IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

AMERICAN LUNG ASSOCIATION and NATIONAL PARKS CONSERVATION ASSOCIATION, Plaintiffs, v. UNITED STATES ENVIRONMENTAL PROTECTION AGENCY, and LISA JACKSON, Administrator, United States Environmental Protection Agency, Defendants.	Civil Action No. 1:12-cv-00243-RLW (Judge Robert L. Wilkins)
STATE OF NEW YORK, et al., Plaintiffs, v. LISA P. JACKSON, as Administrator of the Environmental Protection Agency, and the UNITED STATES ENVIRONMENTAL PROTECTION AGENCY, Defendants.	Civil Action No. 1:12-cv-00531 (consolidated)

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. § 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 -04, 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 the 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 (74 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 health effects of short- and long-term exposure to PM with summary sections that integrate the findings for health outcome categories. Welfare effects related to particles in the ambient air – primarily visibility impairment, effects on materials, and climate interactions, are discussed in the final chapter of the Integrated Science Assessment. Annexes include 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 (74FR

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 Apri12009 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 Primary National Ambient Air Quality Standards: External Review Draft, September 2009 and Particulate Matter Urban-Focused Visibility Assessment - External Review Draft, September 2009 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; (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); and (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 complex 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 C.F.R. 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.

18. As I stated in paragraph 17 of my Declaration of January 13, 2012, EPA's next steps at that point included finishing internal agency review and completing interagency review pursuant to Executive Orders 12866 (58 FR 51735, September 30, 1993) and 13563 (76 FR 3821, January 18, 2011), including completing the steps necessary to prepare and issue the proposed rule.[1] Since January, EPA continued to spend time and resources on preparing the proposed rule for issuance, such as continuing to prepare the preamble and the regulations on issues related to monitoring and handling of air quality data. In addition, EPA expects to submit it for interagency review in the very near term.

19. 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. There is an abundance of new scientific evidence and other

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

information informing this review. 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. §7607(d)(5).

As in other proposed NAAQS rulemakings, EPA expects there will be a large number of significant public comments submitted. For example, in the last review more than 120,000 comments were received from members of the public and various interested groups on the proposed revisions to the PM NAAQS issued on January 17, 2006. Additional comments were received from CASAC. Comments were also received from EPA's Children Health Protection Advisory Committee. A broad variety of stakeholder groups provided comments, including representatives of Environmental/Public Health/Medical organizations, Industry, and States/locals/tribal organizations. In this rulemaking, 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 final decisions. EPA will also develop a comprehensive response to significant public comments, as required under 42 U.S.C. §7607(d)(6)(B). In the 2006 review, EPA's Responses to Significant Comments Document was itself 435 pages long, single spaced. All of these steps are time-consuming and intensive. No less time or effort will be needed to address

comments in this rulemaking. A period for interagency review of a final rule is also called for under the Executive Orders cited above.

20. EPA currently believes approximately one year from issuance of the proposal is reasonable for completion of the rulemaking process. This length of time is based both on the complexity and the importance of the issues. As noted above, the rulemaking deals with primary and secondary standards for both fine and coarse particulate matter, a very 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 will require this amount of time.

Since the last review, a very large body of new science has been developed involving the health effects of PM, and it will be a central focus of the rulemaking. While this itself is not unique, the depth and complexity of the body of health effects evidence on PM, and the approaches open to the agency to evaluate and weigh this evidence have expanded over time, not decreased. As such, more time and effort are needed to interpret and apply the science in the context of this rulemaking compared to the last review, not less.

In the same vein, the body of science has continued to grow since the issuance of the Integrated Science Assessment in December 2009. In this NAAQS

rulemaking as well as others, EPA expects that many commenters will cite to numerous new studies in support of or opposition to various arguments. EPA has traditionally based its decision on studies and related information included in the Integrated Science Assessment (previously Criteria Document), the Risk and Exposure Assessment, and the Policy Assessment (previously the Staff Paper), which undergo CASAC and public review, and intends to do so in this rulemaking. However, as in prior rulemakings, it will also be important that EPA conduct a provisional assessment of the new science, including those studies cited in comments, so that the Administrator will be aware of the new science that is relied upon by commenters but was published too recently to be included in the rigorously reviewed Integrated Science Assessment. 71 FR 61144, 61148 (October 17, 2006). EPA's provisional assessment of that new science is limited to screening and surveying these studies and evaluating the extent to which recent evidence would be likely to change the major conclusions of the Integrated Science Assessment. EPA expects that more time and effort is needed to prepare such a provisional assessment in this rulemaking compared to the last review, not less.

In addition, as in the last review EPA is considering a secondary standard to address the visibility impacts of $PM_{2.5}$ that would be separate and distinct from the primary standard. Compared to the last review, however, as discussed in the Policy Assessment EPA is considering a distinct secondary standard that differs

from the primary standard in all four elements of the standard, indicator, form, averaging time, and level. This clearly increases the range and complexity of issues to address in this review of the secondary standard, compared to the last review.

This amount of time also takes into account the fact that during the same time period for this rulemaking, 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, many with court-ordered or settlement agreement deadlines.

Based on all of the above, EPA's current plan is to take final action on its review of the 2006 PM NAAQS by August 15, 2013. This differs from the June 2013 schedule described in paragraph 18 of the January Declaration, and the reasons for the change in the schedule are those described in paragraph 18 of this Declaration (time and resources spent since January 2012 until the date of this Declaration, preparing the proposed rule for issuance and submission for interagency review), and paragraphs 19, and 20 (as in the January Declaration, the time needed from issuance of the proposal until final action by EPA is approximately one year).

21. At various points in 2010 and earlier, EPA had indicated that it planned to propose and take final action on the review of the 2006 PM NAAQS on a different schedule. This involved finishing the rulemaking at an earlier date, and spending somewhat less time between issuance of the proposal and taking final action. Notwithstanding these plans, EPA was unable to achieve the goals of the rulemaking schedules indicated in 2010 and earlier. This was 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. In addition, the time needed between issuance of the proposal and issuance of the final action needs to be somewhat longer than the previous indications, based on our current consideration of all of the factors discussed above in paragraph 20.

22. 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 the most expeditious schedule that EPA reasonably can meet under the circumstances, for all of the reasons discussed above.

23. It would not be possible to take final action by October 15, 2012, as requested by Plaintiffs. After signature and issuance of a proposed rule on the PM NAAQS, the rule would be published by the Office of Federal Register. As noted above, EPA is required to provide an opportunity for public comment and an opportunity for a public hearing(s). EPA is required to keep the comment period open at least 30 days from completion of the public hearing(s). Based on experience with numerous NAAQS rulemakings, and the complexity of the issues presented in this rulemaking, EPA believes that somewhat more than 3 months is needed from the issuance of the proposed rule to have the rule published in the Federal Register, hold public hearings, and complete the public comment period.

After the comment period closes, significant time and resources have to be spent before final agency action can be taken on the proposed rule. The EPA will review the comments, which are expected to be voluminous and detailed, and develop responses to the comments. As discussed in paragraph 19, this requires a significant amount of time and effort.

Senior management in EPA will be briefed on the comments and potential options for the final rule, and will need to consider and make decisions on the content of the final rule. The EPA will develop a final rulemaking package that embodies and explains these decisions as well as will develop a written response to

comments document. Finally, a period for interagency review of a final rule is also called for under the Executive Orders cited above.

No matter what date EPA were to issue a proposed rule, there would not be enough time to complete the public comment and hearing process, and complete the very significant amount of work that needs to be done between the end of the comment period and the issuance of a final rule, by October 15, 2012.

Regina McCarthy

Assistant Administrator for the Office of Air and Radiation

May 4, 2012