



PM 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

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Overview: Design of Human Health Risk Assessment

- Framework builds upon methodology, analyses, and lessons learned in assessments conducted for previous reviews
- Urban study area-based approach
 - Expand number of cities from 9 (previous review) to 15-20 (current review)
 - Evaluate different air quality scenarios
 - Recent ambient air concentrations (2005-2007)
 - Simulations of air quality to “just meet” current or alternative standards
- Characterization of broader public health impacts

Overview of Risk Assessment Model

Air Quality

- Recent air quality
- Air quality simulated to just meet current and alternative NAAQS
- Policy relevant background

Concentration-Response

- C-R functions derived from epidemiological studies for various health endpoints

Baseline Incidence and Demographics

- Baseline health effects incidence rates
- Population data

Health Risk Model

Risk Estimates

- Recent air quality
- Current or alternative NAAQS scenarios



Areas of Ongoing Methods Development and Design Refinement

- Air quality characterization
- Risk characterization
 - Selection of health effect endpoint categories
 - Specification of concentration-response (C-R) functions
 - Selection of urban study areas
 - Methods for addressing uncertainty and variability
 - Approaches for placing urban study areas in broader national context
- Population exposure analysis



Air Quality Considerations

- Mathematical approach (rollback) to simulate air quality to “just meet” current or alternative standards
 - Historical approach – proportional rollback
 - Planning to update evaluation of proportional rollback approach based on historical trends in ambient $PM_{2.5}$ concentrations
 - Examining potential alternative method – prospective model-based approach
- Characterization of policy-relevant background (PRB)
 - Historical approach – empirical-based estimate
 - Planning to use model-derived estimates developed for and described in ISA



Selection of Health Effect Categories

- Planning to focus on categories classified in ISA as having a *causal* or *likely-causal* relationship with ambient $PM_{2.5}$ exposures
 - Cardiovascular morbidity
 - Respiratory morbidity
 - Mortality
- Exploring inclusion of additional categories classified in ISA as *suggestive* of a causal association
 - Associated with long-term ambient $PM_{2.5}$ exposures
 - Associated with short-term ambient $PM_{10-2.5}$ exposures



Specification of Concentration-Response Functions

- Considering relative emphasis to place on various factors:
 - Greater emphasis on distributed lag models for evaluating potential impacts of short-term exposures
 - Greater emphasis on multi-city studies which provide city-specific effect estimates
 - Equal weight on single- and multi-pollutant models
 - More emphasis on no-threshold C-R functions
 - Primary emphasis on modeling risk increments relative to PRB or lowest reported ambient concentrations
- Considering additional information contained in studies published since release of first draft ISA



Criteria for Selecting Urban Study Areas

- Recent air quality data
- Location-specific C-R function(s)
- Baseline incidence rates and demographic data
- Representativeness
 - Geographic heterogeneity
 - Consideration of sensitive subpopulations
 - Factors that may affect PM_{2.5}-related impacts (e.g., sources/ composition, building characteristics)
- Availability of more refined exposure metrics⁸



Methods for Addressing Uncertainty and Variability

- Qualitative uncertainty assessment
- Quantitative uncertainty assessment
 - Planning to use multi-element sensitivity analysis
 - Consider alternative set of reasonable risk estimates to supplement core set of risk results
 - Provide insights into the impact of uncertainty on the initial set of core risk estimates
 - Not currently feasible to use 2-dimensional probabilistic simulation to evaluate uncertainty and variability
- Consideration of variability related to exposure and risk is integrated throughout the analysis
 - Planning to characterize the degree to which the analysis covers key aspects of variability

Overview of Uncertainty Analysis Approach

Risk Assessment Modeling Elements

Air Quality:

Ambient Monitoring Data for Selected Urban Areas (specification of composite monitor)

Modeled Background Concentrations (PRB)

Air Quality Adjustment (roll-back) Procedures

Concentration-Response:

Selection of Human Epidemiological Studies to Provide Concentration-Response Functions

Specification of Concentration - Response Relationships – consider:

- single- v.s. multi-chemical
- single- v.s. multi-city
- lag
- seasonally-differentiated
- slope of CR function (threshold)

Baseline Health Effects Incidence Rates and Demographics:

Estimates of City-specific Baseline Health Effects Incidence Rates

City-specific Demographic Data

Primary Analysis Generating Core Set of Risk Estimates

Apply criteria for selecting subset of modeling element options for use in the core analysis

Generate core set of risk estimates for each combination of urban study area and air quality scenario

Uncertainty Analysis Producing Additional Set of Plausible Risk Estimates

Apply single-factor sensitivity analysis to identify those modeling elements with a significant impact on risk results

Identify additional plausible modeling options (distinct from those used in the core analysis) for this set of key modeling elements

Conduct multi-factor sensitivity analysis (for this subset of key modeling options) to generate alternative sets of reasonable risk estimates for a subset of urban study areas and air quality scenarios



Characterization of Broader Public Health Impacts of $PM_{2.5}$

- Evaluating representativeness of selected urban areas to understand:
 - Coverage provided for different regions of U.S. defined by similarities in $PM_{2.5}$ -related parameters
 - Coverage of susceptible and vulnerable subpopulations

- Exploring national scale analysis
 - Consider use of Benefits Mapping Analysis Program (BenMAP)
 - Plan to focus estimates on *mortality* effects associated with *long-term* $PM_{2.5}$ exposures associated with recent ambient air quality



Population Exposure Analysis

- Considering exposure analysis to provide insights to inform interpretation of epidemiology evidence
- Framework would build upon methodology, analyses, and lessons learned in assessments conducted for other recent NAAQS reviews (e.g., O₃, NO₂)
 - Model population exposures for a subset of cities evaluated in the risk assessment with city-specific C-R functions selected from key time-series studies
 - Calculate 2 or 3 *a priori* exposure metrics for each city that reflect the effects of factors that differentiate between concentrations and exposures
 - Inspect relationship (if any) between exposure metrics and city-to-city differences in PM_{2.5} C-R functions

Overview of Exposure Assessment Model

