Comments of the American Lung Association on

EPA's Third External Review Draft

Integrated Science Assessment for Ozone and Related Photochemical Oxidants

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The American Lung Association appreciates the effort that has gone into the preparation of this third external review draft of the Integrated Science Assessment (ISA) for ozone. We believe it provides a sound basis for moving forward with the review of the primary National Ambient Air Quality Standards (NAAQS) or ozone.

We would like to offer a few comments on the present draft.

Roadmap of Respiratory Health Effects

First, it would be extremely helpful to include a flow diagram illustrating the cascade of respiratory health effects induced by ozone exposures.

CASAC suggested removing some other diagrams from the beginning chapters of the second draft ISA. We have in mind a different sort of diagram -- something similar to that used to illustrate the cardiovascular effects of particulate matter.

This is important because, as the regulatory process moves forward, health endpoints are too often viewed in isolation.

For instance, the risk assessment reports on lung function decrements as if they are a stand-alone health effect.

To the contrary, the declines in FEV1 are just one endpoint that could be readily quantified for purposes of the risk assessment. Ozone not only depresses lung function but also causes inflammation, heightened airway responsiveness, coughing wheezing, shortness of breath, increased responsiveness to allegens, and reduced ability to fight off respiratory infections, as well as more serious effects such as altered development of the respiratory tract, asthma exacerbations, increased risk of developing asthma and even increased risk of premature death. These respiratory effects may in turn affect the cardiovascular system.

Further down the line, when evaluating the results of the risk assessment, it is important to have a diagram indicating the relationship between lung function, the most readily quantified health effect, and the whole cascade of other harms induced by ozone.

Background Concentrations

In this review, EPA has moved from a discussion of “policy relevant background” to a newly defined “North American Background.” More precise regional and seasonal estimates are provided. The policy implications of this shift are unclear at this time, but it appears that this change could impact the risk assessment results.

The lungs do not distinguish the source of the ozone – natural or manmade, homegrown or imported from abroad. We breathe polluted air and our bodies respond accordingly. Ozone and other photochemical oxidants are powerful oxidizing agents regardless of the source of precursors. The science assessment can try to characterize a background concentration but our lungs are taking in the manmade pollution on top of the background ozone and are responding accordingly to the total exposure. The risk assessment and policy assessment must take this into account.

Air Quality Characterization

2012 was a hot, hazy summer. Already, we know that there were more ozone violations in 2012 than in any of the four prior years (2008, 2009, 2010, 2011). More areas were affected, there were more violation days, and higher concentrations.

The ozone season is not over, and we do not yet have quality-controlled data for 2012. Nevertheless, it is important that the ISA and documents that flow from it acknowledge the fact that air quality representations based on 2008-2010 may grossly underestimate present-day (and possibly future) ozone concentrations.

New Scientific Evidence

The draft ISA frames a new rubric for the classification of susceptible populations. Although the policy implications are not spelled out, the emphasis is on protecting those susceptible populations where the evidence is "adequate" to demonstrate increased risk relative to the general population.

In order to protect public health from the well-established harms of ozone at concentrations below the current standards, the American Lung Association urges that this review move forward quickly. Nonetheless, the delay caused by the preparation of a third draft ISA means that the science has moved forward since the mid-2011 cutoff for the inclusion of studies. EPA's usual practice under such circumstances is to issue a provisional assessment of new science to identify any studies that might alter the general assessment of the science.

There are several studies of note published since July 2011 that may have bearing on the identification of susceptible population, the causal findings, or other aspects of the review. EPA should consider prominent new studies for inclusion in the final ISA. We believe this can be accomplished without requiring additional CASAC review.

Cardiovascular effects

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