UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

FEB - 3 2012

OFFICE OF
AIR AND RADIATION

The Honorable Fred Upton
Chairman
Committee on Energy and Commerce
U.S. House of Representatives
Washington, D.C. 20515

Dear Mr. Chairman:

Thank you for your letter of December 14, 2011, to Administrator Lisa Jackson, co-signed by three of your colleagues, requesting additional information regarding the Environmental Protection Agency's estimates of the public health benefits expected to result from regulatory actions. The Administrator has asked me to respond on her behalf.

Your letter raises several questions about our benefits estimates for reducing fine particle pollution. We believe the health improvements achieved by reducing fine particle exposures represent real benefits to real people, and it is appropriate to provide information to decisionmakers and the public about these expected benefits of cleaner air. These estimates are incorporated in Regulatory Impact Analyses (RIAs), which help inform decisionmakers and the public about the potential benefits and costs of our proposed and final rules. The benefits estimates and RIAs are developed and reviewed as part of the normal rulemaking process, including interagency review and public notice and comment. We prepare these estimates for all economically significant rules. Although we strive to make these analyses as complete as possible, there are often many benefits that cannot be quantified, including a number of significant benefits from reducing mercury and other air toxics.

EPA's approach for estimating benefits from reducing fine particle pollution is science-driven. Studies demonstrate an association between premature mortality and fine particle pollution at the lowest levels measured in the relevant studies, levels that are significantly below the NAAQS for fine particles. These studies have not observed a level at which premature mortality effects do not occur. The best scientific evidence, confirmed by independent, Congressionally-mandated expert panels, is that there is no threshold level of fine particle pollution below which health risk reductions are not achieved by reduced exposure. Thus, based on specific advice from scientific peer-review, we project benefits from reducing fine particle pollution below the level of the NAAQS and below the lowest levels measured in the studies.

Using a no-threshold approach to developing our primary benefits estimates for our rules, which was also the approach we took from 1997 to 2006, is warranted by the extensive scientific review reflected in the *Integrated Science Assessment on Particulate Matter* (PM ISA), the first draft of which was prepared by EPA scientists and technical staff and released in December 2008. All drafts of the PM ISA reflect this conclusion that there is no scientific evidence supporting assumption of a threshold for PM effects.

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risks. The no-threshold approach, and associated projections of benefits, were also specifically reviewed and approved by the Advisory Council on Clean Air Compliance Analysis, another panel of outside experts established by Congress to review EPA studies of the benefits and costs of the Clean Air Act.

Based on the first draft PM ISA released in December 2008, EPA technical staff incorporated the no-threshold approach in benefits calculations, which were subject to intra- and inter-agency review and public notice and comment. We have followed a no-threshold approach to our primary benefits estimate since then.

Detailed responses to a number of specific questions raised in your letter are addressed in the attachment. We have also provided the key documents cited in this letter on the enclosed disc. Again, the Administrator and I thank you for your letter. If you have further questions, please contact me or your staff may call Josh Lewis in the EPA's Office of Congressional and Intergovernmental Relations at (202) 564-2095.

Sincerely,

Gina McCarthy
Assistant Administrator

Attachment

1. **In the regulatory impact analysis for the Portland Cement rule published September 9, 2010, EPA reported that it has changed its assumption concerning the concentration threshold for $PM_{2.5}$-related mortality: "EPA now estimates PM-related mortality without assuming an arbitrary threshold in the concentration-response function." (August 2010, "Regulatory Impact Analysis: Amendments to the National Emission Standards for Hazardous Air Pollutants and New Source Performance Standards (NSPS) for the Portland Cement Manufacturing Industry, Final Report", Section 6.2.1.)**

    a. Did EPA change its assumption concerning the concentration threshold at which PM is likely to cause premature mortality?

    b. If EPA changed the assumption, explain who gave ultimate direction to change the assumption, when was it changed, and what was the basis for making the change.

    c. If EPA changed the assumption, provide all analyses and briefing or decision memoranda, for the EPA Administrator or EPA Assistant Administrator for Air and Radiation, relating to the change in assumptions.

Response: EPA's approach to estimating health benefits is driven by the scientific evidence regarding the health effects associated with $PM_{2.5}$ exposure at various concentration levels. Our approach is well-established, including accounting for benefits that occur below 15 micrograms per cubic meter ($\mu g/m^3$) (the level of the current annual $PM_{2.5}$ National Ambient Air Quality Standards (NAAQS), which were issued in 2006). The Agency is committed to ensuring that its benefits analyses reflect the latest scientific evidence regarding pollution, health and the environment. As a result, the agency must periodically update its benefits assessment methodology.

From 1997 to 2006, EPA's approach for estimating benefits associated with reducing exposure to fine particles reflected the scientific literature, which indicated that health effects can occur along the entire range of potential exposures. EPA's best estimate of $PM_{2.5}$-related benefits reflected this science and assumed no level below which health effects do not occur (i.e., it assumed no threshold). For benefits analyses conducted during this time, EPA recognized the importance of this assumption and conducted various sensitivity analyses showing the impact this assumption would have on the total monetized benefits. EPA's use of the no-threshold model as the best estimate and our use of sensitivity analysis to evaluate the significance of this approach were both reviewed and supported by the outside experts, including the National Academies of Science[1] and the EPA's independent Science Advisory Board[2,3].

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[1] National Research Council (NRC). 2002. *Estimating the Public Health Benefits of Proposed Air Pollution Regulations*. Washington, DC: The National Academies Press.

[2] U.S. Environmental Protection Agency - Science Advisory Board. 1999. The Clean Air Act Amendments (CAAA) Section 812 Prospective Study of Costs and Benefits (1999): Advisory by the Health and Ecological Effects Subcommittee on Initial Assessments of Health and Ecological Effects; Part 1. EPA-SAB-COUNCIL-ADV-99-012. July. Available on the Internet at http://yosemite.epa.gov/sab/sabproduct.nsf/F64A21824D19766885257193005E51CA/$File/conadv12.pdf

[3] U.S. Environmental Protection Agency - Science Advisory Board (U.S. EPA-SAB). 2004. Advisory on Plans for Health Effects Analysis in the Analytical Plan for EPA's Second Prospective Analysis – Benefits and Costs of the Clean Air Act, 1990-2020. Advisory by the Health Effects Subcommittee of the Advisory Council on Clean Air Compliance Analysis. EPA-SAB-COUNCIL-ADV-04-002. March. Available on the Internet at <http://yosemite.epa.gov/sab%5CSABPRODUCT.NSF/08E1155AD24F871C85256E5400433D5D/$File/council_adv_04002.pdf>.

Based on an ambiguous statement in a 2005 letter from EPA's independent Clean Air Scientific Advisory Committee (CASAC)[4], EPA changed its long-standing approach and applied an assumed threshold for the benefits analysis of the 2006 PM NAAQS. As a result, all regulatory analyses of regulations reducing exposure to $PM_{2.5}$ conducted between 2006 and 2009 reflected an assumption that there were no benefits associated with reducing $PM_{2.5}$ below 10 $\mu g/m^3$.

When EPA scientists and technical experts started work on the initial draft of the *Integrated Science Assessment on Particulate Matter* (PM ISA) in 2008, these scientists and experts reached a conclusion that –based on an extensive review of the body of scientific literature— there was no scientific basis for assuming a threshold in the relationship between PM concentration levels and changes in risk of premature mortality (or other adverse PM-related health effects). This conclusion was reviewed by CASAC and incorporated in the second draft of the PM ISA submitted for CASAC review in 2009. EPA scientists and technical experts updated the approach for assessing $PM_{2.5}$-related benefits to be consistent with the scientific literature. The conclusion in all drafts of the PM ISA is that the scientific literature provides no evidence of a threshold below which health effects associated with exposure to fine particles – including premature death -- would not occur (U.S. EPA, 2009)[5,6]. Based on that review, the Agency discontinued use of an assumed threshold in the calculation of $PM_{2.5}$-related benefits and returned to the prior, peer-reviewed practice of using a no-threshold approach. The absence of an assumed threshold means that estimates of the health benefits of reductions in $PM_{2.5}$ concentrations will again be more complete and consistent with the best science by counting reductions in risk in all locations where air quality is improved, including in areas which start with less-polluted air.

EPA's no-threshold approach has been recently confirmed by two separate, independent peer review panels: the Clean Air Scientific Advisory Committee (CASAC)[7] and the Advisory Council on Clean Air Compliance Analysis (Council).[8]

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[4] The CASAC, in their 2005 consensus advisory letter on the PM staff paper, conveyed an ambiguous recommendation pertaining to assumption of a threshold. U.S. Environmental Protection Agency – Science Advisory Board. 2005. *Review of the National Ambient Air Quality Standards for Particular Matter: Policy Assessment of Scientific and Technical Information (Second Draft PM Staff Paper, January2005); and Particular Matter Health Risk Assessment for Selected Urban Areas: Second Draft Report (Second Draft PM Risk Assessment, January 2005).* U.S. Environmental Protection Agency, Washington, DC, EPA-SAB-CASAC-05-007. Available on the Internet at http://yosemite.epa.gov/sab/sabproduct.nsf/e523dd36175eb5ad8525701b007332ae/$file/sab-casac-05-007_unsigned.pdf

[5] EPA released the first draft PM ISA in December 2008, and the document was peer reviewed by the EPA's independent Science Advisory Board in April 2009. EPA released the second draft ISA in July 2009, which was peer reviewed in October 2009. The final ISA was issued in December 2009.

[6] U.S. Environmental Protection Agency. 2009. *Integrated Science Assessment for Particulate Matter (Final Report).* U.S. Environmental Protection Agency, Washington, DC, EPA/600/R-08/139F. Available on the Internet at http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=216546.

[7] U.S. Environmental Protection Agency - Science Advisory Board. 2009a. *Review of EPA's Integrated Science Assessment for Particulate Matter (First External Review Draft, December 2008).* EPA-CASAC-09-008. May. Available at http://yosemite.epa.gov/sab/SABPRODUCT.NSF/81e39f4c09954fcb85256ead006be86e/73ACCA834AB44A10852575BD0064346B/$File/EPA-CASAC-09-008-unsigned.pdf;

U.S. Environmental Protection Agency - Science Advisory Board. 2009b. *Consultation on EPA's Particulate Matter National Ambient Air Quality Standards: Scope and Methods Plan for Health Risk and Exposure Assessment.* EPA-CASAC-09-009. May. Available on the Internet at http://yosemite.epa.gov/sab/SABPRODUCT.NSF/81e39f4c09954fcb85256ead006be86e/723FE644C5D758DF852575BD00763A32/$File/EPA-CASAC-09-009-unsigned.pdf.

In December 2009, the Health Effect Subcommittee of the Advisory Council on Clean Air Compliance Analysis (Council/HES) met to review several aspects of the draft health effects analysis supporting EPA's developing study titled, "The Benefits and Costs of the Clean Air Act from 1990 to 2020." In response to a review charge question specifically requesting advice on EPA's use of a no-threshold model for benefits analysis, the Council/HES endorsed the use of a no-threshold model. The Council's written advisory report subsequently concluded that "[t]he HES fully supports EPA's use of a no-threshold model to estimate the mortality reductions associated with reduced PM exposure."[9]

EPA began implementing this change in analytical methods with the proposed Portland cement rule, soliciting public comment on the appropriateness of both the no-threshold and threshold approaches for $PM_{2.5}$ benefits analysis in the preamble to the proposed rule:[10]

> "EPA strives to use the best available science to support our benefits analyses. We recognize that interpretation of the science regarding air pollution and health is dynamic and evolving. One of the key differences between the method used in this analysis of PM co-benefits and the methods used in recent [Regulatory Impact Analyses] RIAs is that, in addition to technical updates, we removed the assumption regarding thresholds in the health impact function. Based on our review of the body of scientific literature, we prefer the no-threshold model. EPA's draft Integrated Science Assessment (2008), which is currently being reviewed by EPA's Clean Air Scientific Advisory Committee, concluded that the scientific literature consistently finds that a no-threshold log-linear model most adequately portrays the PM-mortality concentration-response relationship while recognizing potential uncertainty about the exact shape of the concentration-response function. It is important to note that while CASAC provides advice regarding the science associated with setting the National Ambient Air Quality Standards, typically other scientific advisory bodies provide specific advice regarding benefits analysis…
>
> "The question of whether or not to assume a threshold in calculating the co-benefits associated with reductions in PM2.5 is an issue that affects the benefits calculations not only for this rule but for many future EPA rulemakings and analyses. Due to these implications, we solicit comment on appropriateness of both the no-threshold and threshold model for PM benefits analysis."

Taking into account subsequent public comments in response to the preamble, as well as advice from outside expert advisory panels, EPA technical staff then prepared the final benefits analysis for the Portland cement rule, relying on analytical results that reflected the no-threshold approach as the best estimate of benefits. The final Regulatory Impact Analysis documented the application, and the basis for, the no-threshold modeling approach.[11]

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[8] U.S. Environmental Protection Agency – Science Advisory Board (U.S. EPA-SAB). 2010. *Review of EPA's DRAFT Health Benefits of the Second Section 812 Prospective Study of the Clean Air Act*. EPA-COUNCIL-10-001. June. Available on the Internet at http://yosemite.epa.gov/sab/sabproduct.nsf/0/72D4EFA39E48CDB28525774500738776/$File/EPA-COUNCIL-10-001-unsigned.pdf.

[9] Ibid, SAB 2010. EPA-COUNCIL-10-001.

[10] 74 FR 21136- 21192

[11] U.S. Environmental Protection Agency. 2010. *Regulatory Impact Analysis: Amendments to the National Emission Standards for Hazardous Air Pollutants and New Source Performance Standards (NSPS) for the Portland Cement Manufacturing Industry*, Office of Air and Radiation, August 2010. Available on the Internet at http://www.epa.gov/ttn/ecas/regdata/RIAs/portlandcementfinalria.pdf

We have provided the key documents cited in the response to this question and throughout this letter on the enclosed disc.

2. For each final economically significant rule issued by EPA after January 1, 2007, what proportion of monetized $PM_{2.5}$ benefits represent reductions in mortality at air concentrations below 15 micrograms per cubic meter averaged annually, the level of the current $PM_{2.5}$ NAAQS?

For final economically significant rules issued after January 1, 2007, the date cited in your question, EPA has not specifically calculated the proportion of monetized $PM_{2.5}$ benefits below 15 micrograms per cubic meter ($\mu g/m^3$).

We do not believe that it is scientifically defensible to look solely at benefits above 15 $\mu g/m^3$ because there are peer-reviewed, scientific studies showing health effects below this level. While 15 $\mu g/m^3$ is the level of the current (2006) annual $PM_{2.5}$ NAAQS, it is not directly related to the studies we use to calculate benefits, which observed health effects associated with exposure to $PM_{2.5}$ concentrations below this level. This is consistent with the fact that NAAQS are not "zero risk" standards. Instead, EPA's current approach is to show the complete distribution of benefits across the entire range of $PM_{2.5}$ concentrations. We believe showing the entire distribution provides much more information than cutpoint analyses.

Below are the figures from four final RIAs that show the distribution of premature deaths across the range of $PM_{2.5}$ concentrations: the Portland Cement MACT and NSPS (8/6/10); the Cross-State Air Pollution Rule (CSAPR) (7/6/11); the 2014-2018 Heavy Duty Vehicle GHG Rule (8/9/11) and the Mercury and Air Toxics Standards (MATS) (12/16/11). These figures illustrate the proportion of benefits associated with exposure to $PM_{2.5}$ concentrations at various concentrations, including above 15 $\mu g/m^3$, even though we have not explicitly reported that proportion in the RIAs. It is important to note that these figures show the percentage of premature deaths, not the monetized benefits.

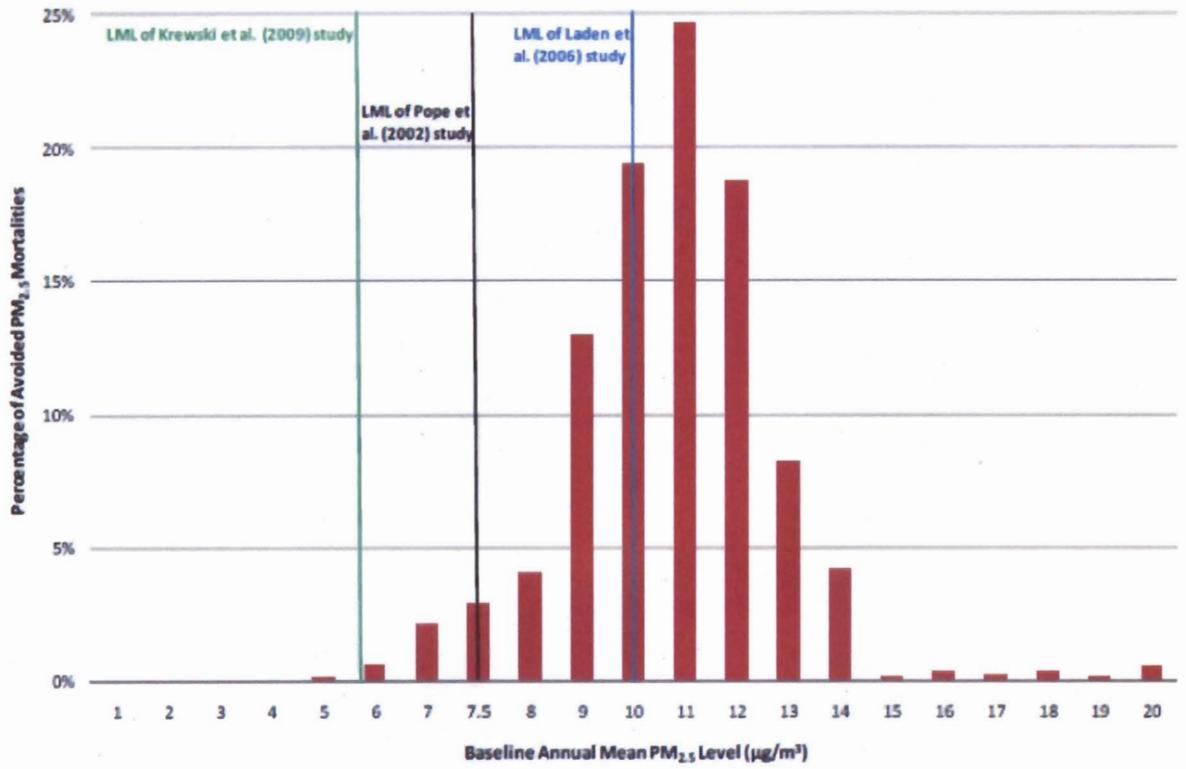
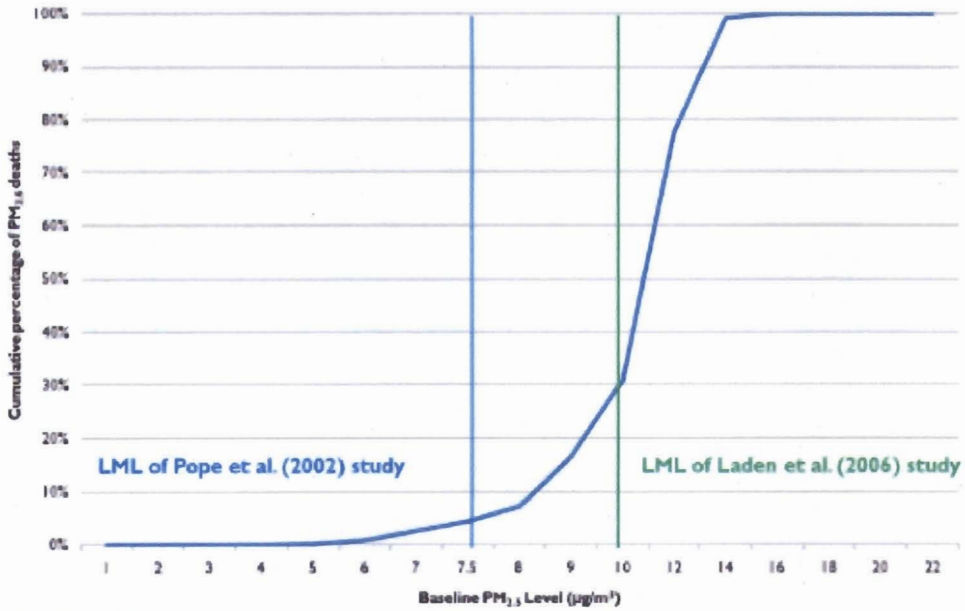


Figure 6-6. Percentage of Total PM-Related Mortalities Avoided by Baseline Air Quality Level for Final Portland Cement NESHAP and NSPS [a]

[a] Approximately 94% of the mortality impacts occur among populations with baseline exposure to annual mean $PM_{2.5}$ levels at or above 7.5 $\mu g/m^3$, which is the lowest air quality level considered in the ACS cohort study by Pope et al. (2002).

Figure 5-19: Distribution of $PM_{2.5}$-related mortality impacts by baseline $PM_{2.5}$ levels, $PM_{2.5}$ epidemiology study and lowest measured level (LML) of each study

For the Final Cross-State Air Pollution Rule

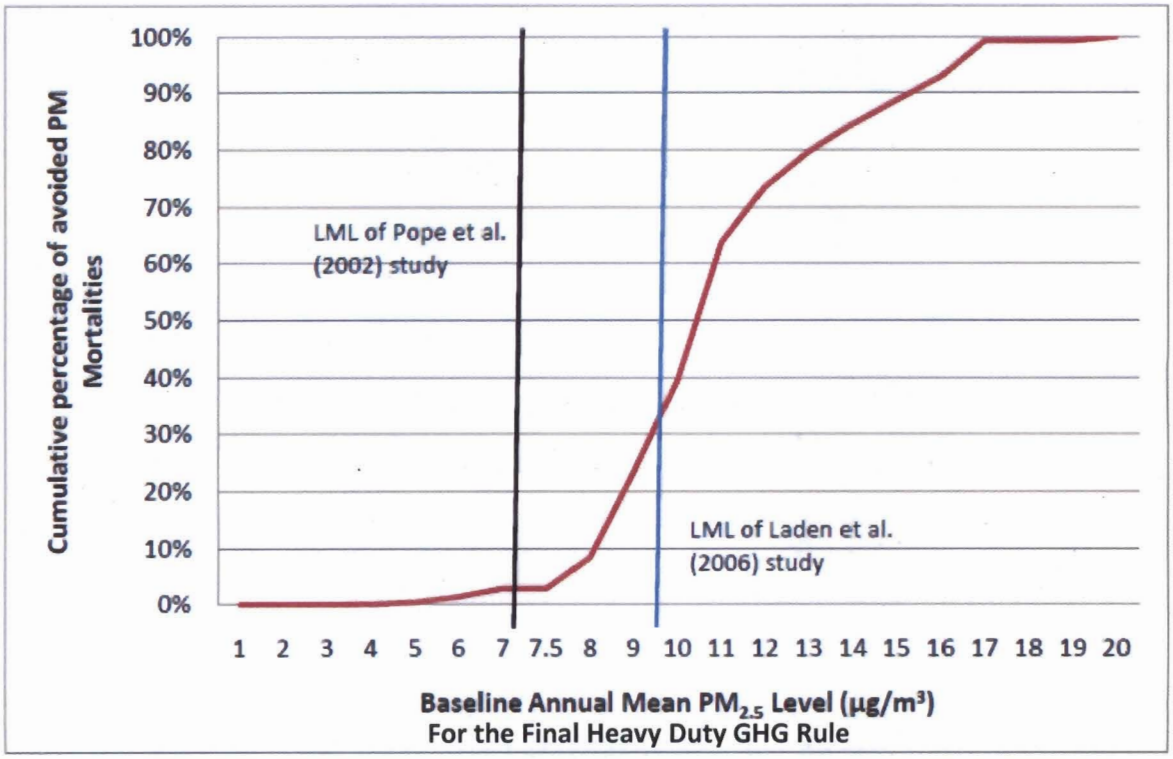


Of the deaths avoided:

96% occur among populations exposed to PM levels at or above the LML of the Pope et al. (2002) study

69% occur among populations exposed to PM levels at or above the LML of the Laden et al. (2006) study

Figure 8-20: Cumulative Percentage of Total PM-related Mortalities Avoided by Baseline Air Quality Level



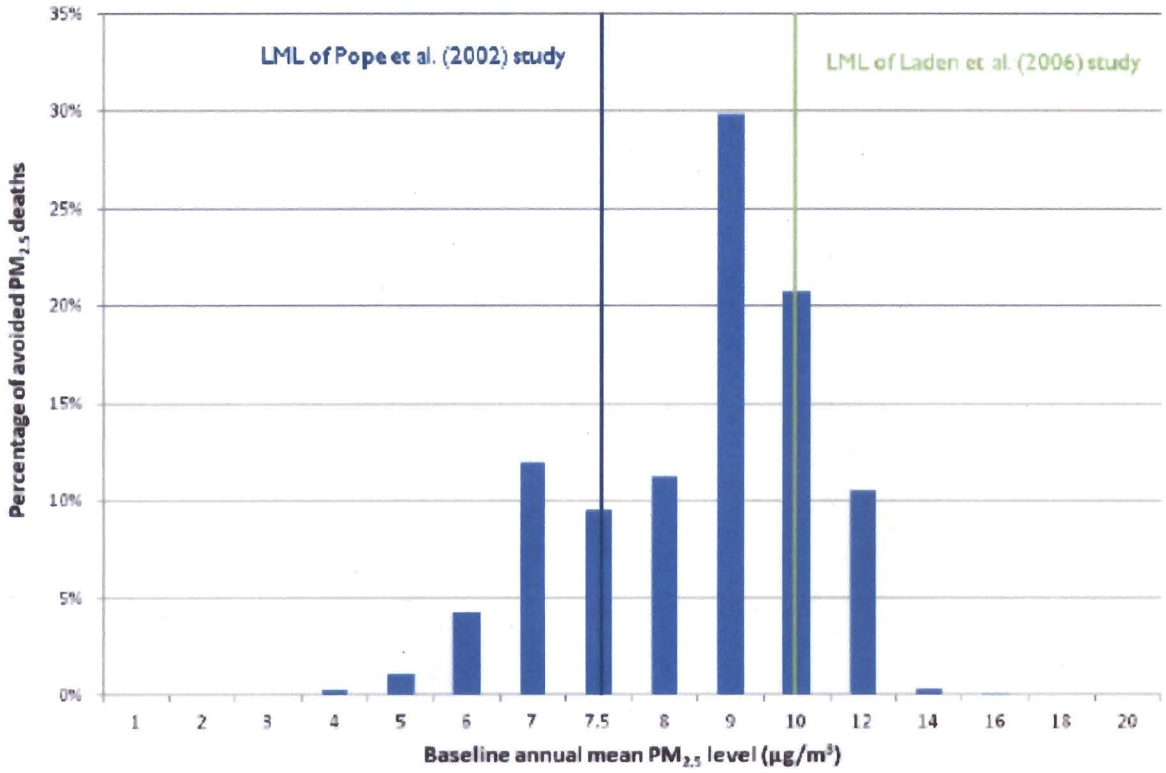


Figure 5-14. Percentage of Total PM-Related Mortalities of the Mercury and Air Toxics Standards in 2016 Avoided by Baseline Air Quality Level[a]

[a] Based on the modeled interim baseline, which is approximately equivalent to the final baseline (see Appendix 5A)

3. For each final economically significant rule issued by EPA after January 1, 2007, what proportion of monetized $PM_{2.5}$ benefits represents reductions in mortality at air concentrations below Lowest Measured Level as defined by EPA in regulatory analyses using Laden, et al. 2006. "Reduction in Fine Particulate Air Pollution and Mortality" (American Journal of Respiratory and Critical Care Medicine)?

4. For each final economically significant rule issued after January 1, 2007, what proportion of monetized $PM_{2.5}$ benefits represents reductions in mortality at air concentrations below Lowest Measured Level as defined by EPA in regulatory analyses using Pope, et al. 2002. "Lung Cancer, Cardiopulmonary Mortality, and Long-term Exposure to Fine Particulate Air Pollution" (JAMA)?

Response to Questions 3-4:
Prior to 2006, EPA did not assume a threshold when calculating the best estimate of $PM_{2.5}$-related benefits. Between 2006 and 2009, EPA assumed a threshold when calculating the best estimate of $PM_{2.5}$-related benefits. The Agency discontinued the assumption of a threshold in April 2009, recognizing that a no-threshold approach best represents the $PM_{2.5}$ mortality concentration-response relationship, thereby providing the most accurate estimate of $PM_{2.5}$-related benefits.

EPA's no-threshold approach has been confirmed by two separate, independent peer review panels: the Clean Air Scientific Advisory Committee (CASAC)[12] and the Advisory Council on Clean Air Compliance Analysis (Council).[13]

After April 2009, EPA transitioned to an approach for characterizing uncertainty in its benefits estimate that was consistent with the scientific literature on $PM_{2.5}$ and health. This approach included returning to our prior use of a no-threshold approach to calculating the primary estimate of benefits, but the new approach also examines benefits above different cutpoints, including the lowest measured levels (LML)[14] from the underlying epidemiology studies. Information regarding these LML analyses, which examined the percent of avoided $PM_{2.5}$ exposures or $PM_{2.5}$-related deaths estimated to occur at concentrations above those cutpoints, is provided below and also is available in the Regulatory Impact Analyses for these rules.

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12 U.S. Environmental Protection Agency - Science Advisory Board. 2009a. *Review of EPA's Integrated Science Assessment for Particulate Matter (First External Review Draft, December 2008).* EPA-CASAC-09-008. May. Available at http://yosemite.epa.gov/sab/SABPRODUCT.NSF/81e39f4c09954fcb85256ead006be86e/73ACCA834AB44A10852575BD0064346B/$File/EPA-CASAC-09-008-unsigned.pdf;

U.S. Environmental Protection Agency - Science Advisory Board. 2009b. *Consultation on EPA's Particulate Matter National Ambient Air Quality Standards: Scope and Methods Plan for Health Risk and Exposure Assessment.* EPA-CASAC-09-009. May. Available on the Internet at http://yosemite.epa.gov/sab/SABPRODUCT.NSF/81e39f4c09954fcb85256ead006be86e/723FE644C5D758DF852575BD00763A32/$File/EPA-CASAC-09-009-unsigned.pdf.

13 U.S. Environmental Protection Agency – Science Advisory Board (U.S. EPA-SAB). 2010. *Review of EPA's DRAFT Health Benefits of the Second Section 812 Prospective Study of the Clean Air Act.* EPA-COUNCIL-10-001. June. Available on the Internet at http://yosemite.epa.gov/sab/sabproduct.nsf/0/72D4EFA39E48CDB28525774500738776/$File/EPA-COUNCIL-10-001-unsigned.pdf.

14 An LML, or lowest measured level, refers to the lowest average ambient $PM_{2.5}$ concentration measured in key epidemiological studies evaluating the association between fine particle exposures and health effects. This is not the same as a lowest observable effects level or a no observed effects level. The science indicates, and our science advisors agree, that health effects are likely below these levels.

Analyses of rules issued between 2006 and 2009

As discussed in our response to question 2, EPA assumed a threshold of 10 $\mu g/m^3$ when calculating $PM_{2.5}$-related benefits for rules issued between 2006 and 2009. This means that all of the estimated benefits for these rules were related to exposures above 10 $\mu g/m^3$. These rules included the RICE Spark Ignition NSPS (12/20/07), the Ozone NAAQS (3/16/08), the Petroleum Refineries NSPS (4/30/08), the Locomotive and Marine Rule (3/14/08), the Small Spark Ignition & Recreational Marine Engines Rule (9/4/08), and the Lead NAAQS (10/16/08).

In 2009, EPA finalized the *Integrated Science Assessment for Particulate Matter* (US EPA, 2009), which concluded that there was no scientific foundation for assuming a threshold for $PM_{2.5}$ health effects. Indeed, the current body of scientific literature on particulate matter and health indicates that there is no evidence of a threshold below which health effects – including premature deaths – would not occur. As discussed above, to ensure that our work continues to reflect the best available science, the Agency discontinued the assumption of a threshold in the calculation of $PM_{2.5}$-related benefits, returning to the no-threshold approach used in pre-2006 rulemaking analyses. The no-threshold approach has subsequently been used in all recent rulemaking analyses.

In December 2009, the Health Effect Subcommittee of the Advisory Council on Clean Air Compliance Analysis (Council/HES) reviewed several aspects of the draft health effects analysis supporting EPA's developing study, titled "The Benefits and Costs of the Clean Air Act from 1990 to 2020." In response to a review charge question specifically requesting advice on EPA's use of a no-threshold model, the Council/HES endorsed the use of a no-threshold model. The Council's written advisory report concluded that "[t]he HES fully supports EPA's use of a no-threshold model to estimate the mortality reductions associated with reduced PM exposure."[15]

Analyses of Rules Issued Between April 2009 and June 2010: Sensitivity Analyses During Transition Period

As EPA transitioned to analyses using the no-threshold model, the Agency conducted sensitivity analyses[16] for several rules to show how changing this assumption affected the benefits estimates, especially for those rules that changed assumptions between proposal and final. Estimates from these sensitivity analyses illustrated the impact of assuming different thresholds for $PM_{2.5}$-related benefits. For the C3 Marine Rule (12/1/09), EPA's sensitivity analysis indicated that 63 percent of the total avoided $PM_{2.5}$-related premature deaths estimated in the full regulatory impact analysis (RIA) were associated with exposures above 10 $\mu g/m^3$, and 83 percent were associated with exposures above 7.5 $\mu g/m^3$. Similarly, for the 2012-2016 Light Duty Vehicle GHG Rule (4/1/10),[17] EPA's sensitivity analysis indicated that 78 percent of the avoided $PM_{2.5}$-related premature deaths estimated in the full RIA were associated with exposures above 10 $\mu g/m^3$ and 93 percent with exposures above 7.5 $\mu g/m^3$.

For the RICE Compression Ignition (CI) NESHAP (2/22/10) and the SO_2 NAAQS (6/2/10), EPA conducted sensitivity analyses that provided information regarding the percent of the $PM_{2.5}$-related benefits monetized in the full RIA that were associated with exposures below 10 $\mu g/m^3$. Assuming a threshold at 10 $\mu g/m^3$ in the sensitivity analysis for the RICE CI NESHAP, EPA estimated that 70

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[15] Ibid, SAB 2010. EPA-COUNCIL-10-001.

[16] Sensitivity analyses are generally conducted to gain insights into sources of uncertainty and variability.

[17] This rule established a national program consisting of new standards for model year 2012 through 2016 light-duty vehicles that will reduce greenhouse gas emissions and improve fuel economy. The majority of projected monetized benefits are associated with greenhouse gas reductions and consumer fuel savings related to reduced oil consumption.

percent of the $PM_{2.5}$-related monetized benefits estimated in the full RIA were associated with exposures above 10 $\mu g/m^3$. In the sensitivity analysis for the SO_2 NAAQS, using that same assumption showed that 66 percent of the monetized benefits estimated in the full RIA analysis were associated with exposures above 10 $\mu g/m^3$.

Lowest Measured Level (LML) Analyses in Rules Issued After July 2010:
July 2010 marked the first time since EPA returned to using a no-threshold approach that the Agency had the data, technical tools and ambient $PM_{2.5}$ concentration information needed to conduct an LML assessment as part of the regulatory impact analyses for certain rules. An LML analysis provides us with additional insights regarding our estimates of health impacts at varying $PM_{2.5}$ concentrations: we have the highest confidence in the magnitude of our estimates of adverse health impacts at concentrations at or above the LML of the underlying epidemiology studies, and somewhat less confidence in the magnitude of our estimates of adverse health impacts at concentrations below the LML.

The final rules completed since EPA began conducting LML analyses in 2010 relied on LMLs from two studies: an LML of 10 $\mu g/m^3$ from the Harvard Six Cities study (Laden et al. 2006)[18] and an LML of 7.5 $\mu g/m^3$ from the earlier study of the American Cancer Society (Pope et al. 2002).[19] Studies from more recent years, during which $PM_{2.5}$ concentrations have fallen, continue to report strong associations with mortality. For example, based on the most recent extended analysis of the ACS study (Krewski et al., 2009),[20] we have confidence in our estimates of avoided $PM_{2.5}$-related deaths down to at least 5.8 $\mu g/m^3$, the LML in this study, and somewhat less confidence in estimates below 5.8 $\mu g/m^3$.

EPA has conducted LML assessments for seven economically significant final rules since July 2010. These assessments vary in terms of how they evaluated $PM_{2.5}$-related health impacts occurring below the LML. When we have sufficient air quality modeling data for a rule, LML analyses estimate the percentage of $PM_{2.5}$-related premature deaths avoided at or above the LML. The number of premature deaths reduced at different concentrations is a good approximation of the monetized, $PM_{2.5}$-related benefits achieved by reductions in exposure at those concentrations.

Thus far, EPA has had sufficient data to assess the proportion of $PM_{2.5}$-related premature deaths avoided in an LML analysis for four final rules. These include: the Portland Cement MACT and NSPS (8/6/10); the Cross-State Air Pollution Rule (CSAPR) (7/6/11); the 2014-2018 Heavy Duty Vehicle GHG Rule (8/9/11) and the Mercury and Air Toxics Standards (MATS) (12/16/11).

For the Portland Cement rule, for example, a very large proportion of avoided $PM_{2.5}$-related impacts in the LML analysis occur among populations exposed at or above the lowest LML of the cohort studies.[21]

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[18] Laden, F., J. Schwartz, F.E. Speizer, and D.W. Dockery. 2006. "Reduction in Fine Particulate Air Pollution and Mortality." *American Journal of Respiratory and Critical Care Medicine* 173:667-672.

[19] Pope, C.A., III, R.T. Burnett, M.J. Thun, E.E. Calle, D. Krewski, K. Ito, and G.D. Thurston.2002. "Lung Cancer, Cardiopulmonary Mortality, and Long-term Exposure to Fine Particulate Air Pollution." *Journal of the American Medical Association* 287:1132-1141.

[20] Krewski, D., M. Jerrett, et al. 2009. "Extended follow-up and spatial analysis of the American Cancer Society study linking particulate air pollution and mortality." *Res Rep Health Eff Inst* 140: 5-114.

[21] U.S. Environmental Protection Agency. 2010. *Regulatory Impact Analysis: Amendments to the National Emission Standards for Hazardous Air Pollutants and New Source Performance Standards (NSPS) for the Portland Cement Manufacturing Industry*, Office of Air and Radiation, August 2010. Available on the Internet at http://www.epa.gov/ttn/ecas/regdata/RIAs/portlandcementfinalria.pdf

That analysis showed that approximately 94 percent of the premature deaths occur among populations with baseline exposure to annual mean $PM_{2.5}$ levels at or above the LML of 7.5 $\mu g/m^3$, with approximately 40 percent occurring at or above the LML of 10 $\mu g/m^3$. Similarly, the LML analysis for the CSAPR showed 96 percent of premature deaths estimated among populations exposed to $PM_{2.5}$ occurred at concentrations at or above an LML of 7.5 $\mu g/m^3$, and 69 percent of the deaths estimated among populations exposed to $PM_{2.5}$ occurred at concentrations at or above the LML of 10 $\mu g/m^3$.[22]

For the 2014-2018 Heavy Duty Vehicle GHG Rule (8/9/11)[23], the LML analysis confirmed that the great majority of the impacts occur at or above each study's LML. The LML analysis shows that approximately 97 percent of PM2.5-related deaths occur at or above an annual mean $PM_{2.5}$ concentration of 7.5 $\mu g/m^3$, while about 60 percent of the avoided impacts occur at or above an annual mean $PM_{2.5}$ concentration of 10 $\mu g/m^3$.[24] The LML analysis for the MATS rule showed approximately 73 percent of premature deaths estimated for population exposures at or above an LML of 7.5 $\mu g/m^3$, and approximately 11 percent estimated for population exposures above an LML of 10 $\mu g/m^3$.[25]

For other rules without air quality modeling data, the LML analyses estimate the percentage of people exposed to $PM_{2.5}$ concentrations below the LML before the rule is implemented. As noted in our analyses, we did not have data to estimate the number of premature deaths occurring at different concentrations for these rules.

While illustrative of baseline air quality conditions, the proportion of people *exposed at a certain concentration before a rule is implemented* is not always a good approximation of the proportion of the *benefits* at that concentration. The reason for this difference is the location of $PM_{2.5}$ improvements that would result from a given rules. If the largest air quality improvements from a particular rule occur in locations where $PM_{2.5}$ concentrations are high before that rule is implemented, then a lot of the benefits would occur in those same areas. As a result, the percentage of benefits at or above the LML would be larger than the percentage of the population exposed to $PM_{2.5}$ at or above the LML before the rule.

Four final rules used the approach described in the preceding paragraph: the RICE Stationary Spark Ignition NESHAP (8/10/10), the Commercial and Industrial Solid Waste Incineration NSPS and Emission Guidelines (2/23/11), the Sewage Sludge Incineration NSPS and Emission Guidelines (2/23/11), the Industrial, Commercial and Institutional Boilers NESHAP (2/23/11), and the Boiler Area Source Rule (2/23/11).

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[22] U.S. Environmental Protection Agency. 2010. Regulatory Impact Analysis (RIA) for the final Transport Rule (CSAPR) Docket ID No. EPA-HQ-OAR-2009-0491, Office of Air and Radiation, June 2011. Available on the Internet at http://www.epa.gov/airtransport/pdfs/FinalRIA.pdf

[23] This rule established a national program consisting of new standards for model year 2014 through 2018 heavy-duty vehicles that will reduce greenhouse gas emissions and improve fuel economy. The majority of projected monetized benefits are associated with greenhouse gas reductions and consumer fuel savings related to reduced oil consumption.

24 U.S. Environmental Protection Agency and the National Highway Traffic Safety Administration, U.S. Department of Transportation. 2011. Final Rulemaking to Establish Greenhouse Gas Emissions Standards and Fuel Efficiency Standards for Medium- and Heavy-Duty Engines and Vehicles: Regulatory Impact Analysis, August 2011. Available on the Internet at http://www.epa.gov/otaq/climate/documents/420r11901.pdf

[25] U.S. Environmental Protection Agency. 2011. *Regulatory Impact Analysis for the Final Mercury and Air Toxics Standards,* Office of Air & Radiation, December 2011. Available on the Internet at http://www.epa.gov/ttn/ecas/regdata/RIAs/matsriafinal.pdf

5. Do you consider the level of air quality that is established through the NAAQS process, including peer review by science advisors, to result in an "arbitrary" threshold; or do you believe that the NAAQS standard represents a level of air quality that is protective of public health, including sensitive populations, with an adequate margin of safety, as required by the Clean Air Act?

a. If the NAAQS standards protect the public health with an adequate margin of safety, explain how can the EPA estimate that short-term exposure to air in attainment areas would result in hundreds of thousands of deaths each year?

Response: National ambient air quality standards (NAAQS) do not represent "arbitrary" thresholds. In setting primary (health-based) standards that are requisite to protect public health with an adequate margin of safety, EPA's task is to establish standards that are neither more nor less stringent than necessary for that purpose, see Whitman v. American Trucking Assn's, 531 U.S 457, 473 (2001), recognizing that the Clean Air Act does not require the Administrator to establish a primary NAAQS at a zero risk-level, but rather at a level that reduces risk sufficiently as to protect public health with an adequate margin of safety. See *Lead Industries v. EPA,* 647 F.2d at 1156 n. 51. In addressing the requirement for an adequate margin of safety, EPA considers such factors as the nature and severity of the health effects involved, the size of at-risk populations, the strengths and limitations of the scientific evidence and related uncertainties, and whether discernible thresholds have been identified below which health effects do not occur. Standards are established to provide protection for a representative sample of persons comprising at-risk populations rather than to the most susceptible single person in such groups. Even in areas that meet the current standards, individual members of at-risk populations may at times experience health effects related to air pollution. The absence of evidence of a threshold below which health effects would not occur is one factor that the Administrator takes into consideration in selecting a NAAQS, including the level of the NAAQS, that in her judgment is sufficient to protect the public from the risks of adverse health effects, with an adequate margin of safety, but is not more stringent than necessary. The question incorrectly implies that EPA estimates that short-term exposure to air in attainment areas would result in hundreds of thousands of deaths each year. EPA has not conducted a national scale assessment of premature mortality associated with *short-term* $PM_{2.5}$ exposure to air in attainment areas. Rather, EPA has estimated the risk in a number of urban study areas associated with simulating ambient conditions to just meeting the current standards as well as alternative standards under consideration. [26] Furthermore, as discussed in the response to question 7 below, EPA conducted a national scale assessment of premature mortality related to *long-term* $PM_{2.5}$ exposure across all areas in the country.

6. Please provide any scientific studies EPA has relied upon to show a causal or associative relationship between fine particulate matter and premature mortality at levels below what EPA calls the "Lowest Measured Level" in the Pope and the Laden studies.

Response: EPA relies on the *Integrated Science Assessment (ISA) for Particulate Matter* (U.S. EPA, 2009) as the scientific basis for the determination that inhalation of $PM_{2.5}$ is causally associated with premature death. Additionally, the scientific evidence indicates that there is no evidence of a threshold below which health effects do not occur. For example, after performing an extensive analysis of the

26 U.S. Environmental Protection Agency. 2010. *Quantitative Health Risk Assessment for Particulate Matter.* Office of Air Quality Planning and Standards, Research Triangle Park, North Carolina, EPA-452/R-10-005. June 2010. Available on the Internet at http://www.epa.gov/ttn/naaqs/standards/pm/data/PM_RA_FINAL_June_2010.pdf.

Harvard Six Cities cohort, Schwartz et al. (2008)[27] were unable to discern such a population threshold between exposure to $PM_{2.5}$ and premature mortality. In addition, the recent reanalysis of the American Cancer Society cohort by Krewski et al. (2009) demonstrates mortality effects associated with long-term exposure to $PM_{2.5}$ across cities with a range of $PM_{2.5}$ concentrations, some of which were below the LMLs observed in the Pope and Laden studies.[28] Consistent with the conclusions presented in the ISA, numerous peer-review panels and nationally and internationally recognized air pollution experts have concluded that there is a lack of evidence for a threshold in the $PM_{2.5}$ mortality relationship. EPA recently summarized the scientific review statements related to the issue of thresholds in the concentration-response function for $PM_{2.5}$ mortality in a Technical Support Document appended to several recent RIAs.[29]

7. According to the most recent Particulate Matter Risk Assessment, EPA estimates that "total $PM_{2.5}$-related premature mortality ranges from 63,000 and 88,000" each year above the lowest measured level. EPA's estimate of benefits from the CSAPR rule, which involves almost all PM-related benefits, notes that mortality, ranges between 130,000 and 320,000 deaths per year.

a. Please explain how EPA came to these two different estimated mortality ranges.

b. Please explain the basis for EPA's monetization of a dramatically higher number than is identified in the peer-reviewed Risk Assessment.

c. Did you or the Assistant Administrator for Air and Radiation approve the public report of a dramatically higher number?

d. If so, please provide all documents relating to such approval.

e. If not, please explain why not.

Response: It is important to note that the CSAPR RIA estimate you reference in your question describes the overall public health burden of recent levels of $PM_{2.5}$ and ozone relative to policy relevant background levels,[30] and not the number of avoided premature deaths associated with emission reductions required by the CSAPR, which are estimated separately and reported in Table 5-17 of the CSAPR RIA.[31]

The most recent Quantitative Health Risk Assessment for Particular Matter and the CSAPR RIA provide similar estimates of the $PM_{2.5}$-related mortality. As you note in your letter, in the *Quantitative Health*

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27 Schwartz J, Coull B, Laden F. (2008). ,,The Effect of Dose and Timing of Dose on the Association between Airborne Particles and Survival.,, *Environmental Health Perspectives*. 116: 64-69.

28 The lowest concentration reported by Krewski et al. (2009) was 5.8 $\mu g/m^3$.

29 U.S. Environmental Protection Agency. 2010. *Technical Support Document: Summary of Expert Opinions on the Existence of a Threshold in the Concentration-Response Function for PM2.5-related Mortality.* Office of Air Quality Planning and Standards, Research Triangle Park, North Carolina, Research Triangle Park, NC. June. Available on the Internet at: www.epa.gov/ttn/ecas/regdata/Benefits/thresholdstsd.pdf

30 Fann N, Lamson AD, Anenberg SC, Wesson K, Risley D, Hubbell B. 2012. "Estimating the national public health burden associated with exposure to ambient $PM_{2.5}$ and ozone." *Risk Analysis*. 32(1): 81-95. DOI: 10.1111/j.1539-6924.2011.01630.x

31 U.S. Environmental Protection Agency. 2011. *Regulatory Impact Analysis for the Federal Implementation Plans to Reduce Interstate Transport of Fine Particulate Matter and Ozone in 27 States; Correction of SIP Approvals for 22 States.* Office of Air and Radiation. June 2011. Available on the Internet at: http://epa.gov/airtransport/pdfs/FinalRIA.pdf.

Risk Assessment for Particulate Matter, EPA estimated that "total $PM_{2.5}$-related premature mortality [resulting from 2005 $PM_{2.5}$ levels] ranges from 63,000 (39,000—87,000) (95^{th} percentile confidence interval) to 88,000 (49,000—130,000), respectively; in each case we estimated deaths per year down to the lowest measured levels (LMLs) in each epidemiological study" (pg G-2). In this same report, EPA also estimated 110,000 to 360,000 $PM_{2.5}$-related mortalities attributable to 2005 $PM_{2.5}$ levels relative to policy relevant background levels, which in most locations is well below the LML from the epidemiology studies. This estimate is comparable to the total $PM_{2.5}$–related mortality estimates cited in the CSAPR RIA of 130,000 to 320,000 premature $PM_{2.5}$-related deaths, which also are based on policy relevant background levels. The estimates reported in the CSAPR RIA are slightly different, because they were generated using more recent air quality information.

As noted in our response above, while we have higher confidence in the estimate of health impacts associated with exposure to $PM_{2.5}$ concentrations above the LML in the underlying epidemiology studies, the available evidence supports a no-threshold model. This means that it is appropriate to include estimates of mortality associated with exposure to even relatively low levels of $PM_{2.5}$, while acknowledging that there is some additional uncertainty regarding the magnitude of health effects attributable to these exposures. Thus, while we have the highest confidence that $PM_{2.5}$-related mortality impacts in 2005 were at least 63,000 to 88,000, as reported in the PM risk assessment, the best estimates for characterizing the overall public health burden of recent levels of $PM_{2.5}$ and ozone is the estimate of 130,000 to 320,000 premature deaths as summarized in the CSAPR RIA.