U.S. National Ambient Air Quality Standards (NAAQS) Program

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Outline

• Strengths of U.S. Air Quality Standards System
• NAAQS Statutory Requirements
• Current NAAQS Standards
• NAAQS Review Process
  – Integrated Science Assessment
  – Risk and Exposure
  – Policy Assessment
  – Rulemaking
• NAAQS Designation and Implementation Process
• Air Quality Trends
Strengths of U.S. Air Quality Standards System

• Clear legislation on air quality standard setting
  - Based on extensive scientific review in order to protect public health and welfare
  - Mechanisms to address interstate transport of pollution
  - Non-attainment areas classified by severity of air pollution problem
  - EPA required to review NAAQS every 5 years

• Robust implementation and enforcement process of NAAQS
  - EPA "designates" an area based on whether or not it is meeting the standard
  - EPA approves and enforces State Implementation Plans
  - EPA develops detailed guidance to interpret NAAQS requirements to assist States
  - Stringency of requirements for attaining NAAQS based on severity of air pollution problem
Background and Statutory Requirements

- EPA sets National Ambient Air Quality Standards (NAAQS) for six criteria pollutants; the Clean Air Act requires EPA to **review the standards every 5 years**
  - Ground-level ozone
  - Carbon monoxide
  - Oxides of Nitrogen
  - Particulate matter
  - Lead
  - Oxides of Sulfur

- **Primary (health-based) standards**: in the “judgment of the Administrator” must be “requisite” to protect public health with an “adequate margin of safety”
  - The term requisite means “sufficient, but not more than necessary” [a zero-risk standard is neither possible nor required]
  - By requiring an “adequate margin of safety”, Congress was directing EPA to build a buffer to protect against uncertain and unknown dangers to human health

- **Secondary (welfare-based) standards**: “…specify a level of air quality the attainment and maintenance of which” in the “judgment of the Administrator” are “requisite to protect the public welfare from any known or anticipated adverse effects”
  - Welfare effects include “effects on soils, water, crops, vegetation, man-made materials, animals, wildlife, weather, visibility and climate . . .”

- In setting NAAQS, EPA is **barred from considering the cost of implementing the standards** or adjusting a protective standard solely on the basis of attainability in light of background concentrations of the pollutant
## Summary of Current U.S. Standards

<table>
<thead>
<tr>
<th>Pollutant</th>
<th>Type</th>
<th>Averaging Time</th>
<th>Level</th>
<th>Form</th>
</tr>
</thead>
<tbody>
<tr>
<td>Carbon Monoxide (CO)</td>
<td>primary</td>
<td>8 hours</td>
<td>9 ppm</td>
<td>Not to be exceeded more than once per year</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1 hour</td>
<td>35 ppm</td>
<td></td>
</tr>
<tr>
<td>Lead (Pb)</td>
<td>primary &amp; secondary</td>
<td>Rolling 3-month average</td>
<td>0.15 µg/m³</td>
<td>Not to be exceeded</td>
</tr>
<tr>
<td>Nitrogen Dioxide (NO₂)</td>
<td>primary</td>
<td>1 hour</td>
<td>100 ppb</td>
<td>98th percentile of 1-hour daily maximum concentrations, averaged over 3 years</td>
</tr>
<tr>
<td></td>
<td>primary &amp; secondary</td>
<td>1 year</td>
<td>53 ppb</td>
<td>Annual mean</td>
</tr>
<tr>
<td>Ozone (O₃)</td>
<td>primary &amp; secondary</td>
<td>8 hours</td>
<td>0.070 ppm</td>
<td>Annual fourth highest daily maximum 8-hour concentration, averaged over 3 years</td>
</tr>
<tr>
<td>Particle Pollution (PM)</td>
<td>PM₂.₅</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>primary</td>
<td>1 year</td>
<td>12.0 µg/m³</td>
<td>annual mean averaged over 3 years</td>
</tr>
<tr>
<td></td>
<td>secondary</td>
<td>1 year</td>
<td>15.0 µg/m³</td>
<td></td>
</tr>
<tr>
<td></td>
<td>primary &amp; secondary</td>
<td>24 hours</td>
<td>35 µg/m³</td>
<td>98th percentile, averaged over 3 years</td>
</tr>
<tr>
<td></td>
<td>PM₁₀</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>primary &amp; secondary</td>
<td>24 hours</td>
<td>150 µg/m³</td>
<td>Not to be exceeded more than once per year on average over 3 years</td>
</tr>
<tr>
<td>Sulfur Dioxide (SO₂)</td>
<td>primary</td>
<td>1 hour</td>
<td>75 ppb</td>
<td>99th percentile of 1-hour daily maximum concentration, averaged over 3 years</td>
</tr>
<tr>
<td></td>
<td>secondary</td>
<td>3 hours</td>
<td>0.5 ppm</td>
<td>Not to be exceeded more than once per year</td>
</tr>
</tbody>
</table>
NAAQS Review Process: Overview

**Planning:** consideration of new scientific information, policy-relevant issues, and other factors relevant to the review
- Call for Information
- Workshop (if warranted)
- Planning Documents

**Assessment:** analysis of current scientific information and its policy implications with regard to standards (indicator, averaging time, form, level)
- Integrated Science Assessment
- Risk/Exposure Assessments (if warranted)
- Policy Assessment

**Rulemaking:** Agency decision making, interagency review and public comment process
- Proposed Decision
- Final Decision

Clean Air Scientific Advisory Committee (CASAC) review
Integrated Science Assessment (ISA)

- Comprehensive evaluation and synthesis of the policy-relevant scientific information that is the foundation for the review
  - Characterization of the strengths and uncertainties of the evidence
  - Conclusions on causality for health and welfare effects
  - Characterization of evidence for at-risk populations
  - Assessment of evidence for dose/concentration-response relationships

http://www.epa.gov/isa
ISA Causality Determinations

- Organize relevant literature for broad health and welfare effect categories
- Evaluate studies, characterize results, extract relevant data
- Integrate evidence across disciplines for health and welfare outcome categories
- Develop causality determinations using established framework
- Evaluate evidence for populations potentially at increased risk
- Consideration of evidence spans many scientific disciplines from source to effect

**Example: Health Effects Integration**
- Atmospheric chemistry
- Exposure
- Controlled human exposure studies
- Epidemiologic studies
- Animal toxicologic studies
- At-risk populations/lifestages

**Informs Hazard Identification step of Risk Assessment Process**
Weight-of-Evidence Approach for Causality Determinations for Health and Welfare Effects

• Provides transparency through structured framework
• Developed and applied in ISAs for all criteria pollutants
• Emphasizes synthesis of evidence across scientific disciplines

• **Five categories** based on overall weight-of-evidence:
  - Causal relationship
  - Likely to be a causal relationship
  - Suggestive of, but not sufficient to infer, a causal relationship
  - Inadequate to infer the presence or absence of a causal relationship
  - Not likely to be a causal relationship
**Ex: PM ISA Health Effects Causality Determinations**

<table>
<thead>
<tr>
<th>Human Health Impacts</th>
<th>PM$_{2.5}$</th>
<th>PM$_{10}$</th>
</tr>
</thead>
<tbody>
<tr>
<td>Respiratory</td>
<td>Short-term Likely Casual</td>
<td>Suggestive</td>
</tr>
<tr>
<td></td>
<td>Long-term Likely Casual</td>
<td>Inadequate</td>
</tr>
<tr>
<td>Cardiovascular</td>
<td>Short-term Casual</td>
<td>Suggestive</td>
</tr>
<tr>
<td></td>
<td>Long-term Casual</td>
<td>Suggestive</td>
</tr>
<tr>
<td>Metabolic</td>
<td>Short-term Suggestive</td>
<td>Inadequate</td>
</tr>
<tr>
<td></td>
<td>Long-term Suggestive</td>
<td>Suggestive</td>
</tr>
<tr>
<td>Nervous System</td>
<td>Short-term Suggestive</td>
<td>Inadequate</td>
</tr>
<tr>
<td></td>
<td>Long-term Likely Casual</td>
<td>Suggestive</td>
</tr>
<tr>
<td>Reproduction and Fertility</td>
<td>Long-term Suggestive</td>
<td>Inadequate</td>
</tr>
<tr>
<td>Pregnancy and Birth Outcomes</td>
<td>Long-term Suggestive</td>
<td>Inadequate</td>
</tr>
<tr>
<td>Cancer</td>
<td>Long-term Likely Casual</td>
<td>Suggestive</td>
</tr>
<tr>
<td>Mortality</td>
<td>Short-term Casual</td>
<td>Suggestive</td>
</tr>
<tr>
<td></td>
<td>Long-term Casual</td>
<td>Suggestive</td>
</tr>
</tbody>
</table>
Assessing Causality from a Multidisciplinary Evidence Base for National Ambient Air Quality Standards

• A committee of the National Academies of Sciences, Engineering, and Medicine will consider frameworks to assess causality of health and welfare effects of air pollutants in EPA’s Integrated Science Assessments (ISAs) conducted as part of EPA reviews of National Ambient Air Quality Standards (NAAQS).

• Advances for integrating scientific evidence will be assessed, and issues concerning confounders, the most useful types of evidence for causal determinations, and whether a single framework for assessing causality is applicable to both health and welfare effects will be considered.

• Recommendations regarding the development and use of future ISA frameworks and priority research will be described.

Risk and Exposure Analyses

The nature and strength of evidence influences selection of appropriate quantitative risk characterization model.

- **Air Quality Monitoring/Modeling**
  - Estimates of ambient air concentrations

- **Exposure Modeling**
  - Estimates of inhalation exposure concentrations
  - Exposure-response and/or health effect-based benchmarks (e.g., O₃, NO₂, SO₂)

- **Dosimetry Modeling**
  - Estimates of internal biomarker concentration (e.g., CO, Pb)

- **Risk Assessment/Characterization**
  - Ambient concentration-response (e.g., PM, O₃)
Evaluating At-Risk Populations

• Quantitative risk and exposure analyses attempt to characterize impacts to U.S. populations, including at-risk groups (children, older adults, people with preexisting disease, etc.)

• Informs the Administrator’s judgement regarding what standard provides an adequate margin of safety

• Example: **PM$_{2.5}$ At-Risk Analysis**
  - 2019 PM ISA and 2022 PM ISA Supplement provide strong evidence for racial and ethnic disparities in PM$_{2.5}$ exposures and PM$_{2.5}$-related health risk
  - EPA used CR functions stratified by race/ethnicity from the Di et al. (2017) Medicare analysis to evaluate how mortality risk changes under alternative standards (evaluated those > 64 years old in U.S.)
PM$_{2.5}$ At-Risk Analysis

Average reduction in PM2.5 exposure concentrations and PM2.5-attributable risk estimates by demographic population when moving from the current to alternative PM2.5 standards.

<table>
<thead>
<tr>
<th>Study Areas</th>
<th>Modeling Scenario</th>
<th>Just meeting 12/35 µg/m$^3$</th>
<th>Just meeting 10/30 µg/m$^3$</th>
<th>Just meeting 12/35 µg/m$^3$</th>
<th>Interpolated to 11 µg/m$^3$</th>
<th>Just meeting 10/30 µg/m$^3$</th>
<th>Extrapolated to 9 µg/m$^3$</th>
<th>Extrapolated to 8 µg/m$^3$</th>
</tr>
</thead>
<tbody>
<tr>
<td>47 areas</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>30 areas</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- White
- Black
- Hispanic
- Asian
- Native American
Policy Assessment

- Presents conclusions regarding the policy options supported by the current scientific evidence and quantitative assessments
- Considers all elements of the standard: indicator, averaging time, form, level

Does the evidence call into question the adequacy of existing standard(s)?
- Scientific evidence assessed in ISA
- Quantitative exposure/risk assessments
- CASAC advice
- Public input

Yes
- Consider revising existing standard(s)

No
- Consider retaining existing standard(s)

Identify array of potential alternative standards appropriate for consideration, based on the evidence, quantitative assessments, CASAC advice, public input
NAAQS Process: Regulatory Steps

• The Agency decision-making process for the proposed and final rulemaking decisions includes internal EPA deliberation of key issues and decisions, development of proposed and final decision notices and review of draft notices by other federal agencies
  - Interagency review is coordinated through the Office of Management and Budget
• Final decisions are informed by scientific evidence, any quantitative analyses conducted, staff conclusions in the PA, CASAC advice, and public comments on the proposal
NAAQS Designations & Implementation

EPA revises National Ambient Air Quality Standards, Monitoring Requirements

EPA Designates Nonattainment Areas

Scientific Research

Ongoing Evaluation by EPA and Air Agency: Air Quality Monitoring, Tracking Emissions and Implementation of Control Programs

Air Agency Submits Plan to EPA and Implements Control Strategies Through Regulatory and Non-regulatory Approaches

Air Agency Assesses Expected Improvement From Federal Measures, and Develops Additional Control Strategies to Attain Standards
NAAQS Designations & Implementation

• Once EPA revises a NAAQS, states provide recommendations on nonattainment areas within 1 year, and EPA is obligated to designate nonattainment areas within 2-3 years based on air quality data, state recommendations, and other factors
  - “Nonattainment area” is an area with air quality that violates the standard, plus the nearby area with sources that contribute to air quality levels that exceed the standard

• States must submit an attainment plan (state implementation plan, SIP) within 18-36 months after nonattainment area designation (depends on the pollutant)
  - Must demonstrate attainment “as expeditiously as practicable”, and no later than defined deadlines tied to the severity of nonattainment
  - Considers expected reductions from existing federal and state programs, as well as additional emission reduction measures from sources in the nonattainment area
  - Includes contingency measures to apply in the event the area fails to attain by its attainment date
  - Plan must be adopted by the state after public notice and comment and must be submitted to EPA for review and approval

• To be redesignated to attainment, state must submit a clean data record
Air Quality Trends Show Clean Air Progress

Nationally, concentrations of air pollutants have dropped significantly since 1990:

- Carbon Monoxide (CO) 8-Hour, ↓ 79%
- Lead (Pb) 3-Month Average, ↓ 85% (from 2010)
- Nitrogen Dioxide (NO₂) Annual, ↓ 61%
- Nitrogen Dioxide (NO₂) 1-Hour, ↓ 54%
- Ozone (O₃) 8-Hour, ↓ 21%
- Particulate Matter 10 microns (PM₁₀) 24-Hour, ↓ 32%
- Particulate Matter 2.5 microns (PM₂.₅) Annual, ↓ 37% (from 2000)
- Particulate Matter 2.5 microns (PM₂.₅) 24-Hour, ↓ 33% (from 2000)
- Sulfur Dioxide (SO₂) 1-Hour, ↓ 91%
- Numerous air toxics have declined with percentages varying by pollutant
Thank you

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