

**Comments of the American Lung Association on
EPA's Policy Assessment for the Review of the Ozone NAAQS,
First External Review Draft - August 2012**

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October 12, 2012

The American Lung Association appreciates the opportunity to provide brief comments on the U.S. Environmental Protection Agency's (EPA) first draft Policy Assessment for the review of the National Ambient Air Quality Standards (NAAQS) for ozone.

Since the last review of the ozone standard completed in 2008, there is considerable new information on the health impacts of exposure at concentrations well below the current standard. The Integrated Science Assessment (ISA), as reviewed at the CASAC meeting September 11-13, 2012 summarizes well the current state of the science on ozone and photochemical oxidants.

Relative to the last review, there is substantial new evidence from controlled human exposure studies of adverse respiratory effects down to 60 ppb, as well as information from more recent toxicological studies.

Perhaps the most striking new evidence available since the last review comes from the epidemiological literature. Epidemiological studies examine associations in real-world populations exposed to contemporary concentrations of ambient air pollution. The epidemiological studies available for ozone examine a spectrum of adverse health effects ranging from impacts on lung function to more serious health endpoints that cannot be assessed in controlled human exposure studies such as increased risk of doctor visits, emergency department visits, hospital admissions, and premature mortality.

The 3rd draft ISA concludes that there is a causal relationship between short-term exposures to ozone and respiratory effects, and a likely causal relationship between short-term exposures and premature mortality. Further, the science assessment finds a likely causal relationship between long-term ozone exposures and adverse respiratory effects. These causal conclusions, which have been reviewed by CASAC, are based on a synthesis of the available evidence from all branches of science. Epidemiological studies provide critical information to inform these causal determinations.

In light of these findings, it is critical that any proposed standards protect against both short- and long-term effects of ozone exposures.

We concur with EPA's conclusion in the draft policy assessment that the current standards are not sufficient to protect the public health with an adequate margin of safety as required by the Clean Air Act:

In light of all of the above considerations, staff reaches the preliminary conclusion that the body of information now available supports consideration of revising the current 8-hour O₃ primary standard, so as to afford greater public health protection against the adverse health effects of short-term O₃ exposures, especially to at-risk groups, and that it does not support retention of the current standard. In so doing, we also recognize that consideration should be given to the extent which such a revised standard would also provide appropriate protection against the adverse health effects of long-term O₃ exposures. (p. 4-45)

In light of these findings, it is critical that any proposed standards protect against both short- and long-term effects of ozone exposures.

EPA has specifically solicited input from Clean Air Scientific Advisory Committee (CASAC) and the public on how to interpret scientific studies for purposes of standard setting. The discussion below responds to that request.

First, the first draft Policy Assessment misses the mark with respect to interpretation of the epidemiology studies. The draft narrows consideration of the broad spectrum of epidemiological literature to focus on just two studies: Silverman and Ito (2010) and Bell et al. (2006). In light of the breadth and depth of community health studies, we strongly object to such a narrow approach. It is unacceptable to dismiss the broad spectrum of epidemiological studies as irrelevant to standard setting.

The American Lung Association favors an approach similar to what EPA used in considering proposed revisions to the NAAQS for fine particulate matter (PM). In the PM Policy Assessment, EPA considered not just mean concentrations reported in the epidemiological studies, but also looked at statistical distributions around those means – more specifically, at concentrations 1 SD below the mean, as recommended by CASAC. This provided a more realistic sense of the range of concentrations at which the bulk of the health effects were concentrated. Further, in the PM Policy Assessment, EPA presented a sophisticated analysis examining the health data relative to the ambient concentrations to ascertain the range of concentrations where between 90 percent and 75 percent of the health effects (such as premature deaths) were concentrated. This analysis provided important additional information to inform the standard-setting process.

The American Lung Association urges that a comparable analysis be prepared for the next draft of the Policy Assessment.

We recognize that there are challenges in considering different time periods used by study authors relative to the 8-hour form of the ozone standards. We suggest that EPA contact the study authors if necessary to gain additional information on air quality levels in the epidemiological studies.

Second, we concur with the comments of CASAC member Dr. Ana Diez Roux that:

In several places the chapter notes that selected epidemiologic studies that were conducted in cities that would not have met the current standard provide no insight into the appropriateness of the degree of public health protection provided by the current standard (this statement is made several times in reference to both short term and long term exposure studies). This seems an overstatement. The informativeness of these studies depends on the actual distribution and range of ozone concentrations investigated rather than on whether the standard was or was not met. To the extent that these studies allow estimation of the dose-response gradient extending into the ozone exposure distribution that would be expected even if the current standard were met, they do indeed provide important evidence that can be used to determine the health benefit that could be expected if the standard were lowered even further.¹

Finally, we remain concerned that the draft risk assessment does not evaluate impacts on children ages zero-five. Children of pre-school age and younger are exposed to air pollution when playing outdoors. By excluding this most vulnerable group of children from the quantitative calculation of risk, EPA analysis will create a misleading impression of the relative impacts of various concentrations of ozone on children's health. As an especially susceptible population, it behooves the Agency to consider alternate approaches to include infants and young children in its risk and exposure assessment.

Thank you for consideration of these comments.

¹ Preliminary Individual Comments on the Policy Assessment for the Review of the Ozone NAAQS (First External Review Draft, August 2012). Available at: [http://yosemite.epa.gov/sab/sabproduct.nsf/BAF7E636BBCA39E785257A7600464707/\\$File/Preliminary+Individual+Comments+on+PA+9-11-12.pdf](http://yosemite.epa.gov/sab/sabproduct.nsf/BAF7E636BBCA39E785257A7600464707/$File/Preliminary+Individual+Comments+on+PA+9-11-12.pdf)