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Administrator Andrew R. Wheeler  
U.S. Environmental Protection Agency  
1200 Pennsylvania Avenue, NW  
Washington, DC 20460

September 30, 2020

**Re: Docket No. EPA-HQ-ORD-2018-0279**  
**Review of the Ozone National Ambient Air Quality Standards**

To the Administrator:

We, the North American Chapter of the International Society for Environmental Epidemiology (ISEE), disagree with the EPA's proposed decision to retain, without revision, the primary and secondary ozone National Ambient Air Quality Standards (NAAQS). In accordance with the Clean Air Act [1], the EPA is required to set standards that provide sufficient public health protection for all, including at-risk groups. Retaining the standard for ground level ozone at 70 parts per billion (ppb) would fail to meet EPA's mandated responsibility, since current scientific evidence unequivocally demonstrates that there are severe adverse respiratory and cardiovascular health effects that occur below that level. A lower standard limit would better protect not only humans, but also our nation's natural environment and agricultural industry.

The EPA itself has published reports since the early 2000s showing that lives would be saved if the ozone standard were lower than 70 ppb. The 2015 Regulatory Impact Analysis of the Final Revisions to the NAAQS for ground level ozone estimated that reducing the ozone standard to 65 ppb would save 400 to 650 lives per year, accounting only for short-term effects of ozone [2]. When accounting for long-term ozone exposure effects on mortality, a standard of 65 ppb could save another 1,500 lives per year (Table 6-20, page 6-79 in [2]). Moreover, a lower 65 ppb ozone standard would also result in reductions in fine particles (PM<sub>2.5</sub>) that would not otherwise happen, avoiding another 900 to 2,000 US deaths per year (Table 6-22, page 6-81 in [2]). Clearly, the EPA's own calculations have shown that lowering the ozone standard below 70 ppb can avoid the loss of a large number of American lives every year. These results are supported by many publications in peer-reviewed scientific journals. Turner et al. used the American Cancer Society's Cancer Prevention II (ACS CPS II) cohort with exposure estimates based on combinations of land

use regression and chemical transport models. They reported a statistically significant positive association between annual ozone and all-cause mortality with a 10 ppb increase in ozone producing a 2% increase in all-cause mortality and a 3% increase in cardiovascular mortality in models that were adjusted for other ambient pollutants such as PM<sub>2.5</sub> and nitrogen dioxide (NO<sub>2</sub>) [3]. This study performed extensive sensitivity analyses showing no evidence that the ozone effects are confounded by individual or area-based measures of socio-economic status or of pollution modeling strategy. The size of these effects have been replicated in other study settings; the Canadian Census Health and Environment Cohorts (CanCHEC) study [4], a population representative cohort of 2.5 million adults reported that per 10 ppb increase in ozone and adjusted for PM<sub>2.5</sub> and NO<sub>2</sub>, there was a 1.8% increase in all-cause mortality and 3.8% increase in cardiovascular mortality. Since the publication of these two studies, other studies of the association of long-term exposure to ozone and health have also been published [5-8]. Importantly, some recent studies have applied methods of causal modeling, which EPA claims have been lacking in epidemiology studies [6, 9, 10]. For example, the Wei et al. study used causal methods and directly evaluated the association of ozone and all-cause mortality [10], restricting to successively lower cut-points for ozone exposure and found no evidence of a threshold, with effects continuing well below 60 ppb for short-term exposure and 32 ppb for annual averages.

Indeed, in its 2020 Integrated Science Assessment (ISA) for Ozone and Related Photochemical Oxidants [11], the EPA itself provided evidence to support an ozone standard lower than 70 ppb. In experimental chamber exposure studies, lung function in healthy adults continued to improve as ozone concentrations decreased to 60 ppb (page IS-1 in [11]). Additionally, when looking at real-world evidence from epidemiologic studies, improved lung function was observed as ozone decreased down to as low as 33 ppb (page IS-25 in [11]). Overall, the 2020 ISA concluded that ozone causally and negatively affects the human respiratory system (page IS-7 in [11]), reaffirming what was already known in 2015, during the last ozone standard assessment, but with even more substantial scientific evidence. The report concluded that there is strong evidence that ozone exposure leads to increased hospital admissions, as well as emergency department visits related to respiratory conditions, which include asthma and chronic obstructive pulmonary disease.

Since 2015, there has been mounting evidence that ozone affects bodily systems in addition to respiration. For example, the aforementioned 2020 ISA itself concluded that short-term exposure to ozone likely causes negative effects on the metabolic system (page IS-7 and Appendix 5 in [11]). Additionally, ozone exposure is associated with impaired insulin tolerance and elevated fasting glucose levels, which are tell-tale symptoms of metabolic syndrome and diabetes [12]. For over 27 million Americans with diabetes, especially those who are most at-risk, ozone exposure makes their lives more difficult to manage, reducing their quality of life. Epidemiologic studies have found that there is an increased risk of diabetes or metabolic syndrome at ozone concentrations below 30 ppb, which is less than half of the current and proposed standard [13] (cited on page 5-31 in [11]).

In addition to the studies reviewed in the 2020 ISA, recent scientific literature has continued to find that a lower ozone standard would result in better public health protection for all Americans. Numerous systematic reviews surveyed the increasing number of studies showing harmful health effects of ambient ozone [14-17]. Recent original epidemiologic research in US populations has

found that long-term exposure to ozone leads to considerable detriments to human health, with both increased morbidity and mortality risks [5, 7, 18-21].

Indeed, the World Health Organization (WHO), in setting its air quality guidelines (AQG) for ozone [22], stated: “These latest time-series studies have shown health effects at ozone concentrations below the previous guideline of 120  $\mu\text{g}/\text{m}^3$  but without clear evidence of a threshold. This finding, together with evidence from both chamber and field studies that indicates that there is considerable individual variation in response to ozone, provides a good case for reducing the WHO AQG for ozone from the existing level of 120  $\mu\text{g}/\text{m}^3$  to 100  $\mu\text{g}/\text{m}^3$ ” (100  $\mu\text{g}/\text{m}^3$  is close to 50 ppb at Standard Temperature and Pressure).

Aside from the expanding body of evidence showing a variety of adverse impacts on human health, ozone also harms our ecosystems. There is a strong causal relationship between ozone exposure and damage to many plant species, as well as reduced vegetation growth and crop yield [23]. Ozone threatens the American agricultural industry as well as the livelihoods of farmers and the nutrition of those who depend on it. Not only would a lower ozone standard relieve the pressures on this already-sensitive American industry, its financial benefits to human health alone, not counting benefits to natural ecosystems, outweigh costs associated with implementing a lower standard (Table ES-5 on page ES-15 in [2]).

We are lagging behind countries around the world that have already acted responsibly to adjust their ozone standards to below 70 ppb. Canada, our neighbor and ally, limits the 3-year average of the annual 4<sup>th</sup> highest daily maximum 8-hour average ozone to be lower than 62 ppb [24].

We urge that the EPA recognize its’ responsibility for protecting the health of Americans, withdraw its decision to retain the ozone standard at 70 ppb, and implement a lower short-term ozone standard based on current epidemiological evidence. Such a lower limit would not only protect the health of millions of Americans, especially those most at-risk, but also benefit our nation’s environment and economy.

Sincerely,

Kelvin Fong, ScD

On behalf of the International Society for Environmental Epidemiology,  
North American Chapter

## References

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