

Draft April 14, 2009



MEMORANDUM

SUBJECT: CASAC Consultation on *Carbon Monoxide National Ambient Air Quality Standards: Scope and Methods Plan for Health Risk and Exposure Assessment*

FROM: Lydia N. Wegman, Director
Health and Environmental Impacts Division (C504-02)
Office of Air Quality Planning and Standards
United States Environmental Protection Agency

TO: Ellen Rubin
Designated Federal Officer
Clean Air Scientific Advisory Committee
EPA Science Advisory Board Staff Office

Attached is a planning document titled *Carbon Monoxide National Ambient Air Quality Standards: Scope and Methods Plan for Health Risk and Exposure Assessment* (Health Assessment Plan), prepared by the Environmental Protection Agency's (EPA) Office of Air Quality Planning and Standards (OAQPS) staff as part of EPA's ongoing review of the primary (health-based) national ambient air quality standards (NAAQS) for carbon monoxide (CO). This plan will be the focus of a consultation by the Clean Air Scientific Advisory Committee (CASAC) CO NAAQS Review Panel (the CASAC CO Panel), scheduled for a public meeting to be held in Chapel Hill, NC, on May 12-13, 2009. I am requesting that you forward this plan to the CASAC CO Panel to prepare for that consultation.

The purpose of the Health Assessment Plan is to outline the scope and approaches that staff is planning to use to conduct a population exposure/dose assessment for CO and to characterize CO-related risks to public health. Since this document is being prepared early in the review process, prior to CASAC and public review of the first draft ISA, it is appropriately general in nature. Nonetheless, it is intended to provide enough specificity to facilitate consultation with CASAC, as well as for public review, in order to obtain advice on the overall scope, approaches, and key issues in advance of the conduct of the exposure/dose and risk characterization analyses and presentation of results in the first draft Risk and Exposure Assessment (REA). The Health Assessment Plan draws upon information presented in *Integrated Science Assessment for Carbon Monoxide: First External Review Draft* (first draft CO ISA, March 2009) prepared by EPA's National Center for Environmental Assessment, Research Triangle Park, NC (NCEA-RTP). CASAC consultation on this plan coincides with their review of the first draft CO ISA. CASAC and public comments on the plan will be taken into

consideration in the development of the first draft REA, the preparation of which will coincide and draw from the second draft ISA. The second draft REA will draw on the final ISA and will reflect consideration of CASAC and public comments on the first draft REA. The final REA will reflect consideration of CASAC and public comments on the second draft REA.

EPA's overall plan and schedule for this CO NAAQS review is presented in the *Plan for Review of the National Ambient Air Quality Standards for Carbon Monoxide*, which was the subject of a consultation by the CASAC CO Panel on April 8, 2008 (see http://www.epa.gov/ttn/naaqs/standards/co/s_co_cr_pd.html/). The Review Plan outlines the Clean Air Act (CAA) requirements related to the establishment and reviews of the NAAQS, the process and schedule for conducting the current CO NAAQS review, and plans for the development of key documents in the NAAQS review process. It also lays out the key policy-relevant issues to be addressed in this review as a series of policy-relevant questions that will frame our approach to determining whether the current NAAQS for CO should be retained or revised. An updated schedule for completing the REA is outlined in the attached Health Assessment Plan. Currently, our court-ordered schedule calls for completion of the CO ISA by January 2010, completion of the REA by May 2010, and proposed and final rules to be issued in October 2010 and May 2011.

Document for Consultation

The following document is being made available to the CASAC CO Panel in the form of an attached electronic file. The document is also available from the EPA website at http://www.epa.gov/ttn/naaqs/standards/co/s_co_cr_pd.html. Printed copies of this document will be sent to Panel members via Federal Express.

- ◆ Attachment: *Carbon monoxide National Ambient Air Quality Standards: Scope and Methods Plan for Health Risk and Exposure Assessment* (Health Assessment Plan, April 2009)

This document is the focus of the scheduled consultation with the CASAC CO Panel, to be guided by the charge questions listed below. Following an introductory chapter, this document discusses CO health effects and the approach to risk characterization in chapter 2, and the scope and approach for a population exposure/dose analysis in chapter 3. A final chapter 4 summarizes the schedule and interim milestones related to these assessments.

Charge to the CASAC CO Review Panel on the Health Assessment Plan

Within relevant chapters of the Health Assessment Plan, questions that we ask the Panel to focus on in its review include the following:

Chapter 2 – Health Effects and Approach to Risk Characterization:

1. As discussed in the Plan, at this time there does not appear to be sufficient controlled human exposure data to support development of quantitative dose-response relationships for the health effects reported in subjects with angina. Following the same overall

approach used in prior CO NAAQS reviews, the planned approach is to characterize risks associated with these effects by estimating exposures and resulting dose (i.e., COHb levels) and estimating the number and frequency of occurrences over several potential health effect benchmark levels for the cardiovascular disease population. The potential health effect benchmark levels are expressed in terms of COHb levels and are based on the evaluation of the controlled human exposure studies in the draft ISA. With regard to this planned approach for risk characterization for cardiovascular related health effects reported in controlled human exposure studies reporting decreased time to onset of angina, what are the Panel members' views on:

- a. The overall planned approach, which is to estimate the number and percent of the population with cardiovascular disease that would exceed potential health effect benchmark levels upon just meeting various CO air quality scenarios;
 - b. The range of potential health effect benchmark COHb levels (i.e., 2.0, 2.5, and 3.0 percent COHb) that staff plans to use to characterize these health risks.
2. While the first draft ISA reaches the conclusion that the overall health effects evidence supports the judgment that ambient CO concentrations are likely causal for cardiovascular morbidity as a category, the document recognizes the uncertainties that exist with respect to evaluating studies of the association between emergency room visit and hospital admissions, respectively, for cardiovascular effects and ambient CO concentrations. In particular, the ISA raises the question of whether ambient CO levels are serving as a surrogate for one or more elements of the traffic-related air pollution mix. With regard to the approach for risk characterization, the Plan raises several study-related issues affecting judgments about whether the evidence is supportive of developing quantitative risk estimates for emergency department visits and hospital admissions for cardiovascular effects related to ambient CO concentrations.
- a. What are the Panel members' views on whether the concerns raised about ambient CO levels potentially serving as a surrogate for one or more components of the overall traffic-related air pollutant mixture limit the utility of a quantitative risk assessment for these health endpoints?
 - b. Given the potential for CO at ambient levels to act as a marker for the effects of another traffic-related pollutant or mix of pollutants, what are the Panel members' views on whether or not the results of co-pollutant models provide sufficient evidence to support a quantitative risk assessment for CO effects at ambient levels?

Chapter 3 – Scope and Approach for Population Exposure/Dose Analysis

1. We plan to build upon the basic structure and design of the exposure assessment conducted in the previous review. Since that time there have been major improvements in the exposure model and in the data for input to the model. Are the Panel members aware of information sources that would help inform further improvements that would be worth considering in the current review?
2. One of the main issues in this analysis is how to estimate ambient CO concentrations on and near roadways, which can be significant contributors to ambient CO exposures. The

relationship between CO levels measured at ambient fixed site monitors is highly variable due to the spatial and temporal variability of on- and near-roadway CO concentrations. In the previous review, proximity factors were used to adjust the concentrations measured at monitors to estimate roadway-related concentrations of CO. We plan to conduct a review of the literature and draw upon the results of near-road studies to update the proximity factor distributions. Do the Panel members have recommendations for improvements or alternatives to this approach?

3. The planned approach for addressing uncertainty is primarily qualitative with a focus on sensitivity analysis and a limited quantitative analysis for those variables determined to be most influential with respect to exposure and/or dose estimation and where supporting data are available.
 - a. What are the Panel members' views concerning this general approach?
 - b. Spatial and temporal gradients in ambient CO relative to CO concentrations measured at fixed-site monitors are potentially a major source of uncertainty in the exposure and dose estimates. Do the Panel members have suggestions for how best to characterize the uncertainties in this relationship?

We look forward to discussing these issues with the CASAC CO Panel at our upcoming meeting. Should you have any questions regarding the Health Assessment Plan, please contact Dr. Karen Martin (919 541-5274; email martin.karen@epa.gov) or Dr. Ines Pagan (919 541-5469; email pagan.ines@epa.gov).

Attachments

cc: Vanessa Vu, SAB, OA
Karen Martin, OAQPS/HEID
John Vandenberg, ORD/NCEA-RTP
Mary Ross, ORD/NCEA-RTP
Tom Long, ORD/NCEA-RTP
David McKee, OAQPS/HEID
Harvey Richmond, OAQPS/HEID
Ines Pagan, OAQPS/HEID
John Langstaff, OAQPS/HEID
Pradeep Rajan, OAQPS/HEID
Souad Benromdhane, OAQPS/HEID