmental Protection Agency ("EPA") for its failure to perform non-discretionary duties related to the review of the national ambient air quality standards for particulate matter. These groups ask that you direct your staff to take the immediate action required under the Act.

As you are well aware, particulate matter pollution in the U.S. continues to cause thousands of premature deaths and tens of thousands of hospital visits every year. *See, e.g.*, EPA, Office of Air Quality Planning and Standards, "Policy Assessment for the Review of the Particulate Matter National Ambient Air quality Standards," at 2-43 (April 2011). EPA last promulgated particulate matter standards on October 17, 2006. *See* 71 Fed. Reg. 61144. Those standards, however, were remanded by the D.C. Circuit Court of Appeals in *Am. Farm Bureau Fed'n v. EPA*, 559 F.3d 512 (D.C. Cir. 2009) because EPA had failed to demonstrate that the standards were adequate to protect public health and prevent adverse welfare impacts.

Now, five years since promulgation of the 2006 standards, EPA has not even proposed a decision based on a review of these standards. Clean Air Act section 109(d)(1) imposes on EPA a non-discretionary duty to review national ambient air quality standards every five years and "make such revisions in such criteria and standards and promulgate such new standards as may be appropriate in accordance with section 108 and subsection (b) of [section 109]." 42 U.S.C. § 7409(d)(1). As of October 18, 2011, EPA is in violation of its mandatory duty to review the inadequate particulate matter standards adopted by EPA in 2006.

[1] American Lung Association, 1301 Pennsylvania Ave. NW, Suite 800, Washington, DC 20004.
[2] National Parks Conservation Association, 777 6th Street, NW, Suite 700, Washington, DC 2001.

Unless the identified deficiencies are promptly mitigated, American Lung Association and National Parks Conservation Association anticipate filing suit in U.S. District Court sixty days after your receipt of this letter. Please feel free to contact me at the address and telephone number provided above to further discuss the basis for this claim, or to explore possible options for resolving this claim short of litigation.

Sincerely,

Paul Cort
Staff Attorney