OZONE NAAQS: Urgent need for ACTION

The American Lung Association and other leading medical organizations are calling for EPA to set a stricter standard for 8-hr ozone.

Ozone is one of the most pervasive and pernicious of the common air pollutants. Ozone is a powerful oxidant, so powerful that it is used to treat and disinfect drinking water supplies. At ambient concentrations, ozone has been shown to cause a variety of harms, including damaging forests and crops and endangering human health.

Ozone enters the human body via the lungs, and that is where the most damage occurs. Respiratory harms range from impeding inspiration to causing inflammation, coughing, and increased susceptibility to colds and flu. Ozone exacerbates asthma, leading to increased reliance on medication and increased visits to hospital emergency departments. There is now strong evidence that ozone increases the risk of premature death.

The long-term effects of ozone are also well documented. When infant monkeys are exposed to high concentrations of ozone, their lung development is...
stunted.\textsuperscript{5} Similarly, children growing up in more polluted areas never develop the lung capacity of their peers raised in less polluted environments.\textsuperscript{6}

Advances in biostatistics have enabled epidemiologists to tease out the effects of ozone from that of other air pollutants and confounding factors. We now know that ozone contributes to a range of public health harms, including respiratory and cardiac effects, and even premature death, at concentrations well below the current standards.\textsuperscript{7}

The U.S. Clean Air Act (CAA) requires the U.S. Environmental Protection Agency (EPA) to set National Ambient Air Quality Standards (NAAQS) that protect the public health, including the health of sensitive populations, with an adequate margin of safety.\textsuperscript{8} The CAA requires EPA to review the standards every five years, in light of advancements in the science, to ensure that the standards are health-protective.

The U.S. Supreme Court has affirmed in a unanimous decision that the NAAQS must be based solely on health protection.\textsuperscript{9} Economic factors are taken into account when developing implementation strategies.

The fact that the current standard is not protective of public health is well established, and has been for many years. Since 2006, the Clean Air Scientific Advisory Committee (CASAC), the independent panel of experts advising EPA, has repeatedly urged that EPA set an 8-hr average ozone standard within the range of 60 to 70 parts per billion (ppb). This has been the unanimous conclusion of three separate CASAC panels under three different Chairpersons for the past nine years.\textsuperscript{10}

**The Scientific Evidence Is Strong**

The evidence base for ozone is stronger than for any other air pollutant. There are strong lines of evidence from all three major scientific disciplines: toxicology, epidemiology, and controlled human exposure studies.

The current review is premised on a comprehensive evaluation of the science completed in 2013. Based upon the substantial new information available, the 2013 Integrated Science Assessment (ISA) reached much stronger conclusions about the health effects of ozone than had been reached in the prior review.\textsuperscript{11} The criteria for evaluating studies and reaching causal determinations is carefully laid out in the ISA, and were thoroughly vetted by the CASAC.\textsuperscript{12} Conclusions are reached based on multiple lines of evidence and multiple studies, demonstrating coherence, consistency, and plausibility.

Specifically, the 2013 ISA:

- concludes that ozone causes adverse respiratory effects;
- evaluates several additional controlled human exposure studies demonstrating respiratory deficits and inflammation in healthy young adults at 60 ppb;
- makes stronger findings that the adverse effect of ozone on cardiovascular health are likely causal;
- reviews new information suggesting reproductive effects, such as increased risk of low birth weight babies;
- reaches new conclusions about suggestive neurological effects;
- reaffirms based on new community health studies strengthening the link between ozone exposure and mortality, even at concentrations below the current standards; and
- identifies new information about the impact of longer-term exposures on respiratory health endpoint, such as pulmonary inflammation and injury, and new onset asthma.

The 2013 ISA found there was a causal relationship between short-term exposure to ozone and respiratory effects.\textsuperscript{12} For almost every other health outcome and exposure duration evaluated, the ISA reached stronger causal determinations in 2013 than in the review completed in 2008.\textsuperscript{12}

There is considerably more certainty for several critical health endpoints than in the prior review, compelling more stringent air quality standards. Under the CAA, EPA is obliged to set air quality standards that protect public health from proven, as well as anticipated health effects.\textsuperscript{13} Revisions to

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the standards must reflect the increased strength of the evidence, and the breadth of adverse health effects now attributable to ozone air pollution.

For a number of important respiratory health endpoints, including lung function decrements, inflammation, hospital and emergency department visits for respiratory causes, the ISA indicates adverse effects at 60 ppb.14 This provides strong support for a standard no higher than 60 ppb.

Several controlled human exposure studies of healthy young adults have demonstrated a reduction in lung function and an increase in inflammation at 6.6-hr exposures of 60 ppb.15 Some individuals respond more severely than the group average.16 Inflammation of the lining of the lungs is a serious health concern.17 Lung function declines especially of concern to children and adults with asthma and chronic obstructive pulmonary disease (COPD), because these individuals have reduced pulmonary reserves.18

Because healthy adults are harmed after 6.6-hr exposures of 60 ppb, the 8-hr standards must be set lower to protect sensitive populations—such as children, children with asthma, and people who work or exercise outdoors—with an adequate margin of safety.19

Community health studies in Europe and North America have demonstrated consistent, positive associations between ozone air pollution and hospital admissions and emergency department visits for respiratory causes.20 Generally, mean 8-hr maximum ozone concentrations were less than 60 ppb.21

Consistent associations between ozone and respiratory mortality have been reported in single-city and multi-city studies. The mean 8-hr maximum ozone concentration in these studies is less than 63 ppb.22 Even when days above 60 ppb are excluded from the analysis, the effect of ozone on mortality is still evident.23

Longer-term studies have also demonstrated the need for a stricter standard to protect against chronic effects. There is increased evidence that chronic exposure to ozone may increase the risk of new onset asthma, at mean annual 8-hr maximum concentrations of 55.2 ppb.24 Active children living in more polluted areas run a greater risk of developing asthma.25 Studies with mean annual 8-hr maximum ozone concentrations less than 41 ppb have found that chronic ozone exposures puts kids with asthma at greater risk of a hospital admission.26

Sensitive Populations Must Be Protected

Several populations are particularly vulnerable to the effects of ozone air pollution. These groups include children, the elderly, and people with respiratory conditions such as asthma. In addition, people who work or exercise outdoors are at increased risk due to their increased exposure to ozone.27 There is growing information on obesity as a potential risk factor for increased susceptibility to ozone air pollution.28 Two-thirds of the U.S. population is classified as overweight or obese, including a growing number of children and adolescents.29 Obese individuals have higher breathing rates, which can increase their exposure to ozone and other air pollutants.30

Under the CAA, the NAAQS must protect these sensitive populations with an adequate margin of safety.31 It follows that standards must be set below the levels shown to cause harm in healthy test subjects.

CASAC Recommends Standard in 60–70 ppb Range

In a recent letter to the EPA Administrator,32 CASAC made clear that:

- the current standard is inadequate to protect public health;
- at 70 ppb, there is substantial evidence of adverse effects, including decrease in lung function, increase in respiratory symptoms, and increase in airway inflammation;
- a standard of 70 ppb provides little margin of safety and advised that the standard should be set below this level to meet the statutory requirement in the Clean Air Act to protect public health with an adequate margin of safety; and

There is now strong evidence that ozone increases the risk of premature death.
• 60 ppb is the most protective option, and the only option that would “certainly” provide an adequate margin of safety.

The American Lung Association and other leading medical organizations, including the American Academy of Pediatrics, American Thoracic Society, American Medical Association, American College of Chest Physicians, American College of Preventive Medicine, American College of Occupational and Environmental Medicine, American Association of Cardiovascular and Pulmonary Rehabilitation and National Association for the Medical Direction of Respiratory Care support an 8-hr average standard of 60 ppb or below, based on strong evidence from the controlled human exposure studies and the epidemiological studies.33

References
12. 2013 Integrated Science Assessment (ISA) at 2-23.
17. 2013 Integrated Science Assessment (ISA) at 6-76.
22. 2013 Integrated Science Assessment (ISA) at 2-22.