

Overview of the Scope and Methods Plan Supporting the Review of the Primary NO₂ NAAQS

Presentation to CASAC

October 25, 2007

Purpose of this Meeting

- Solicit feedback on EPA's planned approach to assessing risks and exposures associated with NO₂

Overview

- Background
 - Schedule
 - Conclusions from previous review
 - Scope of the Planned risk and exposure assessment
- Exposure Assessment
 - Tier I
 - Tier II
 - Tier III
- Risk Assessment
 - Tier I
 - Tier II
- Charge Questions for CASAC

Background: Schedule

Major Milestones		Completion Date	CASAC Review Date
Integrated Review Plan	Draft	April 2007 (complete)	May 2007
	Final	August 2007 (complete)	
Integrated Science Assessment	First Draft	August 2007 (complete)	October 2007
	Second Draft	February 2008	May 2008
	Final	July 2008	
Risk/Exposure Assessment	Plan	September 2007 (complete)	October 2007
	First Draft	March 2008	May 2008
	Second Draft	August 2008	September 2008
	Final	November 2008	
Policy Assessment/Rulemaking	ANPR	December 2008	January 2009
	Proposed	May 2009	
	Final	December 2009	

Background: Overview of Conclusions from Previous Review

- In the previous review of the NO₂ NAAQS, the Administrator concluded that the existing annual standard will...
 - Maintain annual NO₂ concentrations considerably below the long-term levels for which serious chronic effects have been observed in animals
 - Provide protection against short-term peak NO₂ concentrations associated with mild changes in controlled human studies
- Basis for conclusions regarding short-term exposures
 - Air quality assessment evaluated the relationship between annual average NO₂ levels and short-term (1-hour average) NO₂ levels
 - Number of exceedances of various short-term benchmark values was estimated with the assumption of just meeting the current standard
 - Short-term benchmarks evaluated ranged from 0.15 ppm to 0.3 ppm
 - Result: If the existing annual standard is attained, short-term NO₂ levels of potential concern would be unlikely in most parts of the country

Background: Scope of the Planned Risk and Exposure Assessment

- NO₂ will be considered as the surrogate for the gaseous nitrogen oxides
 - Little health data available for other gaseous species
 - Particulate nitrogen oxides are addressed by current NAAQS for particulate matter
 - Most recent review concluded that size-fractionated particle mass, rather than particle composition, remains the most appropriate approach for addressing ambient PM
 - This conclusion will be re-assessed in the next review
 - However, at present it would be redundant to also use the NO₂ NAAQS to protect against the health effects of particulate nitrogen oxides
- Assessment will evaluate the risks and exposures associated with...
 - Recent ambient levels of NO₂
 - Ambient levels of NO₂ associated with just meeting the current standard
 - Ambient levels of NO₂ associated with just meeting potential alternative standards
- Assessment will focus on both short- and long-term exposures/risks

Exposure Assessment: Overview

- Goals of the exposure assessment:
 - Estimate short- and long-term exposures associated with current levels of ambient NO₂ and assuming alternative levels of ambient NO₂
 - Develop quantitative relationships between long-term average and short-term peak concentrations of NO₂
- Approach
 - Tier I: air quality characterization
 - Tier II: screening-level exposure assessment
 - Tier III: refined exposure assessment
- Populations Considered
 - general population
 - susceptible/vulnerable populations (as identified in ISA): children (birth to 18), asthmatic children (birth to 18), asthmatic adults (>19), and the elderly (>65)
- Assessment of uncertainty
 - At each analysis Tier, will progress from qualitative to quantitative depending on availability of data and anticipated magnitude of the uncertainty

Exposure Assessment: Tier I

- Purpose: To estimate potential exposures using
 - historic and current ambient monitoring data (1995-2006) as a surrogate for exposure
 - enhancement factors to estimate on-road NO₂ from ambient monitoring data
 - available concentration data for outdoor (e.g., utilities) and indoor (e.g., gas stoves) sources
- Locations Considered
 - based on air quality trends, data availability, population demographics, location of NO₂ epidemiologic studies, and inclusion of a range of geographic areas
 - Los Angeles, Houston, Atlanta, Philadelphia, Chicago, and aggregation of others
- Expected output
 - Descriptive statistics for NO₂ concentrations in selected locations
 - Relationships of short-term peak levels to long-term average levels
 - Identification of additional areas to be modeled in Tier II and/or III, if needed
- Uncertainty
 - Assessment of uncertainty and variability will be primarily qualitative
- Tier I exposure assessment will provide input to a tier I risk assessment to identify exposures of concern (i.e., exposures that exceed identified health benchmarks)

Exposure Assessment: Tier II

- Purpose: To improve characterization of the relationship between ambient concentrations, local sources, and exposure considering
 - on- and near-roadway concentrations using dispersion model and/or enhancement factors
 - modeled concentrations for other outdoor and indoor sources, if any, identified in Tier I
 - influential factors
 - e.g., time spent in broad microenvironments, decay of NO₂ indoors, population
- Locations Selected
 - Individual locations identified in the Tier I air quality characterization
- Expected output
 - Short-term Exposure Outcome
 - Temporally and spatially resolved ambient levels of NO₂ accounting for local sources
 - Estimates of the number of individuals who may experience exposures of concern
 - Long-term Exposure Outcome
 - Annual average exposure levels for each census tract
 - Ratios of exposure to ambient for assessing exposures in other locations not modeled
- Uncertainty
 - Model to measured comparisons for near-road and microenvironmental concentrations
 - Limited sensitivity analyses on model input data/distributions

Exposure Assessment: Tier III

- Purpose: Refine the approach for addressing personal human attributes (e.g., time-location-activity patterns, human physiology) using
 - on- and near-roadway concentrations using dispersion model and/or enhancement factors
 - EPA's Air Pollutants Exposure Model (APEX)
 - Monte Carlo approach where individuals in a population are simulated as they move through time and space
 - Also used to estimate concentration contribution of indoor sources
- Locations Selected
 - Individual locations used in the Tier II exposure analysis
- Expected Output
 - Counts of people exposed one or more times to several NO₂ levels based on evaluation of the ISA
 - Counts of person occurrences of a particular exposure
- Uncertainty
 - Model inputs
 - assessed with a Monte Carlo approach using specified distributions for each input
 - e.g., air exchange rate, NO₂ decay rate, physiological parameters
 - Model formulation
 - assessed by comparing model predictions to measured values (where data are available), or
 - qualitatively evaluating plausible uncertainties for sub-models

Risk Assessment: Overview

- Goals of risk assessment
 - To estimate number of occurrences of short-term air quality events and number of people exposed at or above various potential health effect benchmarks associated with alternative NO₂ scenarios
 - To provide health risk estimates for NO₂-related health endpoints associated with alternative NO₂ scenarios (if a Tier II assessment is conducted)
 - Identify and characterize key assumptions, variability, and uncertainty associated with the assessments
- Scenarios evaluated
 - Recent air quality levels, air quality levels just meeting the current standard, and air quality levels just meeting potential alternative standards
- Two-tiered approach
 - Tier I: Potential Health effects benchmark levels (based on review of ISA) compared to air quality and/or exposure estimates
 - Tier II: Combine concentration-response or exposure-response data with exposure estimates to generate population risk estimates (if judged feasible and of sufficient utility)

Risk Assessment: Tier I

- Air quality levels (from the tier I exposure assessment) or estimated exposure levels (from a tier II or III exposure assessment) will be compared to potential health benchmark levels for several example urban areas
- Health effect benchmarks will be identified from the 2nd draft ISA
 - Tentative benchmarks: 0.2 to 0.3 ppm (1-hour averaging time) in asthmatics (children and adults)
 - Based on controlled human exposure studies
 - Uncertainty about health effect benchmarks will be qualitatively addressed
 - Will use alternative benchmark levels to illustrate impact of alternative choices about lowest exposure level of concern
 - Variability:
 - Geographic variability addressed by conducting analysis for several example urban areas
 - Population variability in response addressed qualitatively
- Projected outcomes:
 - Number of occurrences of air quality levels at or above several benchmarks
 - Number of times in a given year that a population or individual experiences various exposure levels of concern

Risk Assessment: Tier II

- If conducted, would estimate number of individuals in selected populations for several example urban areas expected to experience specified health effects
- Would be based on epidemiologic literature
 - Preliminary judgment that controlled human exposure studies do not provide enough information to identify credible exposure-response relationships
 - Still evaluating whether or not epidemiological evidence adequate to conduct credible quantitative risk assessment
- Criteria for determining if Tier II assessment conducted
 - Outcome of Tier I assessment
 - Availability of info and data required to conduct a Tier II assessment (e.g., adequate C-R functions, baseline incidence data for urban areas)
 - Utility or value-added to decision process, beyond insights provided by Tier I assessment
 - Feasibility of conducting a Tier II assessment within consent decree schedule and resources

Risk Assessment: Tier II (Continued)

Based on our analysis of the first draft of the ISA...

- A tier II risk assessment, if conducted, would focus on short-term (1- and 24-hour) ambient levels and respiratory-related effects
 - Respiratory-related hospital admissions, especially for asthmatics
 - Respiratory-related emergency department visits, especially for asthmatic children
 - Respiratory symptoms (e.g., cough and wheeze), particularly in children and asthmatics
- Risk estimates based on both single- and multi-pollutant models would be reported
- Uncertainty associated with the NO₂ coefficient in the concentration-response function would be addressed by providing confidence intervals around point estimates of risk and by presenting a range of results based on different epidemiological studies from different cities
- Expected outputs (in each case central tendency and 95% confidence interval estimates would be provided)
 - Estimated incidence (number of cases)
 - Incidence per 100,000 relevant population for each health endpoint
 - Hypothetical change in incidence associated with moving from just meeting current standard to just meeting potential alternative standards

Broader Risk Characterization

- Summary of U.S. air quality information and discussion of various health effects from the ISA
 - Provide context for quantitative risk estimates
 - Will include air quality statistics for all areas of U.S. with NO₂ monitoring data
- National-scale information on size of potentially susceptible populations will be presented

Charge Questions for CASAC

- Does the Panel have comments on the way we propose to use air quality data?
 - Approaches to simulating just meeting current and potential alternative standards
 - Using annual average air quality levels to estimate expected exceedances of short-term health benchmarks
 - Approach to estimating on- and near-roadway NO₂ concentrations
 - Approach to addressing uncertainty and variability
- Does the Panel have comments on the way we propose to assess exposures?
 - Proposed choice of models
 - Identification of groups of interest (children, asthmatics, elderly)
 - Developing individual exposure profiles through the use of APEX
 - Approach to addressing uncertainty and variability
- Does the Panel have comments on the way we plan to assess health risks?
 - Proposed choice of health endpoints
 - The proposed approaches for conducting risk assessments
 - Approach to addressing uncertainty and variability
- Does the Panel have comments on the proposed criteria for deciding whether to proceed to a more sophisticated analysis (i.e., higher tier) for assessing exposures and/or risks?