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**Comments of the American Lung Association on the
U.S. Environmental Protection Agency's
Ozone Health Assessment Plan:
Scope and Methods for Exposure Analysis and Risk Assessment**

April 2005 Draft

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The American Lung Association offers these comments on EPA's draft Ozone Health Assessment Plan: Scope and Methods for Exposure Analysis and Risk Assessment. EPA staff has developed a thoughtful proposal for carrying out a limited quantitative risk assessment to inform the discussion of policy alternatives in the Staff Paper. Because of the potential importance of the risk assessment results in the development of policy options for the ozone standards, the American Lung Association offers a number of suggestions for broadening the scope of the proposed risk assessment to make it more informative.

Exposure Analysis

Our key concern is that the proposed activity profiles for the exposure assessment appear to underestimate ozone exposures and risks.

EPA has proposed to develop detailed exposure profiles for four population groups: the general population; school-age children; active school-age children; and asthmatic school-age children. We have some fundamental questions about the categories and the assumptions that underlie them. In real-world terms, what distinguishes an "active" child from the general population of school-age children? Are asthmatic children assumed to have different activity patterns from "active" school-age children? Why are preschool children, who are also very active outdoors, excluded from the analysis? What about babies and toddlers?

In the last review of the ozone standards in 1996, EPA also analyzed exposures of outdoor workers. Outdoor workers are clearly at increased risk of ozone health effects because of their prolonged exposures and increased respiratory rates due to heavy labor. Why have they been excluded? What about adults who engage in sports or myriad forms of outdoor recreation? What about senior citizens?

Geographic Scope of Analysis

EPA has proposed to include 12 cities in the risk analysis, but for many of the health endpoints, risk estimates would only be generated for a few locations. Table 1 of the draft document indicates that school absences would only be estimated for Los Angeles. Emergency room visits for respiratory illness would be estimated only for Atlanta and Cleveland, and respiratory hospital admissions would be estimated only for New York, Los Angeles, and Cleveland.

Because of different air quality profiles in different cities, a standard that appears to be protective in one city cannot be assumed to represent outcomes in the rest of the country. Without a broader analysis, it is impossible to generalize from the few cities studied to the entire country.

The main constraint appears to be EPA's preference to apply risk functions only in the cities in which they were generated by the original study. This narrow interpretation of the epidemiological studies greatly limits the scope of the analysis. We note that EPA does not adhere to this principle in preparing regulatory impact analyses, which frequently apply risk functions from one or several cities to the national population. For instance, there are a number of studies of ozone and hospital admissions for various causes in Toronto, which provide risk functions that are included in EPA's BenMap model for use in national analysis.¹

Additional Health Endpoints

The long-term effects of exposure to ozone have been excluded from the proposed risk assessment, despite considerable advances made since EPA's last review of the ozone standard. This is likely to produce results which greatly underestimate the overall effect of chronic exposure to ozone.

A number of long term-studies published since the last review have associated diminished lung function with long-term exposure to ozone. EPA should consider including this health endpoint in its assessment.²

The benefits assessment recently conducted by the California Air Resources Board in support of their revisions to the air quality standards for ozone included two health endpoints not reflected in EPA's draft plan, specifically, emergency room visits for asthma for children under age 18, and minor restricted activity days for adults.³ These risks should be evaluated in the risk analysis.

In addition, the BenMAP model includes ozone concentration -response functions for various other respiratory endpoints related to asthma exacerbation including cough, shortness of breath, and wheeze, and it seems highly appropriate to include these health endpoints in the risk analysis.

Short-term Mortality

The inclusion of short-term mortality risk as a health endpoint for ozone is warranted by the draft Criteria Document's conclusion of a likely causal effect.

EPA proposes to rely on two NMMAPS studies to provide the risk function for short-term mortality. However, the design of NMMAPS may result in an underestimate of mortality risks. According to the 2005 California Staff Report on the review of the state ozone standard, the "NMMAPS study may generate an underestimate of the impact of mortality due to the modeling methodology used to control weather factors. Specifically, this effort included four different controls for temperature and dewpoint, where most

other times-series analyses used only two or modeled extreme weather events more carefully and used city-specific models to ensure the best fits.”⁴

The three meta-analyses currently in press in the journal *Epidemiology* were specifically commissioned by the U.S. EPA for use in benefits analyses and risk assessments. The meta-analyses present a synthesis of results from dozens of studies and may produce a more representative estimate than reliance on a particular study. As discussed in detail in our comments on the draft Criteria Document, we suggest that the meta-analyses be used to supply a risk function for the risk assessment.

Hypothetical Thresholds

EPA proposes to conduct a sensitivity analysis that explores the effects of alternative hypothetical thresholds on estimated risks of ozone exposure. Most of the epidemiological studies include very low levels concern in their analysis, and no clear threshold for effects has been reported, except for emergency room visits.

With respect to the chamber studies, the draft Criteria Document reports: “However, the notion of a ‘threshold’ O₃ concentration has been called into question by more recent studies involving lower O₃ concentrations, but greater delivered doses due to longer exposure duration and increased exercise-associated VE (e.g., Folinsbee et al., 1994). The more recent view is that thresholds likely exist on an individual level, but that the variability among individuals is great enough that on a population-wide basis, the threshold is impossible to determine.” CD 11-161

Thus if EPA is planning to analyze risks down to the lowest levels included in the relevant studies, there is no justification for the inclusion of hypothetical thresholds that have no empirical basis.

¹ Abt Associates Inc. U.S. Version BenMAP: Environmental Benefits Mapping and Analysis Program User’s Manual, Prepared for Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, November 2003.

² American Lung Association, Comments on U.S. EPA’s Air Quality Criteria for Ozone and Related Photochemical Oxidants First External Review Draft, U.S. EPA Docket ID No. ORD-2004-0015, April 29, 2005.

³ California Environmental Protection Agency, Air Resources Board. Review of the California Ambient Air Quality Standard for Ozone. Staff Report, March 1, 2005.

⁴ California Environmental Protection Agency, Air Resources Board. Review of the California Ambient Air Quality Standard for Ozone. Staff Report, March 1, 2005, at p. B-9.