The Role of Science and Scientific Advice in Review of the Ozone NAAQS

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DISCLAIMER

• These are my **personal views**
• They do not represent any official position of U.S. Environmental Protection Agency (EPA) or the EPA Clean Air Scientific Advisory Committee (CASAC)
Overview

• Statutory Mandate
• NAAQS Review Process
• Example for Ozone
• Multipollutant Air Quality Management
CASAC

- Clean Air Scientific Advisory Committee (CASAC)
- Independent advice to the EPA Administrator on technical bases for National Ambient Air Quality Standards (NAAQS).
- Established in 1977 under the Clean Air Act (CAA) Amendments of 1977
Statutory Mandate for National Ambient Air Quality Standards

- Section 108 of Clean Air Act
  - Identify and list certain air pollutants
  - Issue air quality criteria for those pollutants.
  - In Administrator’s “judgment, cause or contribute to air pollution which may reasonably be anticipated to endanger public health or welfare;”
  - “the presence of which in the ambient air results from numerous or diverse mobile or stationary sources;”
  - “accurately reflect the latest scientific knowledge”
National Ambient Air Quality Standards: “Primary Standard”

• “the attainment and maintenance of which in the judgment of the Administrator, based on such criteria and allowing an adequate margin of safety, are requisite to protect the public health.”
  – Intended to address uncertainties
  – Reasonable degree of protection
  – Does not require zero risk
  – Interpretation has been reviewed in numerous court cases
“Adequate Margin of Safety”

Factors considered by EPA:

• nature and severity of the health effects
• size of sensitive population(s) at risk, and
• the kind and degree of uncertainties
National Ambient Air Quality Standards: “Secondary Standard”

• “specify a level of air quality the attainment and maintenance of which, in the judgment of the Administrator, based on such criteria, is requisite to protect the public welfare from any known or anticipated adverse effects associated with the presence of [the] pollutant in the ambient air.”

• “Welfare” generally refers to endpoints other than human health. Examples
  – Ecological impact
  – Reduction in visibility
  – Damage to materials
Cost and Standard Setting

• In setting a NAAQS, EPA may not consider costs of implementing the standards (Whitman v. American Trucking Associations, 2001).

• “[a]ttainability and technological feasibility are not relevant considerations in the promulgation of national ambient air quality standards.” (American Petroleum Institute v. Costle)
Key Elements of a NAAQS

• Indicator (Pollutant)
• Level
• Averaging Time
• Form
Current National Ambient Air Quality Standards (NAAQS) as of October 2014

<table>
<thead>
<tr>
<th>Pollutant [final rule cite]</th>
<th>Primary/Secondary</th>
<th>Averaging Time</th>
<th>Level</th>
<th>Form</th>
</tr>
</thead>
<tbody>
<tr>
<td>Carbon Monoxide [76 FR 54294, Aug 31, 2011]</td>
<td>primary</td>
<td>8-hour</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 [73 FR 66964, Nov 12, 2008]</td>
<td>primary and secondary</td>
<td>Rolling 3 month average</td>
<td>0.15 μg/m^3 (1)</td>
<td>Not to be exceeded</td>
</tr>
<tr>
<td>Nitrogen Dioxide [75 FR 6474, Feb 9, 2010] [61 FR 52852, Oct 8, 1996]</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 and secondary</td>
<td>Annual</td>
<td>53 ppb (2)</td>
<td>Annual Mean</td>
</tr>
<tr>
<td>Ozone [73 FR 16436, Mar 27, 2008]</td>
<td>primary and secondary</td>
<td>8-hour</td>
<td>0.075 ppm (3)</td>
<td>Annual fourth-highest daily maximum 8-hr concentration, averaged over 3 years</td>
</tr>
<tr>
<td></td>
<td>PM_{2.5}</td>
<td>Annual</td>
<td>12 μg/m^3</td>
<td>annual mean, averaged over 3 years</td>
</tr>
<tr>
<td></td>
<td>secondary</td>
<td>Annual</td>
<td>15 μg/m^3</td>
<td>annual mean, averaged over 3 years</td>
</tr>
<tr>
<td></td>
<td>primary and secondary</td>
<td>24-hour</td>
<td>35 μg/m^3</td>
<td>98th percentile, averaged over 3 years</td>
</tr>
<tr>
<td></td>
<td>PM_{10}</td>
<td>primary and secondary</td>
<td>24-hour</td>
<td>150 μg/m^3</td>
</tr>
<tr>
<td>Sulfur Dioxide [75 FR 35520, Jun 22, 2010] [38 FR 25678, Sept 14, 1973]</td>
<td>primary</td>
<td>1-hour</td>
<td>75 ppb (4)</td>
<td>99th percentile of 1-hour daily maximum concentrations, averaged over 3 years</td>
</tr>
<tr>
<td></td>
<td>secondary</td>
<td>3-hour</td>
<td>0.5 ppm</td>
<td>Not to be exceeded more than once per year</td>
</tr>
</tbody>
</table>

Primary (health-based) and secondary (welfare-based) standards. Units of measure are parts per million (ppm), parts per billion (ppb) or micrograms per cubic meter of air (μg/m^3). For more information about the standards, visit [http://www.epa.gov/ttn/naaqs/](http://www.epa.gov/ttn/naaqs/).
Statutory Mandate for Five Year Review Cycle

• Section 109(d)(1) requires that “not later than December 31, 1980, and at 5-year intervals thereafter, the Administrator shall complete a thorough review of the criteria published under section 108 and the national ambient air quality standards . . . and shall make such revisions in such criteria and standards and promulgate such new standards as may be appropriate . . . .”
“Thank God! A panel of experts!”
Statutory Mandate for CASAC

• Section 109(d)(2) requires that an independent scientific review committee
  – “shall complete a review of the criteria . . .
  – “and the national primary and secondary ambient air quality standards . . .
  – “and shall recommend to the Administrator any new . . . standards and revisions of existing criteria and standards as may be appropriate . . . .”
NAAQS Review Process
(since 2006, with revisions)
NAAQS Review Process

- IRP Integrated Review Plan
- ISA Integrated Science Assessment
- REA Risk and Exposure Assessment
- PA Policy Assessment
Integrated Science Assessments

- Integrated Science Assessment for Carbon Monoxide
- Integrated Science Assessment for Ozone and Related Photochemical Oxidants
- Integrated Science Assessment for Particulate Matter
- Integrated Science Assessment for Oxides of Nitrogen and Sulfur — Ecological Criteria
- Integrated Science Assessment for Oxides of Nitrogen — Health Criteria
- Integrated Science Assessment for Sulfur Oxides - Health Criteria
- Integrated Science Assessment for Lead
Key Science Issues (Examples)

- Identification of adverse effects
- Weight of evidence determinations
- Basis for quantifying dose-response
  - Clinical studies
  - Toxicology
  - Epidemiologic studies
  - Other (e.g., surveys)
- Metric of exposure
  - Exposure concentration?
  - Ambient concentration?
- Background levels
- Air quality monitoring methods and data
- Air quality modeling
- Quantification of ecosystem effects
- Quantification of other welfare effects
Association and Causality

I used to think correlation implied causation.
Then I took a statistics class. Now I don't.
Sounds like the class helped.
Well, maybe.
### Causal relationship

Evidence is sufficient to conclude that there is a causal relationship with relevant pollutant exposures (e.g., doses or exposures generally within one to two orders of magnitude of current levels). That is, the pollutant has been shown to result in health effects in studies in which chance, confounding, and other biases could be ruled out with reasonable confidence. For example: (1) controlled human exposure studies that demonstrate consistent effects; or (2) observational studies that cannot be explained by plausible alternatives or that are supported by other lines of evidence (e.g., animal studies or mode of action information). Generally, the determination is based on multiple high-quality studies conducted by multiple research groups.

### Likely to be a causal relationship

Evidence is sufficient to conclude that a causal relationship is likely to exist with relevant pollutant exposures. That is, the pollutant has been shown to result in health effects in studies where results are not explained by chance, confounding, and other biases, but uncertainties remain in the evidence overall. For example: (1) observational studies show an association, but copollutant exposures are difficult to address and/or other lines of evidence (controlled human exposure, animal, or mode of action information) are limited or inconsistent; or (2) animal toxicological evidence from multiple studies from different laboratories demonstrate effects, but limited or no human data are available. Generally, the determination is based on multiple high-quality studies.

### Suggestive of a causal relationship

Evidence is suggestive of a causal relationship with relevant pollutant exposures, but is limited. For example, (1) at least one high-quality epidemiologic study shows an association with a given health outcome although inconsistencies remain across other studies that are or are not of comparable quality; or (2) a well-conducted toxicological study, such as those conducted in the National Toxicology Program (NTP), shows effects relevant to humans in animal species.

### Inadequate to infer a causal relationship

Evidence is inadequate to determine that a causal relationship exists with relevant pollutant exposures. The available studies are of insufficient quantity, quality, consistency, or statistical power to permit a conclusion regarding the presence or absence of an effect.

### Not likely to be a causal relationship

Evidence indicates there is no causal relationship with relevant pollutant exposures. Several adequate studies, covering the full range of levels of exposure that human beings are known to encounter and considering at-risk populations and lifestages, are mutually consistent in not showing an effect at any level of exposure.

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**Rule out chance, confounding, and other biases**

- Consistency, coherence, biological plausibility, high-quality studies

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**Evidence is limited**

- Associations found in some high-quality studies but other results inconsistent

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**Evidence is of insufficient quantity, quality, consistency**

**Multiple studies show no effect across exposure concentrations**
### Matrix of Causal Determinations from Recent ISAs

<table>
<thead>
<tr>
<th>Outcome Category</th>
<th>Exposure Period</th>
<th>NO$_2$ (2008 ISA)</th>
<th>SO$_2$ (2008 ISA)</th>
<th>PM$_{2.5}$ (2009 ISA)</th>
<th>PM$_{10-2.5}$ (2009 ISA)</th>
<th>CO (2010 ISA)</th>
<th>O$_3$ (2013 ISA)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cardiovascular Morbidity</td>
<td>Short-term</td>
<td>Inadequate</td>
<td>Inadequate</td>
<td><strong>Causal</strong></td>
<td>Suggestive</td>
<td>Likely Causal</td>
<td>Likely Causal</td>
</tr>
<tr>
<td>Respiratory Morbidity</td>
<td>Short-term</td>
<td>Likely Causal</td>
<td><strong>Causal</strong></td>
<td>Likely Causal</td>
<td>Suggestive</td>
<td>Suggestive</td>
<td><strong>Causal</strong></td>
</tr>
<tr>
<td>Mortality</td>
<td>Short-term</td>
<td>Suggestive</td>
<td>Suggestive</td>
<td><strong>Causal</strong></td>
<td>Suggestive</td>
<td>Suggestive</td>
<td>Likely Causal</td>
</tr>
<tr>
<td>Cardiovascular Morbidity</td>
<td>Long-term</td>
<td>Inadequate</td>
<td>Inadequate</td>
<td><strong>Causal</strong></td>
<td>Inadequate</td>
<td>Inadequate</td>
<td>Suggestive</td>
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<tr>
<td>Respiratory Morbidity</td>
<td>Long-term</td>
<td>Suggestive</td>
<td>Inadequate</td>
<td>Likely Causal</td>
<td>Inadequate</td>
<td>Inadequate</td>
<td>Likely Causal</td>
</tr>
<tr>
<td>Developmental and Birth Outcomes</td>
<td>Long-term</td>
<td>Inadequate</td>
<td>Inadequate</td>
<td>Suggestive</td>
<td>Inadequate</td>
<td>Suggestive</td>
<td>Suggestive</td>
</tr>
<tr>
<td>Mortality</td>
<td>Long-term</td>
<td>Inadequate</td>
<td>Inadequate</td>
<td><strong>Causal</strong></td>
<td>Inadequate</td>
<td>Suggestive of No Causal Relationship</td>
<td>Suggestive</td>
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*Causality Determination*
Ozone
# Members of the Clean Air Scientific Advisory Committee

<table>
<thead>
<tr>
<th>Name</th>
<th>Institution</th>
<th>Location</th>
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<tbody>
<tr>
<td>Frey, H. Christopher</td>
<td>Chair, North Carolina State University</td>
<td>Raleigh, NC</td>
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<tr>
<td>Allen, George A.</td>
<td>Northeast States for Coordinated Air Use Management (NESSCAUM)</td>
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<td>Diez-Roux, Ana</td>
<td>Drexel University</td>
<td>Philadelphia, PA</td>
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<td>Harkema, Jack</td>
<td>Michigan State University</td>
<td>East Lansing, MI</td>
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<td>Suh, Helen</td>
<td>Northeastern University</td>
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<td>Weathers, Kathleen</td>
<td>Cary Institute of Ecosystem Studies</td>
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<tr>
<td>Wyzga, Ronald</td>
<td>Electric Power Research Institute</td>
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Ozone Review Panel

The CASAC Ozone Review Panel is charged with providing advice on the scientific and technical aspects of the policy-relevant science and the National Ambient Air Quality Standards (NAAQS) for ozone.

<table>
<thead>
<tr>
<th>Members:</th>
<th>Chair</th>
<th>Institution</th>
<th>City</th>
<th>State</th>
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<td>Frey, H. Christopher</td>
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<td>Avol, Ed</td>
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<td>Los Angeles</td>
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<td>New Haven</td>
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<td>Grantz, David A.</td>
<td>University of California at Riverside, Kearney Agricultural Center</td>
<td>Parlier</td>
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<td>National Institutes of Health</td>
<td>Research Triangle Park</td>
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<td>Palo Alto</td>
<td>CA</td>
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Review Process for the Ozone NAAQS

- June 2011, draft Scope and Methods Plan (EPA-CASAC-11-008).
- November 2012
  - third draft of the Integrated Science Assessment (EPA-CASAC-13-001)
  - first draft Risk and Exposure Assessments for both human health and public welfare adverse effects. “works in progress” (EPA-CASAC-13-002)
  - first draft of the Policy Assessment (PA), “the PA needs substantial improvement” (EPA-CASAC-13-003)
- March to June 2014:
  - Second draft of the Risk and Exposure Assessment for human health (EPA-CASAC-14-005)
  - Second draft of the Risk and Exposure Assessment for public welfare (EPA-CASAC-14-003)
  - Second draft of the Policy Assessment (EPA-CASAC-14-004)
Source: Reprinted with permission of Nature Publishing Group (Klepeis et al., 2001).

Figure 4-3 Distribution of time that NHAPS respondents spent in ten microenvironments based on smoothed 1-min diary data.
Exposure to Ozone

• Ratios of Indoor to Outdoor Exposure typically range from 0.1 to 0.4
• Ratios of personal exposure to ambient concentrations typically range from 0.1 to 0.3
Ozone Averting Behavior

• Individuals can reduce their exposure to O$_3$ by
  – staying indoors
  – scheduling outdoor activity during periods of low O$_3$ concentration,
  – reducing activity levels or time spent being active outdoors on high-O$_3$ days

• Evidence of individual averting behaviors in response to advisories has been found in several studies, especially for potentially susceptible populations, such as children, older adults, and asthmatics
Health Effects Evidence

• “Mode of Action” – what are the biological mechanisms by which adverse effects occur?
• Epidemiology – what are the statistical associations between exposure and adverse effect
• Clinical studies – controlled exposures for healthy adult volunteer subjects
Exposure-to-Outcome Continuum

Note: Ozone transport follows a path from exposure concentration, to inhaled dose, to net dose, to the local tissue dose. Chapter 5 discusses the concepts of dose and modes of action that result in the health effects discussed in Chapters 6 and 7.

Figure 5-1 Schematic of the O₃ exposure and response pathway.
Clinical Studies

• Healthy adult human subjects
• Exposed to controlled levels of ozone in a lab
• Adverse effect:
  – Reduction in “FEV1” Forced Expiratory Volume in 1 second
  – Evidence of “inflammation” of airways
  – FEV1 decrement of ≥10% with inflammation is considered an adverse effect by the American Thoracic Society
## Exposure and Risk Modifiers

### Table 8-6
Summary of evidence for potential increased risk of O₃-related health effects.

<table>
<thead>
<tr>
<th>Evidence Classification</th>
<th>Potential At Risk Factor</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adequate evidence</td>
<td>Genetic factors (<a href="#">Section 8.1</a>)</td>
</tr>
<tr>
<td></td>
<td>Asthma (<a href="#">Section 8.2.2</a>)</td>
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<td></td>
<td>Children (<a href="#">Section 8.3.1.1</a>)</td>
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<td></td>
<td>Older adults (<a href="#">Section 8.3.1.2</a>)</td>
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<td></td>
<td>Diet (<a href="#">Section 8.4.1</a>)</td>
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<td>Outdoor workers (<a href="#">Section 8.4.4</a>)</td>
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<td>Suggestive evidence</td>
<td>Sex (<a href="#">Section 8.3.2</a>)</td>
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<td>SES (<a href="#">Section 8.3.3</a>)</td>
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<td></td>
<td>Obesity (<a href="#">Section 8.4.2</a>)</td>
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<td>Inadequate evidence</td>
<td>Influenza/Infection (<a href="#">Section 8.2.1</a>)</td>
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<td>COPD (<a href="#">Section 8.2.3</a>)</td>
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<td>Smoking (<a href="#">Section 8.4.3</a>)</td>
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<td>Air conditioning use (<a href="#">Section 8.4.5</a>)</td>
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<tr>
<td>Evidence of no effect</td>
<td>--</td>
</tr>
</tbody>
</table>
Figure 3-2 Conceptual Diagram for Population Exposure Assessment
Figure 3-3  Conceptual Diagram of O₃ Lung Function Health Risk Assessment Based on Controlled Human Exposure Studies
CASAC Findings on the Health Risk and Exposure Assessment (HREA) (1)

• For air quality characterization:
  – Old “quadratic rollback” approach replaced by a Higher-order Decoupled Direct Method (HDDM).
  – HDDM uses the Community Multi-scale Air Quality (CMAQ) photochemical model to simulate the changes in ozone concentrations under the conditions of “just meeting” the existing ozone standard or a different alternative standard, based on reductions in U.S. anthropogenic emissions of oxides of nitrogen and volatile organic compounds.
  – Sources of background ozone are incorporated in the modeling.
  – Separate specification of U.S. background ozone concentrations is unnecessary.
CASAC Findings on the Health Risk and Exposure Assessment (HREA) (2)

• For characterization of human exposure to ozone
  – “The CASAC found that the methods are generally well-presented and are technically sound, particularly with regard to the description of data inputs, the modeling process, and the results.”
CASAC Findings on the Health Risk and Exposure Assessment (HREA) (3)

- “ample scientific evidence from human controlled exposure and epidemiology studies that adverse health effects in young healthy adults occur with exposures to 72 ppb of ozone for 6.6 hours.” (i.e. current standard is not adequate)
- “if subjects had been exposed to ozone using the longer 8-hour averaging period used in the standard, adverse effects would have occurred at lower concentration than 72 ppb.
- “the level at which adverse effects might be observed would likely be lower than 72 ppb for an 8-hour averaging period for more sensitive subgroups, such as those with asthma.”
CASAC Findings on the Health Risk and Exposure Assessment (HREA) (4)

• “reductions in percentage of clinically significant decrements in FEV1 in both children and outdoor workers for the above alternative standard scenarios underscore the need for the current ozone standard to be lower to be protective of public health.”

• Epidemiology-based results: “Based on analysis of 12 selected urban areas representative of the U.S. population, the EPA has appropriately estimated... the annual mean number of premature deaths avoidable for short-term exposure to ozone”
CASAC Findings on the Health Risk and Exposure Assessment (HREA) (5)

• For the long-term mortality estimates, which are based on one (good) epidemiologic study, CASAC recommended more acknowledgment of uncertainty.

• “CASAC finds that there is sufficient scientific certainty of adverse effects based on clinical studies, based on short-term epidemiological studies, and based on the short-term exposure and risk estimates of the HREA, that these sources of information provide a sufficient basis for review and revision of the standard.”
the current primary NAAQS for ozone “is not protective of human health.”

“there is a causal relationship between short-term ozone exposure and a broad range of respiratory effects, including lung function decrements, respiratory symptoms, inflammation, hospital admissions, and emergency department visits”

“all of which are observed below the level of the current ozone NAAQS”
CASAC Findings on the Welfare Risk and Exposure Assessment (WREA) (1)

• “The Second Draft WREA offers scientifically defensible estimates of the impact of ozone exposure on tree biomass loss, crop yields and visible foliar injury.”

• “The estimates of exposures that correspond to predicted levels of tree biomass loss, crop loss and visible foliar injury using the W126 index (a sigmoidally weighted seasonal sum of hourly ozone concentrations) found in the Second Draft WREA are derived with scientifically defensible data, models and assumptions.”
CASAC Findings on the Welfare Risk and Exposure Assessment (WREA) (2)

• “The CASAC supports the EPA’s ecosystem services approach and finds that the analyses at the national scale and case study scale provide scientifically defensible estimates of effects on these services.”

• “Included in these estimates are the effects of biomass loss on timber production, food production, carbon sequestration, and the effects of visible foliar injury on aesthetic values and outdoor recreation.”

• “these estimates represent the current state of the science”
CASAC Findings on the Welfare Risk and Exposure Assessment (WREA) (3)

• Regarding W126, CASAC “reaffirms here its biological relevance and superiority to the current metric for assessing the welfare impacts of ozone.”

• “the current form of the standard is much less biologically relevant for protecting vegetation than is a seasonal, peak weighted index such as the W126, which was designed to measure the cumulative effects of ozone exposure.”
Key Findings from CASAC Review: Primary Ozone NAAQS

• Exposure to ozone for relatively short periods of time (e.g., 8 hours) at high enough levels leads to reduction in lung function, pulmonary inflammation, respiratory symptoms and illness, and premature mortality.

• People with asthma, children, the elderly, and outdoor workers are among groups of people who are either particularly exposed to ozone, more likely to suffer adverse effects, or combinations of both.
Advice on the Elements of a Primary NAAQS (1)

• Indicator: Ozone
  – “appropriate based on its causal or likely causal associations with multiple adverse health outcomes and its representation of a class of pollutants known as photochemical oxidants”

• Averaging Time: 8-hours
  – “justified by the combined evidence from epidemiologic and clinical studies”
Advice on the Elements of a Primary NAAQS (2)

• Form: 4\textsuperscript{th} highest daily maximum 8-hour average (averaged over 3 years)
  – provides \textbf{programmatic stability} by allowing for atypical meteorological conditions that can lead to abnormally high ambient ozone concentrations
  – while providing \textbf{health protection}
Advice on the Elements of a Primary NAAQS (3)

• Level:
  – Science advice: “adequate scientific evidence to recommend a range of levels for a revised primary ozone standard from 70 ppb to 60 ppb”
  – Policy advice:
    • “a level of 70 ppb provides little margin of safety for the protection of public health, particularly for sensitive subpopulations.”
    • “our policy advice is to set the level of the standard lower than 70 ppb within a range down to 60 ppb, taking into account your judgment regarding the desired margin of safety to protect public health, and taking into account that lower levels will provide incrementally greater margins of safety.”
EPA’s Proposal for Primary Ozone NAAQS

• The EPA Administrator has proposed a standard between 65 ppb and 70 ppb and will take comments on levels as low as 60 ppb (November 26, 2014)
EPA’s Final Assessment for Ozone Health Effects

EPA published these estimated on 11/26/14 (post-CASAC review)

Reducing ozone and particle pollution nationwide (excluding California) in 2025 will avoid:

• 750 to 4,300 premature deaths
• 320,000 to 960,000 asthma attacks among children
• 330,000 to 1 million days when kids miss school
• 65,000 to 180,000 missed work days
• 1,400 to 4,300 asthma-related emergency room visits
• 790 to 2,300 cases of acute bronchitis among children
Key Findings from CASAC Review: Secondary Ozone NAAQS

• “adverse welfare effects related to ecosystem services, food and fiber products from crops, and damage to resource use from foliar injury.”
Advice on the Elements of a Secondary NAAQS (1)

• Indicator: Ozone
• Form: W126
• Averaging time: 3-month summation of W126 in a single year resulting in the maximum value
• Level: 7 ppm-hrs to 15 ppm-hrs
  – “The CASAC does not support a level higher than 15 ppm-hrs”
  – “For example, at 17 ppm-hrs, the median tree species has 6% relative biomass loss, and the median crop species has over 5% yield loss.”
Advice on the Elements of a Secondary NAAQS (2)

• Policy advice:
  – “there are specific economically significant crops, such as soybeans, that may not be protected at 15 ppm-hrs but would be protected at lower levels”
  – “A level below 10 ppm-hrs is required to reduce foliar injury”
  – “A level of 7 ppm-hrs is protective of relative biomass loss for trees and offers additional protection against crop yield loss and foliar injury”
  – “lower levels within the recommended range offer a greater degree of protection of more endpoints than do higher levels within the range”
Advice on the Elements of a Secondary NAAQS (3)

• “If, as a policy matter, the Administrator prefers ... a three-year averaging period ..., then the level of the standard should be revised downward”
EPA’s Proposal for Secondary Ozone NAAQS

• Set the same as the primary standard
• Based on comparison of W126 and the indicator, averaging time, and form of the primary standard, and W126 values of 13 ppm-hours to 17 ppm-hours
• Based on a three year averaging time.
• Differs from CASAC advice regarding form, averaging time, and level.
The CASAC recommends that EPA facilitate research needed for the next review of the ozone NAAQS."

- characterization of the exposure-response function
- identification of population thresholds
- role of co-pollutants and temperature
- alternative modeling specifications
- population-based information on human exposure for at-risk populations
- time-activity data to improve population-based exposure and risk assessment
- characterization of background levels
Research Needs: Secondary Standard

– develop data and better methods for extrapolating results to plant species for which exposure-response functions have not been developed
– Assess effects of ozone on climate (and the effects of climate on ozone)
– characterize effects of ozone on whole ecosystem structure and function
– evaluate how the public judges the adversity of various ecological effects including foliar injury and estimated reduced tree biomass growth
Although Research is Needed...

• “we also make clear that there is sufficient scientific evidence, and sufficient confidence in the available research results, to support the advice we have given above for this review cycle of the primary and secondary standards.”
International Transport of Ozone

• “matter separate from our advice regarding the standard”

• “background is only partly natural (lightning, biosphere, fires, stratospheric influence) and is enhanced by anthropogenic sources outside North America.”

• “background ozone is higher than average when ozone concentrations exceed 60 ppb, particularly in the intermountain West”

• “seek opportunities for international cooperation to reduce long-range transport of ozone”
What’s Next?

A decision on the final standard is due October 1, 2015 to meet a court deadline.
Supplemental Materials
Does EPA Follow CASAC Advice?
Summary of Recent CASAC Advice: Particulate Matter Standard for PM$_{2.5}$

- EPA’s Jan. 2013 rule-making that set the primary PM$_{2.5}$ annual standard to 12 ug/m$^3$ while keeping the 24-hour standard of 35 ug/m$^3$ was consistent with CASAC’s advice.
- However, EPA decision to retain the secondary annual standard of 15 ug/m$^3$ departed from CASAC advice to introduce a new speciated PM light extinction indicator.
- Similarly, EPA retained the existing secondary 24-hour average of 35 ug/m$^3$ contrary to CASAC advice regarding a 24-hour light extinction-based indicator and level.
Summary of Recent CASAC Advice: Particulate Matter Standard for PM$_{10}$

- In its Sept. 2010 letter, CASAC recommended that the primary standard for PM$_{10}$ should be revised downwards (below 150 ug/m$^3$).
- CASAC said that while current evidence is limited, it is sufficient to call into question the level of protection afforded by 150 μg/m$^3$.
- The Jan. 2013 decision to retain the current primary and secondary 24-hour average 150 ug/m$^3$ standard departed from CASAC’s advice.
Summary of Recent CASAC Advice: Carbon Monoxide

- CASAC expressed a preference for a lower standard but said current evidence also supports retaining the current suite of standards.
- CASAC acknowledged their preference for a lower standard was based on a judgment as to the weight of the epidemiological evidence.
- EPA’s final August 2011 decision to retain the primary standard and not set a secondary standard was compatible with CASAC’s advice.
Summary of Recent CASAC Advice: Lead

• In 2013, CASAC provided advice that the current standard is adequate
Summary of Recent CASAC Advice: Oxides of Nitrogen

- CASAC had recommended the level of the one-hour NO$_2$ standard should be within the range of 80-100 ppb and not above 100 ppb.
- February 2010: EPA set a 1-hour standard at 100 ppb.
- EPA’s decision was consistent with CASAC’s advice.
Summary of Recent CASAC Advice: Sulfur Dioxide Primary Standard

• CASAC recommended 50 to 150 ppb.
• EPA’s June 2010 decision to establish the 1-hour 75 ppb standard was consistent with CASAC advice.
Summary of Recent CASAC Advice: NO\textsubscript{x}-SO\textsubscript{x} Secondary Standard

• In 2011, CASAC had stated that the levels of the current NO\textsubscript{x} and SO\textsubscript{x} secondary NAAQS were not sufficient, nor the forms of those standards appropriate, to protect against adverse depositional effects.

• EPA’s April 2012 rule-making that retained the existing NO\textsubscript{2} and SO\textsubscript{2} secondary standards was NOT consistent with CASAC’s advice.
Multipollutant Air Quality Management

• In 2004, the National Research Council called for development of “an integrated multipollutant approach to controlling emissions of pollutants posing the most significant risks”

• In 2011, NARSTO released an assessment of needs, barriers, opportunities, and implementation strategy for MPAQM
  – Predictive risk-based framework
  – Retrospective accountability framework
MPAQM Per NARSTO (2011)

Number and strength of linkages and outcomes

Source → Air Quality → Exposure → Adverse Effect

RISK ASSESSMENT: MODELING, PREDICTIVE

ACCOUNTABILITY: MEASUREMENT, DESCRIPTIVE
Phased Approach to MPAQM (NARSTO)

Level 1: Attainment of Existing Standards

Level 2: Attainment of Existing Standards

Level 3: Risk Trade-offs

Level 4: Reduction in Net Risk

- Integrated Framework for Standards for Multiple Sources and Pollutants
Status of Multipollutant Assessment

Existing Capability:

• Primary Emissions
• Secondary Air Pollutants
• Exposure Assessment

Greatest Challenge:

• Lack of robust exposure-response models that take into account multiple pollutants simultaneously
An Initial Attempt at a Multipollutant NAAQS

- EPA Staff and CASAC recommendations for the $\text{SO}_x$ and $\text{NO}_x$ Secondary NAAQS in the last review cycle:
  - “ecological indicator” based on acid neutralizing capacity (ANC) related to:
    - nitrate and sulfate deposition
    - adverse effect (e.g., decline of sensitive fish species and in health of fish populations)
  - Aquatic Acidification Index (AAI)
    - quantifies the relationship between ANC and oxides of nitrogen and sulfur
    - role of deposition of reduced forms of nitrogen
An Initial Attempt at a Multipollutant NAAQS

• CASAC assessment:
  – “a framework for a multipollutant, multimedia standard that is ecologically relevant and reflects the combined impacts of these two pollutants”
  – EPA should engage in monitoring and modeling efforts to further develop the AAI-based approach

• Administrator assessment:
  – “current limitations in relevant data and the uncertainties associated with specifying the elements of the AAI based on modeled factors”
  – “a field pilot program” should be undertaken to address the limitations and uncertainties
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5/28/14: EPA statement that field pilot study was not funded because of automatic spending cuts.

10/7/14: Three environmental groups petition U.S. Court of Appeals for the DC Circuit for rehearing to require EPA to specify alternative actions related to $SO_x/NO_x$.

Reported in December 2014 EM Magazine.
Other Multipollutant Initiatives

• In 2011, the stakeholder-based EPA Clean Air Act Advisory Committee (CAAAC) recommended that EPA develop sector-based multipollutant approaches that consider criteria pollutants, hazardous air pollutants, and greenhouse gases.

• EPA is in the planning stage for “multipollutant science documents”

• Detroit Multipollutant Study

• Air Quality Management Plan (AQMP) pilots

• A new secondary SO$_x$/NO$_x$ review cycle expected to start in 2015
Multipollutant Air Quality Management

• Most recent CASAC advice (June 26, 2014):
  • “as the state of science regarding the joint effects of human exposure to multiple pollutants improves, the EPA should consider how review and revision of the NAAQS can be done synergistically for logical, scientifically relevant groupings of criteria pollutants”
Current and Upcoming CASAC Reviews

Current Active Panels
• Sulfur Oxides Review Panel
• Oxides of Nitrogen Review Plan

Panel Being Formed
• $\text{NO}_x$ and $\text{SO}_x$ Secondary NAAQS Review Panel
• PM Review Panel