Comments to Clean Air Scientific Advisory Committee/EPA on EPA's Integrated Science Assessment in the Review of the National Ambient Air Quality Standards for Ozone

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Good Morning

Thank you for this opportunity to comment.

I am Dr. Shyamala Rajan, National Director of Policy for Healthy Air for the American Lung Association. The Lung Association has a long-standing commitment to the principles embedded in the Clean Air Act, including the setting and enforcement of National Ambient Air Quality Standards for criteria pollutants to protect the health of ALL communities and vulnerable groups.

We want to reiterate our call to CASAC to expeditiously complete its ozone review, and to schedule all related future meetings now to avoid additional logistical delays. Further, we urge CASAC to set a clear timeline for EPA to provide it with the updated Policy Assessment and use its role to ensure that EPA moves forward with urgency. The public health consequences of any delay are unacceptable.

In our detailed written and oral comments[1] that we provided earlier in this review process, we strongly disagreed with EPA's flawed assessment of scientific data and its subsequent erroneous conclusion that current O_3 NAAQS of 70 ppb do not need revision. We cited scientific evidence that warrants the revision of the current standard to no higher than 60 ppb to protect public health. The CAA statutory requirement to apply an adequate margin of safety to ensure effective protection of all vulnerable groups further cements the need for NAAQS revision.

Here we draw attention to a recent report by the National Academies (NA) from its EPA-sponsored study to assess the Agency's causality framework that underlies the NAAQS reviews[2] and the draft CASAC letter to EPA.[3] Both documents raise concerns with EPA's science assessments and flag the significant limitations and the arbitrary application of the frameworks that the Agency used in its Integrated Science Assessment (ISA) to base its conclusion to retain the standard.

1. Causal determinations drive standard setting, but the National Academies report found that "(t)he ISA causal determination framework is not a procedure that can be tested objectively or evaluated against the ground truth."[2]

[1] American Lung Association (May 31, 2022). Comment submitted to the Environmental Protection Agency on its Review of the National Ambient Air Quality Standards for Ozone, Comment ID: EPA-HQ-OAR-2018-0279-0600

[2] National Academies of Sciences, Engineering, and Medicine. (Oct, 2022). *Advancing the Framework for Assessing Causality of Health and Welfare Effects to Inform National Ambient Air Quality Standard Reviews*. Washington, DC, The National Academies Press

[3] Clean Air Scientific Advisory Committee (CASAC). (Oct, 2022). *CASAC Review of the EPA's Integrated Science Assessment (ISA) for Ozone and Related Photochemical Oxidants*. Draft Report to Assist Meeting Deliberations.

2. EPA does not consider heterogeneity in exposure responses between healthy and vulnerable populations in determining causality. In the current framework, EPA explicitly considers only the overall average population effects for causality determination and considers heterogeneity in responses ***only after*** it has made a causal determination.[2] "The current framework separates description of vulnerable groups…from causal determinations, potentially obscuring understanding of causal relationships for the more sensitive groups of subjects".[2]
3. EPA considers co-pollutants to be potentially confounding factors when assessing the potential effects of a criteria pollutant, "but it is not explicit about other types of confounding, such as confounding by weather effects, other environmental factors, or socio-economic or demographic differences within populations."[2] Heterogeneity in responses of individuals & populations exposed to pollutants could be due to life stage (e.g. age, pregnancy, etc.), comorbidities, or other environmental, socio-economic, behavioral, epigenetic or genetic factors.[2] The CASAC draft letter to EPA further states, "the 2020 Ozone ISA gives almost exclusive attention to at-risk communities identified by physiological susceptibility. A thorough analysis of differences in exposure due to spatial variation that is often driven by sociodemographic factors, especially race/ethnicity, class and income is missing."[3]
4. The Population, Exposure, Comparison, Outcome, and Study (PECOS) framework is not transparent and is inconsistently applied to include/exclude studies. The CASAC asks EPA to "not restrict geographic regions of health studies without an appropriate and strong rationale".[3] The NA report specifically cites the 2020 Ozone ISA in which EPA uses PECOS for the first time and uses it selectively to down weight its earlier causal determination of short-term ozone exposure on total (nonaccidental) mortality to "suggestive of, but insufficient to infer, a causal relationship."[2] In summarizing EPA's reasoning in this conclusion, the report states how EPA is "still not explicit about the basis on which some studies are included, and others excluded, under these (PECOS) criteria", and one study "which was included in the 2019 PM ISA (and so presumably passed study quality and relevance screening there)" was excluded from the 2020 ozone ISA.[2] The CASAC points out that the "PECOS determination in the 2020 ISA limits the cardiovascular-relevant studies to North America, Europe, and Australia, which differs from the restriction to the U.S. and Canada for respiratory endpoints without a sufficient rationale for the difference. In addition, the PECOS structure excluded considerable research conducted in Asia that would be useful in addressing existing uncertainties without a sufficient rationale," according to the draft CASAC letter to EPA.[3]
5. Also in the draft CASAC letter, the committee finds that EPA gives undue weight to controlled human exposure (CHE)/lab studies which are "imperfect indicators of actual human exposure to total photochemical oxidants".[3] Additionally, EPA uses inconsistencies between epidemiological and CHE studies "to weaken confidence in health risk attribution or causal determination status."[3] CASAC points out that, in the ISA, "there is no acknowledgement or discussion of the discrepancy between the lowest exposure concentrations at which health effects associations are seen in the epidemiology studies and the lowest effect concentrations in the CHE studies. The latter are substantially higher than the former."[3] Exposure to pure ozone as well as to prior ambient pollutants are among

several issues of CHE which, CASAC states, could explain the differences in response to ozone levels in CHE (no effect at <60-70 ppb) vs epidemiological studies (health impacts at <60 ppb).[3] "Further, when evaluating ozone health effects at low concentrations and in at-risk groups, epidemiological findings should be considered to be just as, or even more, relevant than the CHE findings in determining a "no-effect" exposure level."[3]

We urge EPA to address these serious issues, raised by subject matter experts, in its causality determinations as it revises its Policy Assessment. The Agency should change its determinations for long-term exposure effects on respiratory health to causal (as recommended by the majority of the CASAC members), and revert the cardiovascular and all-cause mortality exposure determinations back to "likely causal". These revisions alone warrant strengthening current standard. Lastly, we want to remind EPA of its statutory requirement to strictly apply an adequate margin of safety to protect public health, especially of all vulnerable populations.

6. Public health protection from air pollution as afforded by the CAA must address the impacts on the most susceptible and at-risk of all populations and demographics including already identified and other potentially vulnerable groups. The NA report refers to the precautionary nature of the CAA and the court decisions that "have repeatedly affirmed that the NAAQS must protect at-risk people who are "particularly sensitive to the effects of pollution" and determined that "Congress directed the Administrator to err on the side of caution" with "subsequent cases echo(ing) this language."[2] "Since the beginning, court decisions have emphasized the precautionary nature of the CAA" stating:

   "Where a statute is precautionary in nature, the evidence difficult to come by, uncertain, or conflicting because it is on the frontiers of scientific knowledge, the regulations designed to protect public health, and the decision that of an expert administrator, we will not demand rigorous step-by-step proof of cause and effect. Such proof may be impossible to obtain if the precautionary purpose of the statute is to be served."[2]

In summary, we urge EPA to thoroughly address all the issues raised by scientific experts and promptly revise its Policy Assessment and set ozone NAAQS at no higher than 60 ppb to adequately protect public health, in compliance with the requirements in the Clean Air Act.

Thank you.