Ozone NAAQS Staff Paper Update

Susan Lyon Stone
stone.susan@epa.gov
Agricultural Air Quality Task Force Meeting
November 29, 2006
Overview

Health effects
- New health information
- Results of exposure and risk analyses
- Findings of 2nd draft Staff Paper
- CASAC comments on 2nd draft Staff Paper
- New analyses for final Staff Paper

Vegetation and ecosystem effects
- New analyses
- Findings of 2nd draft Staff Paper and CASAC comments

Schedule
Types of Health Studies

- **Animal Toxicology**
  - Exposures/doses controlled, uniform population, confounders controlled
  - Issues with extrapolation to humans; high doses often used

- **Controlled human exposure**
  - Exposures and confounders controlled
  - Generally use healthy subjects, health outcomes less severe

- **Epidemiology**
  - Real-world exposures (short- and long-term), including sensitive groups; more severe health outcomes
  - Issues with potential confounders, exposure error, etc.

- **Comparisons between study types:**
  - Dose or exposure levels
  - Population group or subjects
  - Health endpoints
  - Interpretation of results

- **Consistency and coherence**
Pyramid of Effects

- Death
- Hospital Admissions
- Doctor visits
- Asthma attacks, medication use, symptoms
- Lung function changes, immune cell responses, heart rate or heart rate variability responses

Asthma attacks, medication use, symptoms

Doctor visits

Hospital Admissions

Death
Human Lung

- Air conducting
  - Trachea
  - Bronchi
  - Bronchioles

- Gas exchange
  - Respiratory bronchioles
  - Alveoli
Ozone Irritates the Airways

- Symptoms
  - Cough
  - Sore or scratchy throat
  - Pain with deep breath
  - Fatigue
- Rapid onset
- Similar symptoms - people with and without asthma
Ozone Reduces Lung Function

Exposure to 0.22 ppm O₃ (Frampton et al., 1997)
Ozone Causes Inflammation

- Ozone reacts completely in surface layer - forms reactive oxygen molecules
- Influx of white blood cells
- Damages cells that line the airways
- Effect is greater 24 hours after exposure
- Increases airway reactivity
- Inflammation and increased airway reactivity responses greater in people with asthma
- Concern about repeated exposures
Respiratory Hospital Admissions by Daily Maximum Ozone Level, Lagged One Day

(Burnett et al, 1994)
California Children’s Health Study
• 20 ppb increase in $O_3$ associated with an 83% increase in school absences for acute respiratory disease (Gilliland et al., 2001)

• Large economic impact of pollution-related school absences (Hall and Lurmann, 2003)
**CHS: Ozone and New-onset Asthma**

<table>
<thead>
<tr>
<th>Sports</th>
<th>Low O₃ Towns</th>
<th></th>
<th></th>
<th>High O₃ Towns</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>#</td>
<td>asthma</td>
<td>RR</td>
<td>#</td>
<td>asthma</td>
</tr>
<tr>
<td>0</td>
<td>58</td>
<td>1.00</td>
<td></td>
<td>46</td>
<td>1.00</td>
</tr>
<tr>
<td>1</td>
<td>50</td>
<td>1.28</td>
<td></td>
<td>40</td>
<td>1.28</td>
</tr>
<tr>
<td>2</td>
<td>20</td>
<td>0.82</td>
<td></td>
<td>16</td>
<td>1.28</td>
</tr>
<tr>
<td>≥3</td>
<td>9</td>
<td>0.79</td>
<td></td>
<td>20</td>
<td>3.31</td>
</tr>
</tbody>
</table>

McConnell et al., 2002
What’s New?

• Controlled human exposure studies to lower levels - 0.04 ppm
  – Some individuals show moderate lung function responses down to 0.04 ppm, 6.6-hr average
  – Change in group mean averages not statistically significant at lower levels

• Many new studies show asthmatics much more susceptible
  – Larger lung function and symptomatic responses; increased inflammation and airway responsiveness; more ED visits and hospital admissions
  – Epidemiological studies report effects well below 0.08 ppm

• Epidemiological evidence links O₃ with total (non-accidental) and cardiorespiratory mortality
Sensitive Groups for Ozone

- People with lung disease
- Children
- Older adults
- People who are active outdoors
Figure 5-5. Percent of Active Children (Ages 5-18) Engaged in Moderate Exertion Estimated to Experience At Least One Lung Function Response (Decrement in FEV\(_1\) ≥ 15%) Associated with Exposure to O\(_3\) Concentrations That Just Meet the Current and Alternative Average 4th Daily Maximum 8-Hour Standards, for Location-Specific O\(_3\) Seasons (Based on Adjusting 2004 Air Quality)
Figure 5C-1. Percent of Active Children (Ages 5-18) Engaged in Moderate Exertion Estimated to Experience At Least One Lung Function Response (Decrement in FEV₁ ≥ 15 %) Associated with Exposure to O₃ Concentrations That Just Meet the Current and Alternative Average 4th Daily Maximum 8-Hour Standards, for Location-Specific O₃ Seasons: Based on Adjusting 2002 O₃ Concentrations
Figure 5-9. Estimated Incidence of Non-Accidental Mortality per 100,000 Relevant Population Associated with Recent Air Quality (2004) and with Just Meeting Alternative Average 4th Daily Maximum 8-Hour Ozone Standards (Using Bell et al., 2004 – 95 U.S. Cities Function), Based on 2004 Ozone Concentrations
Figure 5C-5. Estimated Incidence of Non-Accidental Mortality per 100,000 Relevant Population Associated with Recent O3 Concentrations and with O3 Concentrations that Just Meet the Current and Alternative Average 4th Daily Maximum 8-Hour Standards: April – September, 2002
Findings of Second Draft Staff Paper

- Options for Administrator’s consideration:
  - Retention of current standard, 0.08 ppm O₃, based on:
    - Consideration of the uncertainties in lung function responses at levels below 0.08 ppm O₃
    - Places more limited weight on evidence of more uncertain, but serious, morbidity (e.g., hospital admissions, ED visits) and mortality effects
  - Revise standard to more protective level, in the range analyzed, 0.06 to 0.07 ppm O₃, with focus on the level of 0.07 ppm, based on:
    - Consideration that some highly responsive individuals experience lung function decrements at exposures as low as 0.06 and 0.04 ppm
    - Consideration of new evidence that people with asthma have bigger responses to O₃ exposure (e.g., bronchoconstriction, inflammation, increased airway responsiveness) than non-asthmatics - risk assessment has not fully addressed the range of health effects likely (e.g., increased medication usage, missed school and work days, physician visits)
    - Places more weight on evidence of serious, but more uncertain, morbidity and mortality effects; some in urban areas with O₃ levels below the current standard
There is no scientific justification for retaining the current primary 8-hr NAAQS of 0.08 parts per million (ppm)

- “New evidence supports and builds upon key, health-related conclusions” drawn in 1997 review
- Several new single-city studies and large multi-city studies provide more evidence for adverse health effects at concentrations lower than the current standard
- Epidemiological evidence is backed-up by controlled human exposure studies (cited Adams 2002, 2006 studies as showing adverse lung function effects in some individuals at 0.06 ppm)
- Lung function studies done in healthy adults; expectation that asthmatics and children would experience larger effects
- Other adverse effects found in studies (e.g., increased school absenteeism, increased respiratory hospital emergency department visits, increased respiratory symptoms in asthmatics, increased medication usage, increased non-accidental and cardiorespiratory deaths) that reported exposure levels “well below the current standard”
• The primary 8-hr NAAQS needs to be substantially reduced to protect human health, particularly in sensitive populations
  – CASAC in “complete agreement” that staff conclusion arguing for consideration of retaining the current standard as an option “is not supported by the relevant scientific data”
  – “No longer significant scientific uncertainty regarding the CASAC’s conclusion that the current 8-hr primary NAAQS must be lowered”

• Unanimously recommended a range of 0.060 to 0.070 ppm for the primary ozone NAAQS, with a range of concentration-based forms from third- to fifth-highest daily maximum 8-hr average
  – Recommend that EPA conduct a broader evaluation of implications of alternative forms of standards on public health protection and stability
  – Monitoring technology supports stating standard in terms of ppb or 3 decimal places for ppm
New Analyses for Final Staff Paper

- Sensitivity analyses of policy relevant background (PRB) ozone concentrations
- Extended lung function and mortality risk analyses to include estimates based on 2003 air quality for 5 of the 12 urban areas
- Sensitivity analysis of model form (linear vs. logistic) for lung function decrement risk estimates
- Quantitative risk estimates of asthmatic children experiencing $\geq 10\%$ reductions in FEV$_1$
- Analyses of a “12th maximum 8-hr average O$_3$ concentration in 3 years” form of the standard
Vegetation and Ecosystem Effects

- Recent studies support and strengthen previous findings:
  - Ambient $O_3$ levels can cause decreased yield and growth in many crops and forest plants, respectively, and reduce the nutritive quality of some agronomic and forage crops.
  - Leaf injury from $O_3$ exposure is widespread across U.S., as documented at US Forest Service bio-monitoring network field sites.
  - $O_3$ effects on sensitive plant species, including loss of vigor and competitive advantage, have implications for ecosystems.
  - A seasonal, cumulative, concentration-weighted index form (such as SUM06 or W126) is a more appropriate index for characterizing vegetation effects than an 8-hr. average form.
2001 Estimated Aspen Seedling Annual Biomass Loss
2001 County-Level Incidence of Visible Foliar Injury
Secondary NAAQS

- Options analyzed:
  - Current standard of 8 hr. avg. of 0.084 ppm, 4th max
  - 8 hr., 0.070 ppm 4th max
  - 3 mo., 12 hr. SUM06 in the range of 15 to 25 ppm-hr
  - 3 mo., 12 hr. W126 in the range of 13 to 21 ppm-hr

- Staff identifies a range of standards with biologically relevant forms as appropriate options for consideration, based on:
  - Continued scientific evidence that exposure duration and concentration are important in eliciting plant response
  - NAS Report/CAAAC recommendations
  - Need to develop appropriate indicators for Agency tracking/accountability
  - 1997 Consensus Report – 16 experts agreed on a cumulative, concentration-weighted form

- CASAC unanimously agreed that it is not appropriate to continue to promulgate identical primary and secondary standards for $O_3$
  - Preferred the W126 metric over the SUM06 metric

For more information contact Dr. Jeffrey Herrick; herrick.jeffrey@epa.gov
Status of Ozone NAAQS Review

- Final CD released March 21, 2006
- Second draft Staff Paper and exposure, health risk, and environmental effects assessments
  - Released to CASAC and the public in July
  - CASAC meeting held August 24-25
  - CASAC letter – October 24
- Final Staff Paper targeted for release in January 2007
- CASAC plans to hold teleconference after release to provide any additional comments to EPA
- Consent decree schedule changed:
  - Proposed rule – May 2007
  - Final rule – February 2008