

Comments on the Policy Assessment for the Review of Ozone National Ambient Air Quality Standards (External Review Draft)
Docket # EPA-HQ-OAR-2018-0279

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November 25, 2019

The "Policy Assessment for the Review of the Ozone National Ambient Air Quality Standards, External Review Draft" (hereafter, the draft Ozone PA) addresses whether newly available scientific evidence and risk-based information support or call into question the adequacy of the public health protection afforded by the current annual primary ozone National Ambient Air Quality Standard (NAAQS).

The draft Ozone PA concludes that new scientific evidence and results from the exposure and risk analyses do not call into question the adequacy of the standard. While this conclusion is appropriate, a review of the evidence and risk-based information indicates that the current standard may be more conservative than necessary to protect public health.

The 2013 Ozone Integrated Science Assessment (ISA) and 2019 draft Ozone ISA concluded that there are casual and likely to be causal relationships between short- and long-term ozone exposure, respectively, and respiratory effects. The 2019 draft Ozone ISA concluded that there is a likely causal relationship between short- and long-term ozone exposure and metabolic effects. However, study quality information is not fully or consistently considered in the ISA's study evaluations. Also, while the draft Ozone ISA emphasizes biological plausibility for each health outcome with regard to ozone exposure, the evidence presented does not demonstrate a complete pathway connecting ambient ozone exposure to downstream health endpoints.

In addition, the 2013 Ozone ISA did not properly consider key limitations in the epidemiology evidence, and newer studies have the same critical issues that impact the validity of the results. Furthermore, key toxicity studies on which EPA relied to support the epidemiology data were conducted at very high exposure levels that are not relevant for assessing the health effects of ambient ozone concentrations.

As discussed in Gradient's comments on the draft Ozone ISA, the NAAQS systematic review and casual determination framework should be updated to allow for conclusions that are reflective of the weight of scientific evidence, and this framework should be followed and described in a transparent manner in the ISA. Suggestions for an updated framework are described in Gradient's comments on the draft Ozone ISA (Gradient, 2019).

Setting this aside, based on the draft Ozone ISA's causal determinations, the draft Ozone PA focuses its risk assessment on respiratory effects following short-term exposure to ozone, as it concludes that the strongest scientific evidence regarding ozone and adverse health effects comes from studies of respiratory endpoints, and, in particular, lung function.

The risk assessment evaluates benchmark ozone exposures of 60, 70, and 80 ppb. Exposure analyses were focused on populations breathing at an elevated rate. Risk was characterized for both children aged 5-18 years and adults with and without asthma; ultimately, children with asthma were chosen as the focus of the assessment. The results presented are the numbers and percentages of individuals in simulated populations estimated to experience one or more days with 7-hour average exposure at or above benchmark concentrations or a lung function decrement at or above 10%, 15%, or 20%, all while breathing at an elevated rate. In addition, results for adjusted air quality condition scenarios in which monitors had a design value equal to 65 or 75 ppb are also presented.

As discussed extensively in our written comments on the draft Ozone ISA and PA, the controlled human exposure studies indicate that there are no statistically significant adverse respiratory effects associated with ozone exposures below 70 ppb, and that effects reported at 60 ppb are not adverse. As such, the inclusion of 60 ppb as a benchmark concentration in the exposure and risk assessment is extremely conservative. Other conservative assumptions in the risk assessment were the evaluation of children with asthma who were breathing at elevated rates.

Considering that the draft Ozone PA evaluated risks of exposures to 60 ppb ozone, and did so in the most sensitive populations, its conclusion that the current primary ozone NAAQS is adequate to protect public health is warranted. In fact, the overly conservative nature of this assessment indicates that the current standard may be more stringent than necessary to protect public health.