

May 19, 2014

VIA ELECTRONIC MAIL (stallworth.holly@epa.gov)

Dr. H. Christopher Frey
Chair, Clean Air Scientific Advisory Committee
Science Advisory Board
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue NW
Washington, DC 20460

Re: Draft Letter on CASAC's Review of the EPA's *Second Draft Policy Assessment for the Review of the Ozone National Ambient Air Quality Standards*

Dear Dr. Frey:

We write regarding the draft letter on CASAC's Review of EPA's *Second Draft Policy Assessment for the Review of the Ozone National Ambient Air Quality Standards* ("NAAQS"), which was posted on May 8, 2014 ("Draft CASAC Letter"). While we agree with some points in the letter, there are several issues on which CASAC should expand and elaborate. Those points are addressed below.

The Draft CASAC Letter states that, "[t]he Second Draft PA is not clear as to how background estimates might impact the primary and secondary standards and whether these impacts may differ regionally." EPA's analysis indicates that the impact could be quite large and, therefore, background ozone levels need to be more fully considered. The lower end of the standard that CASAC is supporting – down to 60 ppb – is very close to levels of ozone that are found naturally in some regions of the country. Also, EPA's models have shown that decreasing anthropogenic sources of ozone could actually lead to *increased* ozone in some areas (because nitrogen oxides both form and destroy ozone). By controlling human sources of ozone to achieve lower standards, many parts of the country may not be able to meet current ozone standards, partially because of naturally formed ozone. In addition, in recent years, scientists have measured increasing amounts of air pollution coming to the United States from overseas. The impacts of international emissions on ozone levels in the United States, however, have not been fully considered during the current review of the ozone NAAQS. Given these issues, EPA should calculate risks that would occur with ozone exposures above background (including impacts of international emissions), and should not set standards for which some areas will be out of attainment as a result of background ozone.

The Draft CASAC Letter also states that there is scientifically sound evidence for several health effects categories, and that this evidence calls into question the adequacy of the current standard. As discussed in the comments submitted by the undersigned to CASAC on March 13, 2014, the available evidence does not support EPA's conclusions regarding long-term ozone-related respiratory effects (including mortality), short-term ozone-related all-cause mortality, or short- and long-term ozone-related cardiovascular morbidity and mortality. For all of these endpoints, there is a lack of definitive evidence supporting an effect of ozone (as opposed to other factors). Also, there is a lack of consistency and coherence within and across studies that also calls into question a causal link. Importantly, evidence of causality for these endpoints is no stronger today than it was in 2006 during the last review of the ozone NAAQS, with epidemiology studies

mostly indicating a lack of association, and other evidence (*e.g.*, animal and mechanistic studies) providing little, if any, additional support.

It is notable that the Draft CASAC Letter states the following:

For the health-based standard, we note that the Second Draft PA outlines key uncertainties and research that needs to be addressed for future reviews of the health based standards. Specifically, we underscore the need for research to address the characterization of the exposure-response function, the identification of population thresholds, the role of co-pollutants and temperature in modifying or contributing to ozone....

These are major data gaps that undermine EPA's and CASAC's conclusion that the evidence indicates the current standard is not health protective. The data gaps also undermine CASAC's conclusion that the likelihood of ozone effects increase at lower exposures. The idea that this uncertainty essentially disappears above 60 ppb simply is not supported by the scientific evidence.

CASAC's discussion of mode of action ("MoA") in the Draft CASAC Letter seems to relate primarily to issues with how the MoA is communicated. CASAC should more carefully evaluate whether EPA's analysis of ozone's MoA was sufficient, particularly whether the discussed MoAs could occur at exposures below the current NAAQS. This MoA analysis is critically important because it could impact the presumed causal associations in the draft Policy Assessment.

Also, CASAC supports the view that ozone effects occur down to 60 ppb based on controlled human exposure studies, and concludes that any non-statistically significant findings in these studies are a result of low statistical power. However, it is unclear from the few studies that have considered exposures down to 60 ppb whether a lack of statistical significance is a result of low power or because there is no true association. In addition, even if results were statistically significant, CASAC did not discuss issues related to the relatively large uncertainty and variability associated with lung function tests or whether the study results indicated adverse effects. Lung function deficits greater than 10% can occur after some people exercise or spend time in hot or cold climates; such deficits should not be considered adverse effects on which to base a regulatory standard. Since these effects of ozone are not adverse, that should be taken into account in the current review of the ozone NAAQS.

Finally, the Policy Assessment is based on the Integrated Science Assessment, the Health Risk and Exposure Assessment (HREA), and the Welfare Risk and Exposure Assessment ("WREA"). CASAC has brought up several issues with the second draft HREA and, perhaps more importantly, EPA has indicated that it will conduct additional analyses before finalizing the HREA. Similarly, although it did not request additional analyses in the WREA, CASAC did request revisions to the interpretation placed upon the existing analyses with regard to the degree of welfare protection provided by the current standard or by a W126 standard. The public and CASAC should have an opportunity to review the additional health risk analysis and any revision to EPA's interpretation of the analyses of welfare protection. Therefore additional drafts of the HREA and the WREA – and the Policy Assessment that is based on these documents – are necessary before any of the documents can be finalized.

In closing, we maintain that there is no new significant evidence since the last review indicating that the ozone standard should be lowered below 75 ppb. Moreover, CASAC should include 75

ppb in any range that it considers.¹ We urge CASAC to consider addressing the issues discussed herein as it finalizes its letter to EPA on the *Second Draft Policy Assessment for the Review of the Ozone National Ambient Air Quality Standards*.

If you have any questions about these comments, please contact Mary Martin, Energy, Clean Air & Natural Resources Policy Counsel at the U.S. Chamber of Commerce at 202.463.5986 or by email at mmartin@uschamber.com, or Timothy Hunt, Senior Director for Air Quality Programs at the American Forest & Paper Association and American Wood Council at 202-463-2588 or by email at tim_hunt@afandpa.org or thunt@awc.org. Thank you for your consideration.

Submitted on Behalf of,

American Chemistry Council
American Forest & Paper Association
American Petroleum Institute
American Wood Council
American Iron and Steel Institute
Corn Refiners Association
Council of Industrial Boiler Owners
National Oilseed Processers Association
Portland Cement Association
Treated Wood Council
U.S. Chamber of Commerce
Utility Air Regulatory Group

¹ Also, one CASAC member commented that one cannot really distinguish risks in 1 ppb increments. However, such a small increment could have a large impact on whether a certain area could attain an ozone standard, thereby translating into significant economic impacts. CASAC should consider recommending exposure levels at which studies were conducted, even if these levels do not coincide with the 5 ppb increments that EPA considered.