

United States Senate

COMMITTEE ON ENVIRONMENT AND PUBLIC WORKS

WASHINGTON, DC 20510-6175

BETTINA POIRIER, MAJORITY STAFF DIRECTOR
ZAK BAIG, REPUBLICAN STAFF DIRECTOR

May 19, 2014

The Honorable Gina McCarthy
Administrator
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue NW
Washington, DC 20460

Dear Administrator McCarthy:

In response to compelling testimony before EPA's Clean Air Act Scientific Advisory Committee (CASAC) Ozone Panel, EPA issued a memorandum¹ last week announcing its intent to conduct a "sensitivity analysis" to estimate the respiratory mortality risks from long-term exposure to ozone using a threshold model. In this same memorandum, EPA also stated that it would not have the results of this sensitivity analysis before the Ozone Panel's scheduled May 28 final conference call to review and finalize CASAC's assessments of EPA's *Health Risk and Exposure Assessment for Ozone (HREA)* and EPA's *Policy Assessment for the Review of the Ozone National Ambient Air Quality Standards (PA)*.

EPA's decision to finally evaluate the respiratory mortality risks from long-term exposure to ozone using a threshold model is an important first step; however, the predetermination that this critical analysis will not be completed before CASAC's final scheduled conference call is inappropriate. Further, I am concerned that it also appears to be EPA's intention not to complete its correction of the population mortality risk data, which at present significantly overstates the population mortality risks in the HREA and PA, before the call. Given that CASAC will be relying on information in these two documents to form its recommendations to the Administrator on the need to revise the existing ozone standard, these omissions are unacceptable. EPA must provide CASAC complete and correct data and analyses upon which the Panel may base informed recommendations on a standard that could impose significant costs and consequences on taxpayers. It is integral for you to provide this information prior to the Panel's scheduled May 28 call.

EPA's decision to employ a threshold model in assessing long-term respiratory mortality risks is long overdue. The study EPA relies on for estimating long-term respiratory mortality, Jerrett *et. al.* 2009, "Long-Term Ozone Exposure and Mortality,"² finds that a model with a

¹ Memorandum from Health and Environmental Impacts Divisions, Office of Air Quality Planning and Standards, United States Environmental Protection Agency to Clean Air Scientific Advisory Committee, (April 28, 2014), "Response to Comments Regarding the Potential use of a Threshold Model in Estimating the Mortality Risks From Long-term Exposure to Ozone in the *Health Risk and Exposure Assessment for Ozone, Second External Review Draft*" (February 3, 2014).

² Jerrett, Michael, R. T. Burnett, C. A. Pope, III, K. Ito, G. Thurston, D. Krewski, Y. Shi, E. Calle, M. Thun 2009. "Long-Term Ozone Exposure and Mortality." *New England Journal of Medicine* 360:1085-1095.

threshold of 56 ppb provides a better fit for the data than a no-threshold model. In fact, although the test for whether the 56 ppb threshold exists is not statistically significant at the “standard” 95th percent confidence level, it is only one point shy, i.e. it has a 94 percent confidence level. The draft HREA, however, ignored these important facts, and instead noted, to the contrary, that the epidemiological evidence for a threshold is “limited.”³ During the March 27, 2014, meeting on the draft HREA, two CASAC members discussed whether the threshold model should, in fact, be the “core” or primary model to assess risk rather than simply one of many sensitivity analyses.⁴

Analyzing the impact of a threshold effect should not take a month to complete, and EPA’s assertion that it cannot present the results to CASAC before it makes any final decisions on the adequacy of the draft documents is absurd. Above all, it should be presented to CASAC prior to the panel making any recommendations to you regarding the adequacy of the current ozone standard.

I also ask that EPA complete its correction of the data before the CASAC meeting, including the many sensitivity analyses in the Appendices that assess the change in respiratory mortality risk from lowering the current standard. As a result of comments submitted to the Agency on the draft HREA, EPA confirmed the existence of important errors in both the population estimates and the mortality incidence levels that are key to its assessment of population mortality risk.⁵ Specifically, in the broader core based statistical areas (CBSA), population estimates were overstated by a factor of 2.25, resulting in as much as a 60 percent lower estimate of risk when corrected. Population estimates in epidemiology-study areas were also off by a factor of 1.4 to 5.8, resulting in significant errors in multiple EPA tables in the draft HREA Appendices. When corrected, these sensitivity analyses could show approximately a 30 to 82 percent lower estimate of risk than what is currently included in the draft HREA. So far, EPA has corrected the tables that appear in Chapter 7 but not the many additional tables that appear in the Appendices to Chapter 7. These are the only tables that include the base case risk for the CBSA areas and any risk estimates for the epidemiology study areas.

It is critical for EPA to complete its task of fully correcting the data, including the data in the HREA Appendices that provide a detailed assessment of the potential impact of changing the standard on population risks. Without this corrected, detailed information, it will be impossible to assess whether tightening the existing standard provides net benefits to exposed populations. CASAC should not be asked to make any decisions without fully seeing and weighing the results of the corrected data and the threshold model runs.

³ United States Environmental Protection Agency, “*Health Risk and Exposure Assessment for Ozone, Second External Review Draft*” (February 3, 2014).

⁴ CQ Newsmaker Transcripts, “*EPA Holds Meeting of Clean Air Scientific Advisory Committee Ozone Review Panel, Day 3*” (March 27, 2014).

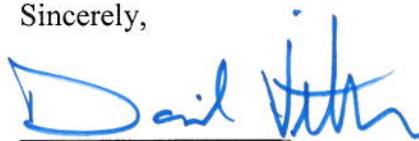
⁵ CQ Newsmaker Transcripts, “*EPA Holds Meeting of Clean Air Scientific Advisory Committee Ozone Review Panel, Day 2*” (March 26, 2014); See also Memorandum from Health and Environmental Impacts Divisions, Office of Air Quality Planning and Standards, United States Environmental Protection Agency to Clean Air Scientific Advisory Committee, (April 28, 2014), “*Corrections to Estimates of Epidemiology-based Mortality and Morbidity Risks Presented in the Health Risk and Exposure Assessment for Ozone, Second External Review Draft*” (February 3, 2014).

Prior to the CASAC Ozone Panel's May 28 scheduled final conference call EPA must:

1. Evaluate the respiratory mortality risks from long-term exposure to ozone using a 56ppbthreshold model, as announced in the April 28 memorandum.
2. Complete the correction of the population mortality risk data, including for risk estimates in the appendices.

If EPA is unable to complete the above tasks prior to the scheduled May 28 final conference call, EPA must request CASAC delay the call until the results of the threshold model and the fully corrected mortality risk data are available.

Sincerely,



David Vitter
Ranking Member

cc: Dr. H. Christopher Frey, Chair, EPA Clean Air Scientific Advisory Committee
Members of CASAC Ozone Review Panel
Dr. Holly Stallworth, CASAC Designated Federal Officer