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Commentary

Are the elements of the proposed ozone National Ambient Air Quality Standards informed by the best available science?

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ABSTRACT

The United States Environmental Protection Agency (US EPA) issues National Ambient Air Quality Standards (NAAQS) for six criteria pollutants, including ozone. Each standard has four elements: an indicator, level, averaging time, and form. Ozone levels (*i.e.*, air concentrations) alone in scientific studies are not directly comparable to the "level" element of the NAAQS because the standard considers the level in the context of its relation to the remaining elements. Failure to appreciate this has led to misunderstandings regarding NAAQS that would be health-protective. This can be seen with controlled human ozone exposure studies, which often involved small numbers of people exercising quasi-continuously for a long duration at an intensity not common in the general population (and unlikely achievable by most sensitive individuals), under worst-case exposure profiles. In addition, epidemiology studies have used different averaging times and have had methodological limitations that may have biased results. Such considerations can make it difficult to compare ozone levels and results across studies and to appropriately apply them in a NAAQS evaluation. Relating patterns and circumstances of exposure, and exposure measurements, to all elements of the NAAQS can be challenging, but if US EPA fully undertook this, it would be evident that available evidence does not indicate that proposed lower ozone standards would be more health protective than the current one.

1. Introduction

The Clean Air Act (CAA) was first passed in 1963 (US Congress, 1963). In 1970, amendments to the CAA required the listing of air pollutants that "may reasonably be anticipated to endanger public health and welfare" and that the United States Environmental Protection Agency (US EPA) issue National Ambient Air Quality Standards (NAAQS) for them (US Congress, 1970a). In 1971, US EPA first set NAAQS for photochemical oxidants (later regulated as ozone), carbon monoxide, lead, nitrogen oxides (NO_x) (regulated as nitrogen dioxide), particulate matter (PM, later regulated as total suspended particulates, then as PM_{10} and $PM_{2.5}$), and sulfur oxides (regulated as sulfur dioxide) – collectively called criteria pollutants.

Section 109 of the CAA (US Congress, 1970a) directs the US EPA Administrator to propose and promulgate "primary" and "secondary" NAAQS for criteria pollutants. Primary standards are intended to protect public health, including that of sensitive populations (*e.g.*, asthmatics, children, and the elderly). Specifically, the legislative history of section 109 indicates that a primary standard is to be set at "the maximum permissible ambient air level... [that] will protect the health of any [sensitive] group of the population," and that, for this purpose, "reference should be made to a representative sample of persons comprising the sensitive group rather than to a single person in such a group" (US Congress, 1970b). Secondary standards are intended to prevent welfare effects, which are described as including, but not being limited to, "effects on soils, water, crops, vegetation, manmade materials, animals, wildlife, weather, visibility and climate, damage to and deterioration of property, and hazards to transportation, as well as effects on economic values and on personal comfort and well-being (US Congress, 1990)." The present commentary is focused on the ozone primary standard, but most of its points are applicable to other criteria pollutants and to secondary standards, as well.

Ozone is a secondary air pollutant that is formed by photochemical reactions between precursor gases, primarily NO_x and volatile organic compounds from both natural and anthropogenic sources, in the presence of ultraviolet rays from the sun. Typically, ozone concentrations begin increasing as the sun rises, reach a peak near mid-day, and decrease markedly after sunset (US EPA, 2006). Ozone formation and breakdown are complex

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and depend on the relative concentrations of precursor gases and meteorological factors (*e.g.*, sunlight intensity and atmospheric mixing); thus, ambient ozone concentrations vary widely both spatially and temporally (US EPA, 2013a). Mean background ozone concentrations across the US range from 0.027 to 0.040 ppm (ppm) during the spring and summer, and sometimes reach higher than 0.060 ppm in the intermountain West (Zhang et al., 2011; Vingarzan, 2004; US EPA, 2013a). In some places, background concentrations contribute to over 80% of total ozone, which can make compliance with the current ozone NAAQS challenging (Zhang et al., 2011).

Each NAAQS has four elements: an indicator, an averaging time, a level, and a form (US EPA, 2013a). The indicator defines the pollutant that is measured in ambient air. The current indicator for photochemical oxidants is ozone. The averaging time is the period over which air quality measurements are averaged or cumulated, and is based on evidence of effects associated with various time periods of exposure (*e.g.*, 1 h, 8 h, 24 h, annual). The level defines the acceptable numerical air quality concentration of the indicator. Finally, the form of the standard provides the appropriate statistical basis to consider (*e.g.*, a percentile or mean) and whether it should be averaged over several years. All of these elements must be taken into account when determining whether an area is compliance with a standard.

Several elements of the ozone NAAQS have changed since it was first promulgated in 1971 (Table 1; McClellan et al., 2009; US EPA, 2015). From 1971 to 1979, the indicator was photochemical oxidants; since then, it has been ozone, the most prevalent oxidant. Until 1997, the primary ozone standard was a daily 1-h maximum concentration of 0.12 ppm that was not to be exceeded more than once a year. Attainment of the 1-h standard could vary from year to year in a given area, depending primarily on meteorological conditions (NRC, 1991). In 1997, US EPA determined that an 8-h averaging time for ozone would provide greater stability for meeting the standard and more accurately reflect the way humans respond to ozone (Anderson and Bell, 2010). With the change in the averaging time from a 1-h daily maximum to a daily 8-h average maximum, the level of the standard was reduced from 0.12 to 0.08 ppm (equivalent to 0.084 ppm using standard rounding conventions). In 2008, the ozone NAAQS was revised so that the annual fourth-highest daily maximum 8-h concentration, averaged over three years, should not exceed 0.075 ppm. In 2014, the US EPA Administrator recommended lowering the level of the standard to between 0.065 and 0.070 ppm, but accepted comments for a range between 0.060 and 0.075 ppm (US EPA, 2014b).

The CAA requires that US EPA review the health effects evidence for each criteria pollutant every five years to determine whether new evidence suggests the need to amend the NAAQS. The NAAQS review process includes a literature review and synthesis by US EPA staff and consultants, review and comment by the Agency's Clean Air Scientific Advisory Committee (CASAC), and public review and comment. First, US EPA evaluates the body of available scientific literature to draw conclusions regarding the weight of evidence for causal relationships between exposure to criteria pollutants and human health and welfare effects in an Integrative Science Assessment (ISA) (US EPA, 2013a). Building on the information in the ISA, US EPA prepares a Health Risk and Exposure Assessment (HREA) to place the scientific evidence reviewed in the ISA into the context of past, current, and projected exposure conditions and associated risks (*e.g.*, US EPA, 2014a). Based on the ISA and HREA, the Agency summarizes the key scientific information associated with various options for re-affirming or revising the NAAQS in a Policy Assessment (PA) (*e.g.*, US EPA, 2014c). At the final stage, the US EPA Administrator releases a proposal for re-affirmation or revision of the NAAQS for public comment (Proposed Rule), followed by the promulgation of a final

Table 1
History of the ozone National Ambient Air Quality Standard.

Year	Indicator	Averaging time	Level (ppm)	Form
1971	Total photochemical oxidants	1-h	0.08	Not to be exceeded more than once per year
1979	Ozone	1-h	0.12	Not to be exceeded more than once per year
1997	Ozone	8-h	0.08	Annual fourth-highest daily max, averaged over 3 years
2008	Ozone	8-h	0.075	Annual fourth-highest daily max, averaged over 3 years

Levels are identical for primary and secondary ozone standards.
ppm = parts per million.
Adapted from US EPA (2015).

NAAQS (Final Rule). Ultimately, while the US EPA Administrator's conclusions regarding the elements of the NAAQS are informed by the scientific evidence, they are a policy judgment regarding an acceptable level of risk (McClellan, 2012).

The types of scientific studies US EPA considers when evaluating the weight of evidence for causal associations and for estimating human health risks include controlled human exposure, epidemiology, and experimental studies. In the current ozone evaluation, US EPA gives the most weight to controlled human exposure and epidemiology studies. Mode-of-Action (MoA) evidence, or information regarding functional or anatomical changes at the cellular level, is also considered by US EPA to a limited extent, but it does not appear that US EPA relies on this to inform the level of the proposed standard. Although a weight-of-evidence evaluation of each realm of evidence is currently the best way to assess the state of the science, in reality, none of these research approaches is ideal for addressing the health effects of or setting standards for criteria pollutants. It is also notable that US EPA does not fully consider the form or averaging time of the standard when evaluating this evidence. This is also true for some proponents of lower standards, such as the American Thoracic Society (*e.g.*, Rice et al., 2015).

US EPA (2014b) concludes that there is a causal association between short-term ozone exposure and respiratory effects, and likely causal associations between long-term ozone exposure and respiratory effects (including mortality), as well as short-term ozone exposure and total non-accidental mortality and cardiovascular effects (including mortality). We have discussed the evidence regarding cardiovascular effects and all-cause mortality in detail elsewhere (Goodman et al., 2014; Prueitt et al., 2014; Goodman and Sax, 2012). Below, we discuss some of the issues associated with the use of controlled human exposure and epidemiology studies to inform the various elements of the NAAQS, using ozone and respiratory effects as an example.

2. Controlled human exposure studies

In the controlled human exposure studies, subjects were exposed to ozone through a facemask inhalation system or *via* whole-body exposure in an environmental chamber for several hours, often while performing quasi-continuous exercise. Almost all studies included a control scenario in which subjects were exposed to filtered air with no ozone.

Several controlled ozone exposure studies evaluated short exposure durations (2–2.5 h), with exposures ranging from 0.1 to 0.5 ppm (McDonnell et al., 1983; Seal et al., 1993; Adams, 2003; Folinsbee et al., 1978); others evaluated longer exposure durations (6.6–7.6 h), with exposures ranging from 0.04 to 0.12 ppm (McDonnell et al., 1991; Adams, 2002, 2006; Schelegle et al.,