

**The American Lung Association
Comments on EPA's
Quantitative Health Risk Assessment for Particulate Matter
Second External Review Draft
EPA-452/P-10-001 February 2010**

**Prepared by Deborah Shprentz
Consultant to the American Lung Association**

**March 15, 2010
Docket ID No. EPA-HQ-OAR-2007-0492**

The American Lung Association offers these comments on EPA's Second Draft Risk Assessment for Particulate Matter.

Expanded Scope is Step in the Right Direction

The Lung Association appreciates the efforts that EPA has made to expand the scope and breadth of the risk assessment from earlier reviews.

We favor inclusion of an even broader range of health endpoints, including those deemed to be "suggestive" of a causal relationship, such as the effects on pregnant women and their babies.

We also have favored inclusion of a larger number of cities in the risk assessment. In this analysis, EPA has analyzed 15 cities, up from 12 in the last review. The results in this draft demonstrate how the residual risks are driven by air quality profiles in the selected cities, and how different alternative standards may be more effective in different cities. Since EPA's task is to set standards to that protect public health with an adequate margin of safety, a larger the number of cities analyzed provide more information to meet the Clean Air Act's requirement. For example, the draft analysis shows that 3 of the 15 study areas would not experience reductions in long-term exposure related mortality if reductions were only made to the annual average fine particle standard, without also reducing the 24-hour standard. This suggests that both the annual average and 24-hour average standards need to be rolled back to protect public health with an adequate margin of safety.

The national assessment of mortality risks, included for the first time, points to the magnitude of the public health risk posed by fine particle pollution based on 2005-2007 air quality. EPA estimates that premature mortality ranges from 63,000 to 88,000 per year due to fine particle pollution. EPA estimates that long-term exposure to PM_{2.5} contributes to 3-9 percent of premature death in half the counties in the U.S., with a range from 0 to 3 percent in the other half of counties. EPA is using the most recent extended

analyses of the major long-term cohort studies, which is appropriate, as these are the best designed, most comprehensive multi-city studies. The extended analyses cover a longer exposure period and encompass a greater number of deaths making them most suitable to use in the risk analysis. The lower estimate is based on the Krewski et al. (2009)¹ extended analysis of the American Cancer Society cohort, and the higher estimate is based on the Laden et al. (2006)² extended analysis of the Six Cities cohort.

EPA has used a log-linear all-cause mortality risk coefficient derived from both studies. Risks are estimated down to the lowest measured pollution levels in each study. In the case of the Krewski study, this is $5.8 \mu\text{g}/\text{m}^3$, while in the Laden study, it is $10 \mu\text{g}/\text{m}^3$. These studies are finding that there is a linear relationship between exposure and risk, with no clear threshold, that is, risk increases above the lowest measured level. This is confirmed by Schwartz et al. (2008), which did not find evidence of a threshold in an extended analysis of the Six Cities study.³

EPA has also estimated PM_{2.5}-related premature mortality down to the policy-relevant background level. This practice is consistent with EPA's approach in the Regulatory Impact Analysis it recently issued for the review of the sulfur dioxide NAAQS.⁴ Premature deaths attributable to PM_{2.5} ranged from 110,000 to 360,000 when considering risks down to the policy-relevant background concentrations.

Risk Assessment Must Evaluate Lower Annual Average Standards

In selecting policy alternatives to evaluate, it appears that EPA limited itself to policy options considered in the last review. In the current review, the ISA evaluated a large number of new long-term studies confirming the relationship between PM exposure and premature deaths. These studies are reporting effects at lower concentrations than previously studied. We see a disconnect between the alternate standard levels evaluated, and the risk assessment assumptions and results. In light of the conduct and results of the national assessment, it is reasonable to consider the impacts of annual average standards of $11 \mu\text{g}/\text{m}^3$ PM_{2.5}, $10 \mu\text{g}/\text{m}^3$, and even lower concentrations. If measurable risks are evident down to the lowest measured level in these long-term studies, it is reasonable to evaluate the efficacy of standards down to these levels to mitigate the risk of premature deaths. By restricting itself to limited alternatives, e.g. $12 \mu\text{g}/\text{m}^3$ as the lowest annual average standard evaluated, EPA seems headed down a path that will not protect public health with an adequate margin of safety.

¹ Krewski D; Jerrett M; Burnett RT; Ma R; Hughes E; Shi Y; Turner MC; Pope AC III; Thurston G; Calle EE; Thun MJ (2009). Extended follow-up and spatial analysis of the American Cancer Society study linking particulate air pollution and mortality. Health Effects Institute. Cambridge, MA. Report Nr. 140.

² Laden F; Schwartz J; Speizer FE; Dockery DW. Reduction in fine particulate air pollution and mortality: extended follow-up of the Harvard Six Cities study. *Am J Respir Crit Care Med*, 2006; 173: 667-672.

³ Schwartz J; Coull B; Laden F; Ryan L. The effect of dose and timing of dose on the association between airborne particles and survival. *Environ Health Perspect*, 2008; 116: 64-69.

⁴ U.S. EPA. Regulatory Impact Analysis. Proposed Revisions to the Sulfur Dioxide NAAQS, 2009.

National Assessment Must Evaluate Alternative Standard Levels

We agree with CASAC's earlier comments that the national assessment should evaluate the impact of alternative standard levels in redressing premature deaths on a national scale. EPA claims that it would take too much time and money to conduct this extra step of the analysis. However, since it is basing its national scale analysis on the BenMAP model, it is a routine matter to consider alternative standard levels. This extra step would provide valuable information for the Policy Analysis. Additionally, it would be useful to consider additional health endpoints in the national analysis, such as emergency room visits, hospital admissions, etc.