CO NAAQS Review: Overview of Scope and Methods Plan for Health Risk and Exposure Assessment

Consultation with Clean Air Scientific Advisory Committee

Office of Air Quality Planning and Standards

U.S. EPA

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Overview

- Overview of the Risk Characterization
  - Based on Controlled Human Exposures
  - Based on Epidemiological Studies
- Overview of the Exposure/Dose Analysis
  - Previous Assessments
  - Scope and Approach of the Current Assessment

Risk Characterization Approach

- Overall approach builds upon methods and analyses conducted in prior reviews
  - Prior reviews did not include quantitative risk assessment
  - Rather, approach characterized risk by estimating number and percent of cardiovascular disease population and number of occurrences exceeding specified COHb levels for selected urban areas
  - COHb levels of interest informed primarily by controlled human exposure studies that focused on time to onset of angina
  - Estimates based on combined exposure/dose model (i.e., pNEM/CO)

Planned Risk Characterization Approach for Cardiovascular-Related Effects Observed in Controlled Human Exposure Studies

- We seek CASAC input on general approach:
  - Reduced time to onset of angina observed in range of 3 to 6% COHb (measured by CO-oximeter)
  - No clear pattern across different studies and COHb levels with respect to magnitude of response or fraction of population responding
  - Staff judge that insufficient data to support development of quantitative dose-response relationship
- We seek CASAC input on appropriate benchmark levels for use in risk characterization
  - Levels identified in plan include: 2.0, 2.5, 3.0% COHb

Risk Characterization Approach for Cardiovascular-Related Effects Reported in Epidemiological Studies

- Considerations for decision on whether to conduct a quantitative risk assessment for health effects based on associations reported in community epidemiological studies:
  - Weight of evidence for specific health endpoints
  - Data availability
  - Anticipated utility of assessment results to inform decisions on adequacy of current CO NAAQS and to provide insights on alternative standards

Risk Characterization Approach for Cardiovascular-Related Effects Reported in Epidemiological Studies (Cont'd)

- Plan raises several study-related issues about whether evidence is supportive of developing quantitative risk estimates for ED visits and hospital admissions for CO-related cardiovascular effects
- We seek CASAC input on the following:
  - Whether 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?
  - Whether or not results of co-pollutant models provide sufficient evidence to support a quantitative risk assessment for CO effects at ambient levels?

Overview of Previous Exposure/Dose Assessment

- Adults with cardiovascular heart disease
- Denver and Los Angeles were the example study areas
- Two major indoor sources were included
  - Passive Smoking
  - Gas Stoves
- pNEM exposure model was used
- Number and percent of cardiovascular disease population and number of occurrences exceeding various COHb levels were estimated

Approach For the Current Assessment

- Builds upon previous approach
  - APEX model evolved from pNEM
  - Improvements in algorithms and data
- Estimate blood COHb levels using the Coburn, Forster, Kane model
- Estimate # of individuals and # of occurrences of COHb exceeding each benchmark level
- Estimate distribution of 8-hour average CO exposures in the populations
- Identify key assumptions and related uncertainties in the exposure and dose estimates

Exposure/Dose Model

- Air Pollutants Exposure Model (APEX version 4)
  - PC-based population exposure model for inhalation, derived from the probabilistic NAAQS Exposure Model (pNEM)
  - Part of EPA's Total Risk Integrated Methodology (TRIM) model framework
  - State-of-the-art population exposure model
  - Simulates movement of individuals through time and space
  - Estimates time-varying blood COHb levels in individuals
  - APEX version 4 updated October 2008 with User's Guide and Technical Support Document
  - Fate, Exposure and Risk Analysis (FERA) website: http://www.epa.gov/ttn/fera/human_apex.html

Selection of Modeling Areas and Years

- Exposure studies in Denver and Los Angeles
- Denver and LA are among urban areas with the highest ambient CO levels
- LA (85%) and Denver (68%) have the largest proportion of population within 15 km of a monitor, among cities in the U.S.
- Denver and LA were included in the previous CO NAAQS review
- Modeling 3 years: 2006-2008

Major Improvements from Previous Exposure Assessment – Algorithms

- Modeling individuals in a population – not cohort approach
- Improved method for estimating breathing rates (EPOC)
- New method for constructing longitudinal sequences of daily activity diaries
  - Variability (within- and between-person)
  - Autocorrelation (daily activities)

Major Improvements from Previous Exposure Assessment – Data

- Additional diary data in ORD's Consolidated Human Activity Database (CHAD)
- Better indoor-outdoor air exchange rate distributions (affects indoor CO levels)
- Tract-level commuting database
- Distributions of physiological parameters

In-Vehicle and Near-Roadway Exposures

- Concentration distributions at near-road monitors
  - Consistency between near-road monitors
  - Relationships between near-road monitors and other monitors in the study area
- Review in-vehicle and near-road measurement studies in other areas
  - Distributions of CO concentrations near roads and in vehicles
  - Relationships between near-road and in-vehicle concentrations

Sensitivity and Uncertainty Analyses

- Variability
  - APEX captures variability in distributions of inputs and results
- Sensitivity analysis
  - Model input variables
  - Model Behavior over exposure parameters
- Qualitative discussion of key uncertainties
  - Overall exposure/dose results
- Quantitative Assessment
  - Monte Carlo uncertainty analysis to the extent that data are available