Key Health Effects Information in Recent NAAQS Reviews

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Overview

• Type of health effects data considered in reviews of primary National Ambient Air Quality Standards (NAAQS)

• Recent/ongoing NAAQS reviews
  • Particulate matter (PM)
  • Nitrogen Dioxide (NO$_2$)
  • Lead (Pb)
Types of Health Effects Evidence

• Epidemiological studies
  – Health outcomes associated with normal exposures to ambient mix of air pollutants (e.g., PM)
  – Health outcomes associated with levels of internal marker (e.g., Pb)

• Controlled human exposure studies
  – Human responses to known exposures

• Toxicological studies
  – Animal studies, short- and long-term exposures

• *In vitro* studies
NAAQS Assessments . . .

**Hazard and “Dose”**

- Hazard characterization – weight-of-evidence approach, using all relevant information
  - Patterns of exposure
  - Nature and severity of effects
  - Nature and size of at-risk populations
  - Kind and degree of uncertainties
  - Consistency/coherence across all types of available evidence

- “Dose”-response evaluations – based on nature of available evidence from human studies, generally with no discernable thresholds (effects observed at current ambient concentrations)
Causality Determinations

- Integrated Science Assessment (ISA) employs a 5-level hierarchy to characterize causality judgments
  - Sufficient to infer a causal relationship
  - Sufficient to infer a likely causal relationship
  - Suggestive, but not sufficient to infer a causal relationship
  - Inadequate to infer the presence or absence of a causal relationship
  - Suggestive of no causal relationship
Type of Health Effects Evidence Affects How Characterize Risk

- Air Quality Monitoring/Modeling
- Inhalation Exposure Modeling
- Dosimetry Modeling

Risk Assessment/Characterization

- ambient concentration-response (e.g., PM, NO₂)
- exposure-response (e.g., O₃)
- internal dose-response (e.g., CO, Pb)
NAAQS Assessments . . .

*Exposure*

- Inhalation exposure assessment
  - Air quality monitoring/modeling and simulations of “just attaining” alternative standards
  - Pollutant concentrations within relevant microenvironments (home, yard, car, office)
  - Amount of time in different microenvironments and level of exertion (time-activity and breathing rate data)
  - Population demographics (census data, commuting patterns)
  - Probabilistic assessment (including uncertainty, variability, sensitivity analyses)

- Provides ability to identify and characterize exposure distributions for at-risk groups
NAAQS Assessments . . .

Risk Characterization

• Risk characterization – qualitative and quantitative approaches
  – Integration of evidence on health effects associated with short- or long-term exposures (strengths, weaknesses, uncertainties)
    • Identification of and focus on at-risk groups
  – Expert judgments on adversity of effects (severity, duration, frequency)
  – Qualitative and quantitative assessments of population exposures of concern and/or risks to public health

• Risk communication – put risk characterization into public health policy context
Some populations are at increased risk ...

- People with heart or lung disease
- Older adults
  - Greater prevalence of heart and lung disease
- Children
  - More likely to be active
  - Breathe more air per pound
  - Bodies still developing
- Conditions making some populations more vulnerable
  - Low SES (e.g., less access to health care)
- Residence near roadways
- Others?
Risk Characterization: Understanding Broader Public Health Impacts

Proportion of Population Affected

Severity of Effects

Death
ER visits, Hospital admissions, Heart attacks
Doctor visits, School absences, Lost work days
Respiratory symptoms, Medication use, Asthma attacks
Lung function decrements, Inflammation, Cardiac effects

Risk Characterization: Understanding Broader Public Health Impacts
NAAQS Review

Health Research

Ambient Air Monitoring Data

NAAQS Implementation
Particulate Matter (PM)
Particulate Matter

- Larger particles (> PM$_{10}$) deposit in the upper respiratory tract
- Smaller, inhalable particles (≤ PM$_{10}$) penetrate deep into the lungs
- Both coarse particulate matter and fine particulate matter can penetrate to lower regions of the lung
- Deposited particles may accumulate, react, be cleared or absorbed
<table>
<thead>
<tr>
<th>Final Rule</th>
<th>Indicator</th>
<th>Ave. Time</th>
<th>Level</th>
<th>Form</th>
</tr>
</thead>
<tbody>
<tr>
<td>1971</td>
<td>TSP - Total Suspended Particles (≤ 25-45 µm)</td>
<td>24-hour</td>
<td>260 µg/m³ (primary) 150 µg/m³ (secondary)</td>
<td>Not to be exceeded more than once per year</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Annual</td>
<td>Annual average</td>
</tr>
<tr>
<td>1987</td>
<td>PM₁₀</td>
<td>24-hour</td>
<td>150 µg/m³*</td>
<td>Not to be exceeded more than once per year</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Annual</td>
<td>Annual average</td>
</tr>
<tr>
<td>1997</td>
<td>PM₂₀.₅</td>
<td>24-hour</td>
<td>65 µg/m³</td>
<td>98th percentile</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Annual</td>
<td>Annual arithmetic mean, ave. over 3 years</td>
</tr>
<tr>
<td></td>
<td>PM₁₀</td>
<td>24-hour</td>
<td>150 µg/m³</td>
<td>Initially promulgated 99th percentile form; when 1997 standards were vacated, form of 1987 standards remained in place (not to be exceeded more than once per year on ave. over a three year period)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Annual</td>
<td>Annual arithmetic mean, ave. over 3 years</td>
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<tr>
<td>2006</td>
<td>PM₂₀.₅</td>
<td>24-hour</td>
<td>35 µg/m³</td>
<td>98th percentile, ave. over 3 years</td>
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</tbody>
</table>
Remand of 2006 PM NAAQS: Overview

• D.C. Circuit Court issued decision on February 24, 2009

• PM$_{2.5}$ standards:
  – Remanded primary annual PM$_{2.5}$ standard (retained at 15 µg/m$^3$) and secondary PM$_{2.5}$ standards (set identical to primary standards)
  – Primary 24-hour PM$_{2.5}$ standard (revised to 35 µg/m$^3$) not challenged

• PM$_{10}$ standards:
  – Upheld decisions to retain 24-hour PM$_{10}$ standard and revoke annual PM$_{10}$ standard
  – Based on finding EPA reasonably explained decision to regulate all coarse PM (including nonurban PM) and use of PM$_{10}$ as indicator for coarse PM
Remand: Primary Annual $\text{PM}_{2.5}$ Standard

- Court concluded EPA failed adequately to explain why annual $\text{PM}_{2.5}$ standard is sufficient to protect public health with an adequate margin of safety.

- Remanded annual standard for further consideration of:
  - Whether it provides an adequate margin of safety from the risk of short-term exposure to $\text{PM}_{2.5}$
  - Whether it provides an adequate margin of safety against morbidity in children and other vulnerable subpopulations.
PM$_{2.5}$ National Air Quality – 2007
PM$_{2.5}$ Speciation Select Urban Areas
2005-2007

Legend

- Yellow: Sulfate
- Red: Nitrate
- Black: EC
- Light Blue: OCM
- Brown: Crustal

20 µg/m$^3$
10 µg/m$^3$
Evidence-based Considerations

- Evidence-based considerations play central role in reviewing the PM NAAQS
  - Primary emphasis given to epidemiological evidence
  - Controlled human exposure and toxicological studies provide coherence and biological plausibility; support a number of potential biologic mechanisms or pathways for PM-related effects
  - Associations and related uncertainties generally characterized with regard to different size fractions, components, sources, and environments
  - Look for trend in ambient levels where adverse health effects are seen across epidemiology studies
  - Decision is complicated by lack of clear threshold, or lowest observable effects level
Effects Associated with Short-term Exposures to PM$_{2.5}$

- New multi-city U.S. studies
  - Use uniform methodologies to investigate the effects of PM$_{2.5}$ on health with data from multiple locations representing varying regions and seasons representative of different climate and air pollution mixes

- Premature mortality
  - All-cause
  - Cause-specific (cardiovascular- and respiratory-related)

- Morbidity effects as indexed by emergency department (ED) visits and hospitalizations including new Medicare cohort studies
  - Respiratory disease-related
  - Cardiovascular disease-related

- Focusing on effects observed in areas that would meet the current PM$_{2.5}$ NAAQS
Effects Associated with Long-Term Exposures to PM$_{2.5}$

- Extended analyses of large multi-city studies largely consistent with previous reports of premature mortality; strongest evidence for cardiovascular-related effects

- New study showing decrease in PM$_{2.5}$ concentrations associated with increased life expectancy

- New evidence of premature mortality and cardiovascular effects in post-menopausal women with no pre-existing cardiovascular effects

- New evidence of effects in at-risk populations
  - Extended analyses of So. California Children’s Health Study provide further evidence of respiratory symptoms and reduced lung function growth
  - New study of cystic fibrosis cohort
  - Emerging evidence for developmental effects

- Focusing on effects observed in areas that would meet the current PM$_{2.5}$ NAAQS
Effects Associated with Short-Term Exposure to PM$_{10-2.5}$

- More limited air quality data to consider in evaluating health evidence; measurement errors larger than for PM$_{2.5}$
- New multi-city US studies provide evidence of premature mortality
  - Different methods used for estimating ambient concentrations
  - Co-pollutant confounding
- Morbidity
  - Most consistent evidence is for asthma-related outcomes among children
  - Less consistent evidence among adults
Overview of PM 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 selected 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
Quantitative Risk Assessment
15 urban study areas and 7 regions
Figure 4-1. Estimated Percent Reductions From the Current Standards to Alternative Set of Standards in All Cause Mortality Associated with Long-Term Exposure to PM2.5 (source: US EPA, 2009)
Next Steps in Current PM NAAQS Review

• Finalize assessment documents – Dec 2009
  – Integrated Science Assessment
  – Quantitative Risk Assessment
  – Urban-focused Visibility Assessment

• Develop external review draft Policy Assessment for CASAC review and public comment – Feb 2010
Nitrogen Dioxide (NO$_2$)
Background: History of the NO$_2$ NAAQS

- 1971: Primary NAAQS set at 0.053 parts per million (ppm) (equivalent to 53 ppb), annual average
  - Based on epidemiologic studies that reported associations of long-term exposure to NO$_2$ with respiratory illness and lung function in children
  - Quantitative basis for the annual standard level was later called into question

- 1985 and 1996: Existing standard retained
  - Standard would maintain annual NO$_2$ concentrations considerably below long-term levels for which serious chronic effects have been observed in animals
  - Areas that met an annual standard of 53 ppb unlikely to experience 1-hour NO$_2$ concentrations that had been associated with respiratory effects in controlled human exposure studies

- September 2005: Deadline suit filed by Center for Biological Diversity (and others)

- Current Review scheduled to be completed on or before Jan 22, 2009
Background: NO₂ Air Quality

- All areas of the U.S. are currently in attainment
- Annual average ambient NO₂ levels, as measured at fixed-site monitors, decreased 41% between 1980 and 2006
  - National average now about 10-20 ppb
- However, because mobile sources are important sources of NO₂, concentrations on/near roadways can be appreciably higher than concentrations measured at fixed-site ambient monitors
  - Can be 30 to 100% higher near roads and 2- to 3-fold higher in vehicles
- Therefore, short-term NO₂ exposures would be considerably higher than indicated at ambient monitors in individuals who spend time near roadways and/or in vehicles on major roadways
Evidence for NO$_2$-Related Health Effects

• For purposes of characterizing health risks, focused on endpoints for which the evidence was judged sufficient to infer a **causal** or **likely causal** relationship
  – Adverse respiratory morbidity (e.g., respiratory symptoms, ED visits, hospital admissions, physiological endpoints)
  – Support comes from epidemiologic, controlled human exposure, and animal toxicological studies

• Evidence-based considerations including additional endpoints with suggestive evidence of a causal relationship
  – Cardiopulmonary and non-accidental mortality with short-term exposure
  – Respiratory morbidity with long-term exposure
NO₂: Overview of Epidemiologic Evidence

• Epidemiologic studies provide the strongest evidence supporting a link between NO₂ and adverse respiratory effects
  – A large number (50+) of studies of respiratory morbidity effects (i.e., symptoms, ED visits, hospital admissions) and short-term NO₂ exposure published since previous NO₂ NAAQS review
  – Look for trend in ambient levels where adverse health effects are seen across studies
    • Ambient, indoor, and personal NO₂ concentrations evaluated
    • Consistent results reported in studies of ambient concentrations conducted in multiple U.S. cities (e.g., Atlanta, LA, NYC) as well as cities in Canada, Asia, and Europe
      – In the locations where a number of these studies were conducted, NO₂ concentrations were below levels allowed by the current NO₂ NAAQS
Health Effects of NO₂: Overview of Controlled Human Exposure Evidence

- EPA conducted a meta-analysis that combined individual data from 19 separate studies on airway responsiveness in asthmatics.

- Meta-analysis reported that most asthmatics experienced an increase in airway responsiveness following exposure to NO₂ concentrations at or above 100 ppb.
  - Approximately 70% of asthmatics experienced an increase.
Rulemaking

- Proposed rule – July 15, 2009 - (74 FR 34404)
  - Scientific evidence
    - Calls into question the adequacy of the current standard to protect public health
    - Supports consideration of a short-term standard to provide increased health protection for at-risk populations
  - Exposure- and risk-based assessments reinforce need to revise current standard so as to provide increased public health protection
  - Proposed to strengthen the primary NAAQS by:
    - Adding a 1-hour NO₂ standard at a level between 80-100 ppb to focus on peak short-term exposures
    - Retaining annual NO₂ standard at a level of 53 ppb
  - EPA also proposed changes to the NO₂ air quality monitoring network

- Final rule – January 22, 2010
Revision to NAAQS for Lead
October 2008
Background - Lead (Pb) Air Pollution

- Pb occurs naturally and is emitted by many anthropogenic sources
  - Highest levels are generally found near lead smelters
- Pb is generally emitted into the air in the form of particles
  - Can end up in water, soil and dust on surfaces
- People are exposed by inhaling Pb in air or ingesting Pb that has settled onto surfaces or soils
  - Ingestion is the main route of human exposure to air Pb
  - Children are more likely to be exposed to Pb because they exhibit greater “hand-to-mouth” activity
  - Once in the body, Pb is rapidly absorbed into the bloodstream
- Pb is persistent
  - People can be exposed to Pb emitted just yesterday or years ago
Impacts of Lead on Public Health

• Broad range of health effects
  – Damage to the central nervous system, cardiovascular system, kidneys, immune system and red blood cells

• Effects in children include:
  – Effects on developing nervous system, which can cause impacts into adulthood include
    • IQ loss
    • Poor academic achievement, permanent learning disabilities, increased risk of delinquent behavior
  – Weakened immune system

• Effects in adults include:
  – Increased blood pressure
  – Cardiovascular disease
  – Decreased kidney function
Changes in Children’s Blood Lead Levels Since 1978

- Significant reduction
- From a median of 15 $\mu$g/dL in late 1970s to 1.6 $\mu$g/dL in 2003-04

www.epa.gov/envirohealth/children

DATA: Centers for Disease Control and Prevention, National Center for Health Statistics, National Health and Nutrition Examination Survey
http://epa.gov/envirohealth/children/body_burdens/b1-graph.htm
New Health Evidence in Recent Review

• Many new studies published since standard set in 1978
  – >6,000 published since 1990

• Serious health effects shown to occur at much lower blood Pb levels than those recognized as harmful in late 70s
  – Strong evidence of adverse effects at blood Pb levels well below 10 micrograms per deciliter (µg/dL)
  – No threshold or “safe” level for lead in blood has been identified

• Epidemiological studies in children demonstrate associations of blood Pb levels with loss of IQ and other neurocognitive effects
  – Results are remarkably consistent across numerous studies with varying designs and study populations
  – Associations have continued to be observed in most recent studies involving populations with lower blood Pb levels
  – The evidence indicates that the effect of Pb on IQ on incremental basis (per µg/dL) is greater at lower blood lead levels
Revisions to the Lead Standards: Level

- 1978 standard of 1.5 μg/m³ not requisite to protect public health with an adequate margin of safety
  - Health effects demonstrated at much lower exposures that we understood in the past
- Primary standard strengthened to a level of 0.15 μg/m³
  - Provides increased protection for public health
    - Especially the health of children and particularly for children near sources, where air levels are highest
    - In combination with decisions on indicator, averaging time and form - provides requisite protection of public health, including health of sensitive groups, with an adequate margin of safety
Revisions to the Lead Standards: Level (continued)

• Primary standard strengthened to a level of 0.15 μg/m³
  – Decision guided by framework that integrates evidence for relationships between …
    • Pb in air and Pb in children’s blood
      – Studies of children whose Pb exposures differ mainly with regard to air Pb levels
    • Pb in children’s blood and IQ loss
      – Studies of children’s IQ and blood Pb, with control for major IQ-influencing factors
  – Level of 0.15 μg/m³ estimated to protect against air Pb-related IQ loss in most exposed children
    • Based on weight of scientific evidence
  – Quantitative risk assessment results supportive of framework estimates
Revisions to the Lead Standards: Averaging Time and Form

• New standard is in terms of a maximum (not-to-be-exceeded) rolling three-month average evaluated over a three-year period.

• As compared to previous averaging time of calendar quarter, new standard is:
  – More scientifically appropriate
    • Rolling average gives equal weight to all three-month periods, and
    • New calculation method gives equal weight to each month within each three-month period
  – More health protective
    • Rolling average yields 12 three-month averages each year to be compared to the NAAQS (versus four averages in each year for block calendar quarters)
Revisions to the Lead Standards: Indicator

- Pb in total suspended particles (Pb-TSP) retained as indicator
  - Reflects evidence that Pb particles of all sizes pose health risks

- Use of Pb-PM$_{10}$ monitoring allowed in place of Pb-TSP monitoring in certain limited circumstances
More Information on All NAAQS Reviews

http://www.epa.gov/ttn/naaqs/