

**AMERICAN ACADEMY OF PEDIATRICS ▪ AMERICAN COLLEGE OF CHEST PHYSICIANS
AMERICAN ASSOCIATION FOR CARDIOVASCULAR AND PULMONARY REHABILITATION
AMERICAN COLLEGE OF OCCUPATIONAL AND ENVIRONMENTAL MEDICINE
AMERICAN COLLEGE OF PREVENTIVE MEDICINE ▪ AMERICAN HEART ASSOCIATION
AMERICAN LUNG ASSOCIATION ▪ AMERICAN MEDICAL ASSOCIATION
AMERICAN PUBLIC HEALTH ASSOCIATION ▪ AMERICAN THORACIC SOCIETY
ASTHMA AND ALLERGY FOUNDATION OF AMERICA
CHILDREN'S ENVIRONMENTAL HEALTH NETWORK
FOUNDATION FOR SARCOIDOSIS RESEARCH ▪ THE LAM FOUNDATION
NATIONAL ASSOCIATION FOR THE MEDICAL DIRECTION OF RESPIRATORY CARE
NATIONAL ASSOCIATION OF COUNTY AND CITY HEALTH OFFICIALS
PHYSICIANS FOR SOCIAL RESPONSIBILITY
SCIENCE AND ENVIRONMENTAL HEALTH NETWORK**

March 22, 2010

The Honorable Lisa P. Jackson
Administrator
U.S. Environmental Protection Agency
1200 Pennsylvania Ave. NW Mail code 6102T
Washington, DC 20460

Re: Science Review Compels Stricter National Ambient Air Quality Standards (NAAQS) for Ozone
75 Fed. Reg. 2938 Docket ID No. EPA-HQ-OAR-2005-0172

Dear Administrator Jackson:

As leading medical, public health, disease and patient advocacy organizations, we welcome your decision to reconsider the 2008 decision on the National Ambient Air Quality Standards for ozone air pollution. We urge you to adopt a much stronger, more protective standard of 60 parts per billion.

EPA Must Protect the Health of the Public, including Sensitive Populations

The National Ambient Air Quality Standards (NAAQS) are precautionary standards that must protect public health with an adequate margin of safety. Standards must be set at levels that will protect children, people with asthma and other lung diseases, seniors, outdoor workers and otherwise healthy “responders” who are especially sensitive to ozone exposure.

Section 109(b)(1) of the Clean Air Act directs the Administrator of the U.S Environmental Protection Agency to promulgate a primary NAAQS for ozone that is “requisite to protect public health” with “an adequate margin of safety.”¹ As stated by the U.S. Court of Appeals for the D.C. Circuit, the federal court with primary jurisdiction for the Clean Air Act, the “margin of safety requirement was intended to address uncertainties associated with inconclusive scientific and technical information ... as well as to provide a reasonable degree of protection against hazards that research has not yet identified.”² Further,

the D.C. Circuit Court has asserted unequivocally that “NAAQS must protect not only average healthy individuals, but also ‘sensitive citizens’--children, for example, or people with asthma, emphysema, or other conditions rendering them particularly vulnerable to air pollution. If a pollutant adversely affects the health of these sensitive individuals, EPA must strengthen the entire national standard.”³ In sum, EPA must err on the side of protecting public health, including that of sensitive individuals, when exercising its discretion in setting national air quality standards.

Clear evidence of the need for a much stronger standard is in the record from the prior review.

Our scientific and medical understanding of the mechanisms by which exposure to ambient ozone pollution impacts human health grew considerably stronger between 1997 and 2007. After EPA revised the ozone NAAQS in 1997, more than 1,700 peer-reviewed studies examining the health effects of ozone were published.⁴

Extensive reviews of this body of evidence by EPA staff scientists⁵ and by EPA’s Clean Air Scientific Advisory Committee⁶ (CASAC) have confirmed that the 2008 primary ozone standard is set at a level that is not sufficient to protect public health with an adequate margin of safety. Made prior to the 2008 decision by the Administrator, the recommendations were for a much more protective standard than was subsequently adopted. After reviewing the 2,000 page summary of the scientific research on the health effects of ozone and an extensive additional analysis by the EPA staff, the 23-member CASAC panel unanimously concluded that an 8-hour ozone standard should be set in the range of 60-70 ppb.⁷

After EPA published its final decision in 2008, CASAC sent a rare letter to the Administrator stating that they disagreed with the decision to set the standard at 75 ppb. These scientists notified the Administrator that they “do not endorse the new primary ozone standard as being sufficiently protective of public health.” (emphasis in the original). They urged that the Administrator or his successor “select a more health-protective” standard in the next review cycle, in the range of 60-70 ppb.⁸

In February 2010, CASAC fully endorsed the proposed range, stating: “EPA has recognized the large body of data and risk analyses demonstrating that retention of the current standard would leave large numbers of individuals at risk for respiratory effects and/or other significant health impacts including asthma exacerbations, emergency room visits, hospital admissions and mortality.”⁹

We share the conclusion of the CASAC letter of April 7, 2008: EPA cannot justify retention of the current standard based on the health evidence. Clinical and epidemiological studies have shown that breathing ozone can cause adverse health effects at concentrations lower than the 75 ppb 8-hour average standard.

Below is a summary of some of the evidence for a stronger standard than 75 ppb.

Respiratory Health Effects

Clinical studies of healthy adults show decreased lung function and increased respiratory symptoms in some individuals after 6.6-hour exposures to 60 ppb.¹⁰ Because people in clinical studies are typically healthy adults, standards must be set to provide the additional protection needed by infants, children, and people with moderate or severe asthma.

A dozen epidemiological studies have found that adverse health effects ranging from respiratory symptoms, lung function changes, emergency department visits for respiratory disease, and hospital admissions are associated with 8-hour ozone concentrations below 70 ppb.¹¹ Numerous other community health studies report adverse respiratory effects in newborns, asthmatic children, outdoor workers and exercisers at concentrations below 60 ppb.¹²

Cardiovascular Health Effects

Evidence is beginning to emerge about the potential cardiovascular effects of ozone. Numerous recent studies point to adverse associations between ozone exposure and various cardiovascular health endpoints, including alterations in heart rate variability in older adults,¹³ cardiac arrhythmias,¹⁴ strokes,¹⁵ heart attacks,¹⁶ and hospital admissions or cardiovascular diseases.¹⁷

Mortality Effects

Breathing ozone can kill. Short-term increases in ozone were found to increase deaths from cardiovascular and respiratory causes in a large 14-year study in 95 U.S. cities. The relationship between mortality and ozone was evident even on days when pollution levels were below the EPA 8-hour standard of 75 ppb.¹⁸ A series of meta-analyses and multi-city studies has documented an increase in premature death following ozone exposures below 75 ppb, particularly among the elderly.¹⁹ Furthermore, new research has focused on controlling for weather variables in assessing the effect of ozone on mortality. A case crossover study of over one million deaths in 14 U.S. cities found that “the association between ozone and mortality risk is unlikely to be caused by confounding by temperature.”²⁰

Sensitive Groups

Factors such as age, preexisting disease and genetics can influence individual susceptibility to ozone pollution, whereas vulnerability is determined by one’s likelihood of exposure while at heightened breathing rates. After reviewing groups known to be susceptible with those considered to be vulnerable, EPA has identified a number of groups as sensitive or “at risk” to ozone exposure. EPA is obligated under the Clean Air Act to set the ozone NAAQS at a level appropriate to protect the health of these sensitive groups.

Children are acutely vulnerable to the hazardous effects of air pollution.²¹ Relative to adults, they tend to spend more time out of doors, they are often more physically active, they breathe more rapidly, their airways are narrower and they inhale relatively more pollutants in proportion to their body weight.²² Additionally, lung growth continues long after birth, with as much as 80 percent of the aveoli developing during childhood and adolescence.²³ Epidemiologic evidence indicates that children face additional health risks beyond the adverse effects observed in the general population. Children experience acute effects such as difficulty breathing,²⁴ increased hospitalizations²⁵ and emergency room visits²⁶ from ozone exposure at concentrations below the current standard and may suffer long-lasting effects such as stunted lung function in young adulthood.²⁷ Ozone exposure can impact prenatal health, with recent research finding that in-utero exposure to ozone is associated with lower birth weight and intrauterine growth retardation.²⁸

Several other groups have shown above-average susceptibility. Based upon a number of recent studies investigating age-related differences in the mortality effect of ozone,²⁹ the Criteria Document concludes

that the elderly are at increased risk of ozone-related mortality.³⁰ Individuals with preexisting lung disease comprise another susceptible population group, and studies show that low level ozone exposure exacerbates respiratory symptoms in child asthmatics³¹ and increases hospitalization among adults suffering from chronic obstructive pulmonary disease.³² Outdoor workers³³ as well as active adults who exercise outdoors³⁴ are particularly vulnerable to ozone exposure due to greater levels of exposure.

The Clean Air Act requires that the EPA set the standard based on the need to protect public health “with an adequate margin of safety.” In 2001, the Supreme Court unanimously ruled that protecting health was the only basis for the standard. The existing standard fails to protect public health with a margin of safety. EPA must strengthen it.

Given the weight of evidence, we urge you to set the eight-hour ozone standard at 60 ppb to protect against known and anticipated adverse health effects and to provide a margin of safety as required by the Clean Air Act. As the American Thoracic Society’s own Environmental Health Policy Committee urged in a February 15 editorial in the ATS journal supporting a 60 ppb standard: “Second chances are rare and should not be wasted.”³⁵

Thanks to your decision to review the 2008 ozone standard, the nation has a rare opportunity to provide widespread protection to the health of millions of people, especially those most at risk. The current ozone NAAQS of 75 ppb fails to provide the protection they are entitled to under the Clean Air Act. This conclusion is scientifically established and unequivocal. EPA must substantially strengthen the ozone standards. We urge you to adopt an 8-hour ozone standard of 60 ppb.

Thank you for your consideration of these critical issues.

Sincerely,

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¹ 42 U.S.C. § 7409 (b)(1).

² *Lead Industries Assn. v. EPA*, 647 F.2d 1130, 1154 (D.C. Cir. 1980)

³ *American Lung Association v. EPA*, 134 F.3d 388, 390 (D.C. Cir. 1998). *See also: Lead Industries Assn Inc. v. EPA*, 647 F.2d 1130, 1153 (D.C. Cir. 1980).

⁴ Testimony of Stephen L. Johnson, Administrator, U.S. Environmental Protection Agency before the U.S. Senate Environment and Public Works Committee, Subcommittee on Clean Air and Nuclear Safety, July 11, 2007.

⁵ U.S. EPA, OAQPS Staff Paper: Review of the National Ambient Air Quality Standards for Ozone: Policy Assessment of Scientific and Technical Information (January 2007).

⁶ Letter from Dr. Rogene Henderson, Chair, Clean Air Scientific Advisory Committee to Stephen L. Johnson, Administrator, U.S. Environmental Protection Agency, re Clean Air Scientific Advisory Committee's (CASAC) Peer Review of the Agency's 2nd Draft Ozone Staff Paper, EPA-CASAC-07-001, October 24, 2006; and Letter from Dr. Rogene Henderson, Chair, Clean Air Scientific Advisory Committee to Stephen L. Johnson, Administrator, U.S. Environmental Protection Agency, re Clean Air Scientific Advisory Committee's (CASAC) Review of the Agency's Final Ozone Staff Paper, EPA-CASAC-07-002, March 26, 2007.

⁷ Letters from Dr. Rogene Henderson, October 24, 2006 and March 26, 2007.

⁸ Letter from Dr. Rogene Henderson, Chair, Clean Air Scientific Advisory Committee to Stephen L. Johnson, Administrator, U.S. Environmental Protection Agency, re Clean Air Scientific Advisory Committee Recommendations Concerning the Final Rule for the National Ambient Air Quality Standards for Ozone, EPA –CASAC 08-009, April 7, 2008.

⁹ Letter from Dr. Jonathan M. Samet, Chair, Clean Air Scientific Advisory Committee to The Honorable Lisa P. Jackson. Review of EPA's proposed Ozone National Ambient Air Quality Standard (*Federal Register*, Vol. 75, No. 11, January 19, 2010), EPA-CASAC-10-007, February 19, 2010.

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