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September 30, 2004

Dr. Rob Elias  
Project Manager for PM  
National Center for Environmental Assessment -RTP (B243-01)  
U.S. Environmental Protection Agency  
Research Triangle Park, NC 27711

**Re: Comments on Chapter 9 of PM Criteria Document (CD)**

**Via Email:** [elias.robert@epa.gov](mailto:elias.robert@epa.gov)  
**cc:** [butterfield.fred@epa.gov](mailto:butterfield.fred@epa.gov)

Dear Dr. Elias,

The American Lung Association appreciates this opportunity to offer comments on EPA's August 2004 draft of Chapter 9, the Integrative Assessment of the Air Quality Criteria Document for Particulate Matter.

Our major concern lies with EPA's decision to eliminate Appendix 9A from the chapter. Appendix 9A contained three tables which presented "Key Quantitative Estimates of Relative Risk for Particulate Matter-Related Health Effects Based on Epidemiologic Studies of U.S. and Canadian Cities." The tables that included important information not found in such a succinct form in earlier chapters.

Specifically, the tables detailed effect size estimates, by health endpoint, from the key North American epidemiological studies, and identified the mean concentration levels and ranges in these studies for each pollutant of concern: PM<sub>10</sub>, PM<sub>2.5</sub>, and PM<sub>10-2.5</sub>. Included in these tables are the results of the studies deemed so important that they were subject to extensive reanalyses.

The information in these tables is absolutely critical to the purpose of the CD and to the interpretation of the scientific evidence. Early on, the Lung Association advocated for the Criteria Document to include information on the concentration levels recorded in epidemiological studies. We were pleased to see this information included in the detailed tables in Chapter 8. However, the summary tables in Chapter 9 served the purpose of an integrative summary chapter by excerpting the information on the key North American studies most relevant to decision making.

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The information detailed in the tables clearly indicates that adverse health effects—morbidity and mortality—are occurring at levels below the current 24-hour and annual average standards for PM<sub>2.5</sub>. The CD should clearly state this in the text of chapter 9.

If the Appendix was deleted to attempt to respond to CASAC comments about the length of the text in the chapter, it fails to do so since its tables were never in the chapter. Dropping the appendix eliminates information critical to the purpose of the Criteria Document: that is, to provide the Administrator with adequate information needed to select a NAAQS that will protect public health with a margin of safety. Therefore, Tables 9A-1, 2 and 3 should be reinstated when EPA publishes the final PM Criteria Document.

Overall, we find the tone and conclusions to Chapter 9 to be very cautious and conservative, and replete with numerous caveats, even relative to EPA's recently published 5-year progress report on the PM research program.<sup>1</sup>

This version of Chapter 9 contains much cogent material. For example, we'd like to specifically praise the inclusion of Tables 9-5 and 9-6 on prevalence of respiratory conditions and cardiopulmonary disorders.

However, as we pointed out regarding the fourth draft of Chapter 9, we believe that effects on infants and children are downplayed given the vast number of new studies and the weight of the scientific evidence.

Finally, we'd like to emphasize that hundreds of new health studies have been published since 2002, the cutoff date for inclusion in this CD.

Given the length of this process and the critical health risks from particulate matter, we remind you that upon completion of the PM CD next month, EPA must immediately commit to the gathering and interpretation of the post 2002 scientific data for inclusion of the next edition of the Criteria Document. The stakes are too high to allow excessive years of delay between the publication of data and the setting of standards that protect public health.

Thank you for your consideration.

Sincerely,

/signed/

Joseph Bergen  
Executive Vice President and Chief Operating Officer

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<sup>1</sup> U.S. Environmental Protection Agency, Office of Research and Development. Particulate Matter Research Program: Five Years of Progress. EPA 600/R-04/058, July 2004.