



January 19, 2025

U.S. Environmental Protection Agency
William J. Clinton Building
1200 Pennsylvania Avenue, NW
Washington, DC 20460

Re: Comment on EPA's Integrated Review Plan for the National Ambient Air Quality Standards for Ozone and Related Photochemical Oxidants (EPA-HQ-OAR-2023-0460)¹

The American Lung Association offers the following comments to EPA on Volume 2 of its Integrated Review Plan (IRP) for the National Ambient Air Quality Standards (NAAQS) for Ozone and Related Photochemical Oxidants.

The Clean Air Act requires that the NAAQS be set solely on the basis of what is requisite to protect human health with an adequate margin of safety. At every stage of the NAAQS review process for ozone, EPA staff, leadership and scientific advisors must be guided solely by the health science.

EPA must also thoroughly address the comments and recommendations made by the 2022 ozone CASAC panel during the reconsideration process and the recommendations made by CASAC on the NAAQS process overall.

With regard to the Integrated Science Assessment (ISA), a thorough review of the relevant science is crucial – and EPA must follow the 2022 panel's recommendation that the Population, Exposure, Comparison, Outcome, and Study Design (PECOS) criteria be expanded to include studies beyond the North America, and that the agency must apply a consistent and transparent rationale for study inclusion and exclusion. EPA should also expand its timeframe, including studies earlier than the previous ISA.

EPA should further follow the recommendation of the 2022 panel that the agency should consider revising its approach to interpreting and weighting controlled human exposure (CHE) and epidemiological studies. This is critical for properly accounting for the fact that CHE studies typically recruit young, healthy fit adults. Heavily weighting CHE studies makes it more likely that individuals who have lung disease, heart disease or are pregnant; children; and older adults are not reflected in the research despite their increased likelihood of harm from ozone, a situation at odds with the Clean Air Act's requirements that the NAAQS provide an adequate margin of safety.

EPA should further follow the recommendation to look further into whether the form of the standard is adequate; this current review should evaluate all elements of the ozone NAAQS. As we have noted in comments on other NAAQS processes, exceedances allowed in Design Value calculations – through the current forms of the NAAQS, in monitor data completeness requirements, in data truncations or rounding conventions in addition to demonstrated

¹ Federal register notice on the availability of Volumes 1 and 2 of the *Integrated Review Plan for the National Ambient Air Quality Standards for Ozone and Related Photochemical Oxidants*

exceptional event exceedances – may not constitute NAAQS violations in regulatory assessments, but nonetheless affect public health. Therefore, a comprehensive assessment of all components of the ozone NAAQS is needed to ensure effective public health protection.

The Lung Association has also consistently called for a consideration of cumulative impacts to ensure the standard reflects real-world conditions and offers real-world protection. The agency should evaluate multipollutant exposures, not only in the context of evaluating confounders in epidemiologic studies, but in their cumulative effects (interactions and their additive/multiplicative effects) on human health. It is also important to account for the enhanced conditions for ozone formation that climate change is currently driving and how those effects will increase over time.

As the agency drafts Volume 3 of the IRP to map out the process for the Policy Assessment (PA), it is critically important that that process return to what the law and the longstanding practice require: consideration of alternative standards. EPA must follow the advice that CASAC offered on the NAAQS process that the agency provide the committee and the Administrator with a set of alternative standards to consider. This approach is essential to meeting the Clean Air Act's clear requirement of a standard that is requisite to protect health with an adequate margin of safety. The Policy Assessment must not provide deference to the current level of the standard. It must instead look across the range of options, current standard notwithstanding, based on the health science. The agency must then present alternative policy options for consideration, even if retaining the standard is one such option. It is critical that the agency does not fixate on whether to retain or revise the current standard, but rather focuses on what the standard should be based on current scientific evidence.

We appreciate the opportunity to provide comments and look forward to weighing in throughout the process of this ozone NAAQS review.

Signed,

The American Lung Association