May 2, 2012

MEMORANDUM

SUBJECT: Updates to information presented in the Scope and Methods Plans for the Ozone NAAQS Health and Welfare Risk and Exposure Assessments

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TO: Holly Stallworth
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Clean Air Scientific Advisory Committee
EPA Science Advisory Board Staff Office

Since the Clean Air Science Advisory Committee (CASAC) Ozone Panel conducted a consultation on EPA's Scope and Methods Plans[1] for the ozone NAAQS health and welfare risk and exposure assessments in May 2011, we have been moving forward in developing the first drafts of the risk and exposure assessments for health and welfare effects of ozone. As this work has proceeded, the EPA has determined that changes are needed to certain elements of the scope and methods plan. This memorandum provides an overview of these changes to inform the CASAC Ozone Panel and the public as they prepare to review the first drafts of the Risk and Exposure Assessments. The overview focuses on the elements of the scope and methods plan to which EPA has made changes and provides a brief explanation of each change and the reason for it. The EPA does not intend to issue a revised scope and methods plan.

I would appreciate it if you would forward this information to the CASAC Ozone Panel. This memorandum will also be available on the EPA website:
http://www.epa.gov/ttn/naaqs/standards/ozone/s_o3_index.html.

We plan to make the first draft Risk and Exposure Assessments available to CASAC and the public in early July. We look forward to discussing these drafts with the CASAC Ozone Panel and the public at our meeting scheduled for September 11-13, 2012. Should you have any questions regarding this information on changes to elements of the scope and methods plans, please contact me (919-541-5505; email wegman.lydia@epa.gov) or Dr. Bryan Hubbell (919-541-0621; email hubbell.bryan@epa.gov). Thank you.

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[1] These documents are EPA's *Ozone National Ambient Air Quality Standards: Scope and Methods Plan for Health Risk and Exposure Assessment* (April 2011) and *Ozone National Ambient Air Quality Standards: Scope and Methods Plan for Welfare Risk and Exposure Assessment* (April 2011).

Attachments

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Attachment 1
Updates to Information Presented in the Scope and Methods Plan for Ozone NAAQS
Health Risk and Exposure Assessment

SECTION 1.3.2 EXPOSURE ASSESSMENT

- The EPA originally planned to model population exposures to ambient ozone in three or more of the 12 urban areas modeled in the previous review (Atlanta, Boston, Chicago, Cleveland, Detroit, Houston, Los Angeles, New York, Philadelphia, Sacramento, St. Louis, and Washington D.C.), as well as a high-elevation area such as Denver. The EPA is now planning to model population exposures to ambient ozone in the following 12 urban areas: Atlanta, Boston, Cleveland, Denver, Detroit, Houston, Los Angeles, New York, Philadelphia, Sacramento, St. Louis, and Washington D.C. Atlanta, Denver, Los Angeles, and Philadelphia will be modeled in the first draft Risk and Exposure Assessment (REA) and all 12 areas will be modeled in the second draft REA.

- The EPA originally planned to model exposure and health risks based on air quality information from 2008-2010. We are now planning to model exposure and health risks using air quality information from 2006-2010.

SECTION 2.4 BACKGROUND OZONE (formerly referred to as policy relevant background)

- The EPA originally planned to estimate exposures and risks above background using different definitions of background ozone (i.e., North American background, U.S. background, and natural background). We also planned to identify the contributions of global methane emissions to ozone concentrations.

- The EPA is now planning to estimate risks for the full range of ozone concentrations represented in the epidemiological and clinical studies that form the basis for the risk assessment. For example, risks will be estimated for ozone concentrations greater than the lowest observed level in the epidemiological studies. We are still evaluating the information on the relevant range of exposures based on the clinical studies. In addition, as discussed in greater detail below, the EPA now plans to consider a range of options for examining confidence in risk estimates across the distribution of ozone air quality concentrations (see further discussion under section 5.3).

- The evidence and information on background ozone that is assessed in the Integrated Science Assessment (ISA) will now be considered in the Policy Assessment (PA). The PA will consider risk estimates across the full range of ozone concentrations, within the context of the confidence characterization in the REA and the assessment of background in the ISA. With regard to background ozone concentrations, the PA will consider available information on ambient ozone concentrations resulting from natural sources, anthropogenic sources outside the U.S., and anthropogenic sources outside of North America.

SECTION 3.2 THE APEX POPULATION EXPOSURE MODEL

- We are clarifying that we plan to use version 4.4 of the APEX model. The model and updated documentation will be available by May 1 at http://www.epa.gov/ttn/fera/apex_download.html.

SECTION 3.3 POPULATIONS MODELED

- The EPA originally planned to model exposure for an elderly population defined as aged 70 and older.

- The EPA is now planning to model exposure for an elderly population defined as aged 65 and older.

SECTION 4.3 SELECTION OF EXPOSURE-RESPONSE FUNCTIONS

- The EPA originally planned to follow the same approach used in the previous ozone NAAQS review, based on the same set of clinical studies.

- Based on additional studies identified in the second draft ISA, the EPA now plans to update the exposure response function using results from two additional recent clinical studies, Kim et al, 2011 and Schelegle, et al, 2009.[2]

SECTION 5.2.2 AIR QUALITY CONSIDERATIONS

- The EPA originally planned to use a single three-year block of monitoring data (2008-2010). The EPA now plans to use 5 years of monitoring data in two three-year blocks (2006-2008 and 2008 to 2010) - this allows us to reflect both a lower and relatively higher period of ozone ambient levels.

- The EPA originally planned to consider the use of more representative methods for developing composite monitors (e.g., use of results of detailed exposure modeling to weight monitors to reflect potential population exposure, use of fused model/monitor surfaces). The EPA now plans to present options for refining exposure surrogates used in the city-specific analyses. As part of our evaluation, we plan to consider heterogeneity in air measurements across urban study areas in determining whether to use more representative exposure surrogates that are more spatially heterogeneous than the composite monitors used in the source epidemiology studies. Based on these evaluations

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[2] Kim, Chong S., Neil E. Alexis, Ana G. Rappold, Howard Kehrl, Milan J. Hazucha, John C. Lay, Mike T. Schmitt, Martin Case, Robert B. Devlin, David B. Peden, and David Diaz-Sanchez. "Lung Function and Inflammatory Responses in Healthy Young Adults Exposed to 0.06 ppm Ozone for 6.6 Hours." American Journal of Respiratory and Critical Care Medicine 183, no. 9 (2011): 1215-1221.

Schelegle, Edward S., Christopher A. Morales, William F. Walby, Susan Marion, and Roblee P. Allen. "6.6-Hour Inhalation of Ozone Concentrations from 60 to 87 Parts per Billion in Healthy Humans." American Journal of Respiratory and Critical Care Medicine 180 (2009): 265-272.

and feedback from CASAC and the public, we plan to consider including additional   risk assessment results based on these alternative exposure surrogates as part of sensitivity analyses in the second draft REA.

- The EPA originally planned to apply the same quadratic rollback approach as used in the previous Ozone NAAQS review.

- For the first draft REA, to facilitate evaluation of the risk assessment methodology, we are using the same quadratic rollback method applied in the previous review. Based on the current understanding of how ozone forms and reacts to changes in emissions, reductions in emissions that would be needed to meet the current standards are likely to lead to reductions in hourly concentrations for most hours of the day, but may have little impact on concentrations for some hours, and in some cases can lead to increases in ozone concentrations particularly during nighttime hours. The quadratic rollback method has difficulty representing these complexities in ozone chemistry and reduces ozone concentrations over all hours. To address this issue in the rollback methodology for the first draft REA, we are planning to impose a lower bound on ozone concentration values based on modeled ozone levels after eliminating all U.S. anthropogenic emissions of ozone precursors (NOx and VOC) These estimates will be developed using the GEOS-Chem global chemical transport model. This approach is applied so that ozone concentrations for any particular hour cannot go below the estimated lower bound values.

- The EPA now plans to evaluate approaches for simulating attainment of current and alternative standards that are based on modeling the response of ozone concentrations to reductions in anthropogenic NOx and VOC emissions, using the Decoupled Direct Method (DDM) capabilities in the Community Multi-scale Air Quality (CMAQ) model. This modeling incorporates all known emissions, including emissions from non-anthropogenic sources and anthropogenic emissions from sources in and outside of the U.S. As a result, the need to specify values for U.S. background is not necessary, as it is incorporated in the modeling directly. In simulations of just meeting the standards used to inform the risk assessment, DDM sensitivities can be applied relative to ambient measurements of ozone and emissions reductions can be applied in order of emissions from the U.S., emissions from North America, and international emissions outside of North America. The evaluation of this new approach will be presented in the first draft REA while the quantitative application will not be completed until the second draft REA.

SECTION 5.3 SELECTION OF HEALTH EFFECTS ENDPOINT CATEGORIES

- The EPA originally planned to consider potential long-term health effect categories including: (A) exposure-related birth outcome effects and (b) respiratory mortality.

  The EPA now plans to lay out an approach for modeling long-term exposure related mortality (including conceptual and technical challenges associated with modeling this endpoint category) as part of the first draft REA. Based on feedback from CASAC and the public, we will then determine whether (and if so, how) to model long-term exposure related mortality as part of the second draft REA. At this time, we are not planning to

model exposure-related birth outcomes due to challenges in specifying the appropriate temporal exposure metric to use in generating risk estimates.

- The EPA originally planned to only include non-threshold models for short-term exposure related endpoints.

  The EPA now plans to consider a range of options for examining confidence in risk estimates (with emphasis on estimates generated at lower ozone exposure levels). These include (a) modeling risk down to (but not below) the lowest measured ozone levels reflected in the underlying epidemiological studies that provide the underlying effect estimates, (b) identifying a range of ozone exposure levels from the underlying epidemiological studies providing the effect estimates (e.g., 10th to 25th percentile monitored levels) that are associated with reduced confidence in characterizing risk and considering the magnitude of risk generated above that range and (c) considering the results of research such as that presented in the Bell et al., 2006 study which explored the sensitivity of effect estimates to a range of potential thresholds. These various approaches towards examining confidence in risk estimates may be reflected in different sensitivity analyses included the first draft REA. As part of the first draft REA, the EPA would seek input from both CASAC and the public to the approaches used in characterizing confidence in the risk estimates generated and would consider updating its approach for characterizing that uncertainty as part of the second draft REA.

SECTION 5.4.5 REPRESENTATIVENESS ANALYSIS

- The EPA originally planned to model the set of urban areas included in the time series study that provided the effect estimates used in the primary estimate of short-term mortality generated for our urban study areas. While the mortality estimate for short-term exposure would not be truly national (in that it would not cover all counties in the country), by including most of the larger urban areas in the U.S. it would provide close to a national estimate.

- The EPA now plans to estimate mortality risk for all counties in the U.S. For counties not included in the multi-city epidemiological studies, we will apply the national average effect estimate from those studies. Because the mortality estimates in rural areas are less certain, we will denote the portion of the total deaths attributable to ozone occurring in urban areas (inclusive of those urban areas not specifically covered by the epidemiological studies, as we still have high confidence in transferring the average across the covered urban areas to the excluded urban areas) to indicate the portion for which we have the highest confidence.

Attachment 2
Updates to Information Presented in the Scope and Methods Plan for Ozone NAAQS
Welfare Risk and Exposure Assessment

SECTION 2 AIR QUALITY CONSIDERATIONS

- The EPA is reconsidering the role of information related to background concentrations of ozone.

- The EPA originally planned to estimate welfare risks in excess of background ozone concentrations. The EPA originally planned to develop estimates of background ozone concentrations related to three different definitions of background. We also planned to identify the contributions of global methane emissions to ozone concentrations. This information would then be used in the estimation of exposures and risk, to provide estimates of exposure and risk above background for the different definitions of background ozone

- The EPA is now planning to estimate risk for the full range of ozone concentrations supported by the welfare effects literature. Information on background ozone concentrations will be considered in conjunction with the estimates of risks across the full range of ozone concentrations in the PA.

SECTION 3.1.2 ESTIMATION OF BIOMASS LOSS

- In addition to the approaches for evaluating biomass loss associated with ozone exposure discussed in the Scope and Methods Plan, we are now planning to add an additional analysis incorporating the Importance Values (representing in part the relative abundance of a species within a forest ecosystem) derived using FIA data. Importance values will be used to weight the species biomass loss to provide additional insight into the likely impacts of ozone on forest ecosystems.

SECTION 3.2.2 ESTIMATION OF VEGETATION EFFECTS IN URBAN AREAS

- The EPA originally planned to analyze vegetation effects in urban areas by using GIS to compare vegetation maps in urban areas to the national ozone surface to provide an overall estimate of foliar damage and total biomass loss. We also planned where available to use GIS data for public trails and recreational areas to compare aerial extent of foliar damage.

- The EPA now plans to rely on the results of the i-Tree model to provide estimates of Ecosystem Services in urban areas. The i-Tree model is a state-of-the-art, peer-reviewed set of software components from the USDA Forest Service that provides urban forestry analysis. The i-Tree model and documentation is available at http://www.itreetools.org/

SECTION 4.1.3.1 and 4.1.3.2 ESTIMATION OF YIELD LOSS FOR NCLAN CROPS/ ECONOMIC VALUATION ASSOCIATED WITH CROP YIELD LOSS

- The EPA originally planned to estimate yield loss and economic value of yield loss for NCLAN crops using the AGSIM© agricultural sector model.

- The EPA has evaluated the available agricultural and forestry sector models and determined that the Forest and Agricultural Sector Optimization Model (FASOM) is the most appropriate model for addressing integrated agricultural and forestry related impacts based on this evaluation. The EPA now plans to use FASOM for both agricultural and forestry impacts. As a result, the EPA no longer plans to provide a separate agricultural analysis using AGSIM©.

SECTION 4.1.3.3 MODELING OF TREE GROWTH AND ECONOMICS

- During the consultation on the Scope and Method Plan, a CASAC member recommended that EPA consider the Dynamic Landuse Ecosystem Model (DLEM) to evaluate impacts of ozone on overall forest health and dynamics. The EPA evaluated this model and due to issues with obtaining the DLEM model due to the proprietary nature of the model, EPA is not planning to use the DLEM. As an alternative to DLEM, the EPA is planning to explore in the second draft REA the use of PnET as a method to evaluate impacts on large scale ecosystem services. PnET is a suite of three nested computer models which provide a modular approach to simulating the carbon, water and nitrogen dynamics of forest ecosystems. Documentation for PnET is available at http://www.pnet.sr.unh.edu/. We plan to propose the use of PnET in the first draft REA to allow for CASAC and the public to provide comment on the appropriateness of the PnET model for use in evaluating risks of ozone to forest ecosystems.