

# Ozone NAAQS Staff Paper Update



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**Agricultural Air Quality Task Force Meeting**  
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# Overview

## Health effects

- New health information
- Results of exposure and risk analyses
- Findings of 2<sup>nd</sup> draft Staff Paper
- CASAC comments on 2<sup>nd</sup> draft Staff Paper
- New analyses for final Staff Paper

## Vegetation and ecosystem effects

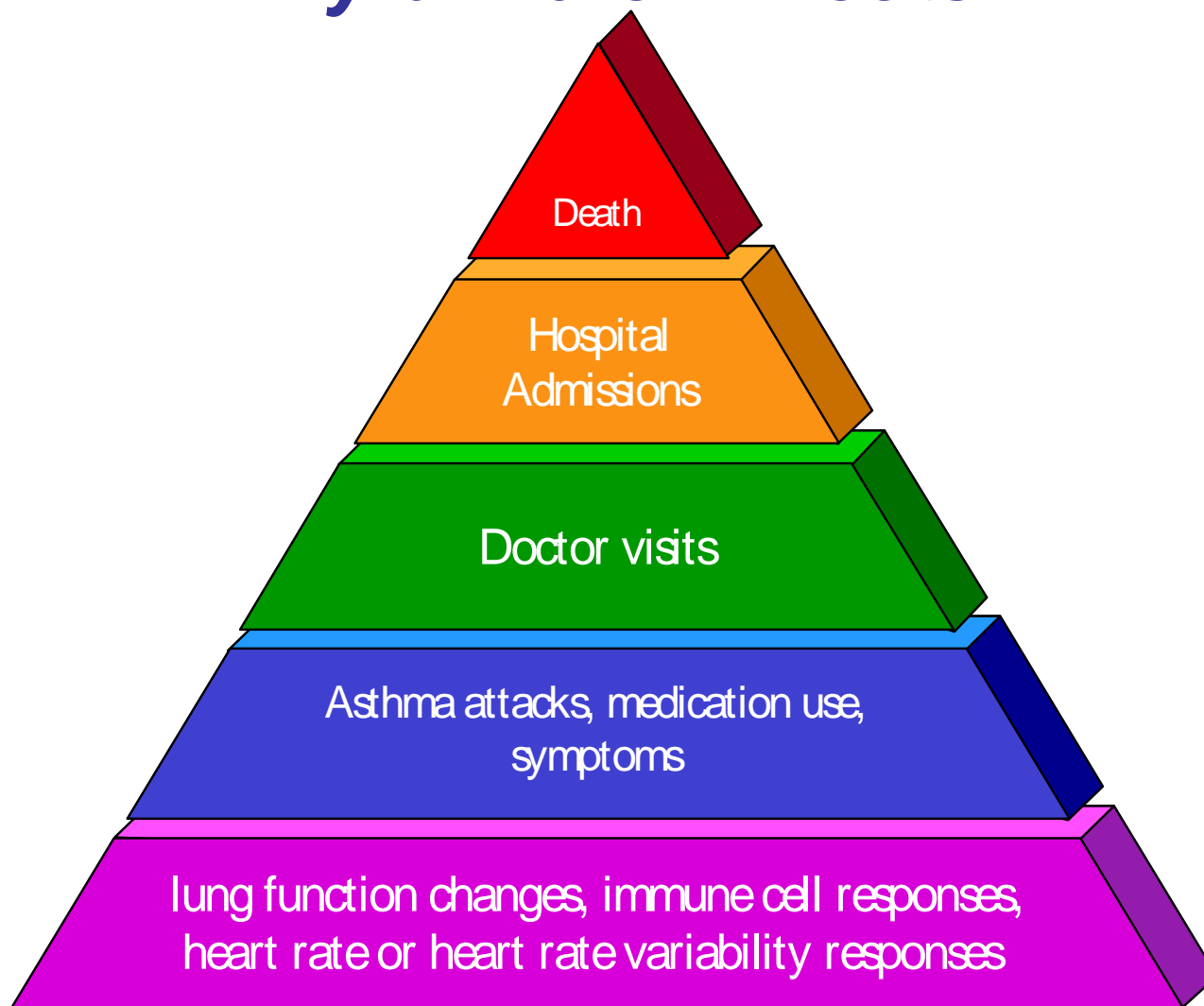
- New analyses
- Findings of 2<sup>nd</sup> draft Staff Paper and CASAC comments

## Schedule

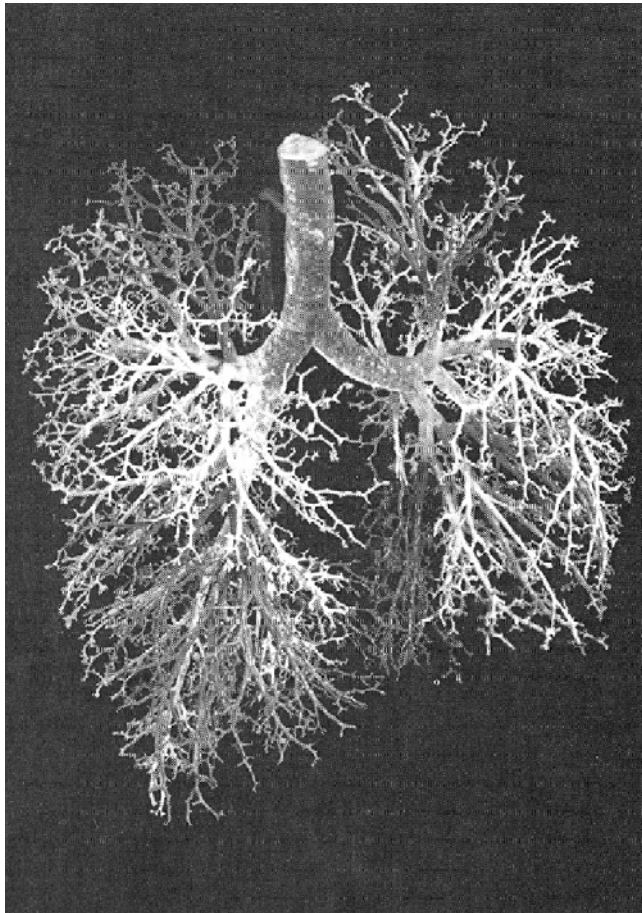
## *Types of Health Studies*

- 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*



## *Human Lung*



- Air conducting
  - Trachea
  - Bronchi
  - Bronchioles
- Gas exchange
  - Respiratory bronchioles
  - Alveoli

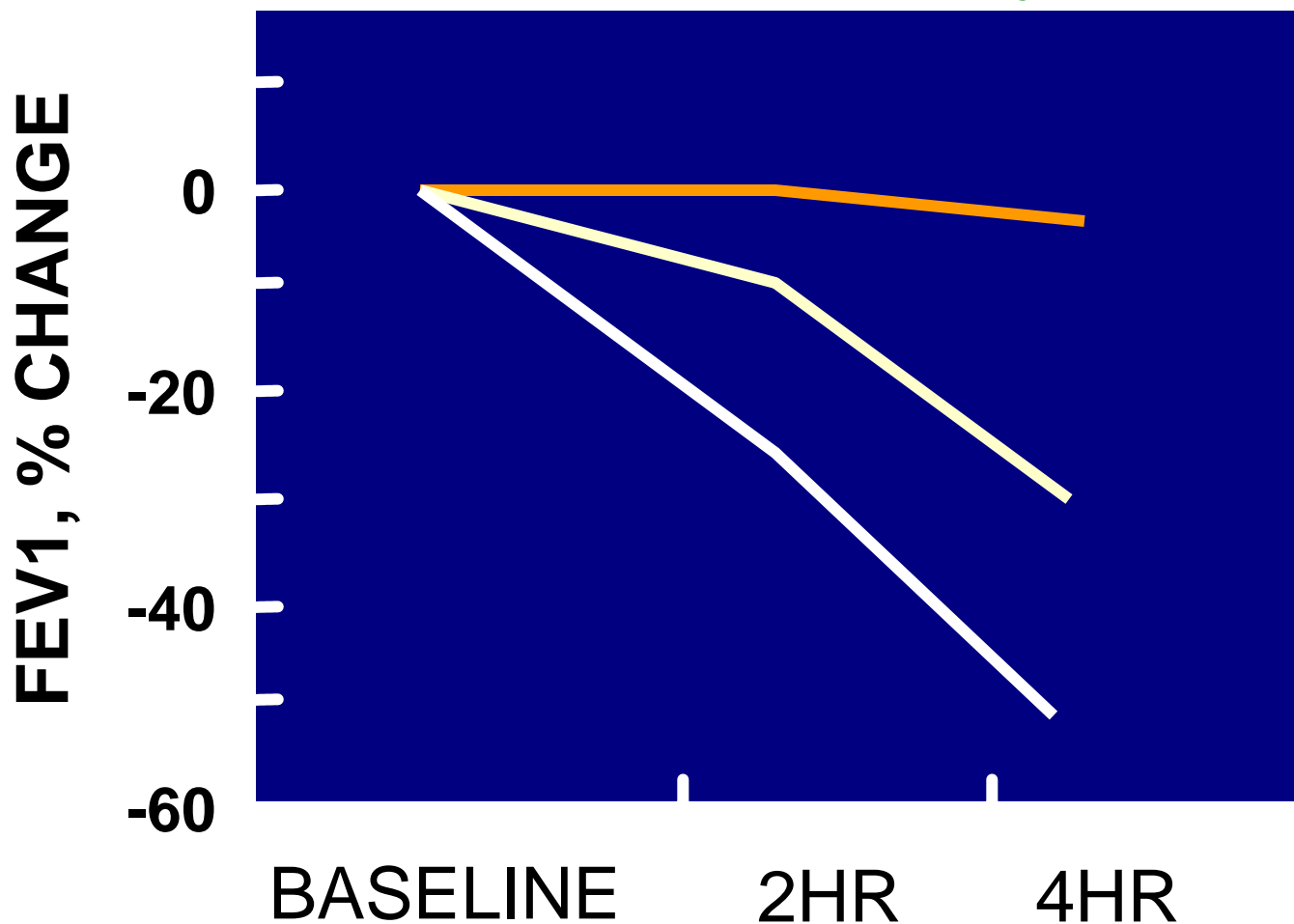
## *Ozone Irritates the Airways*

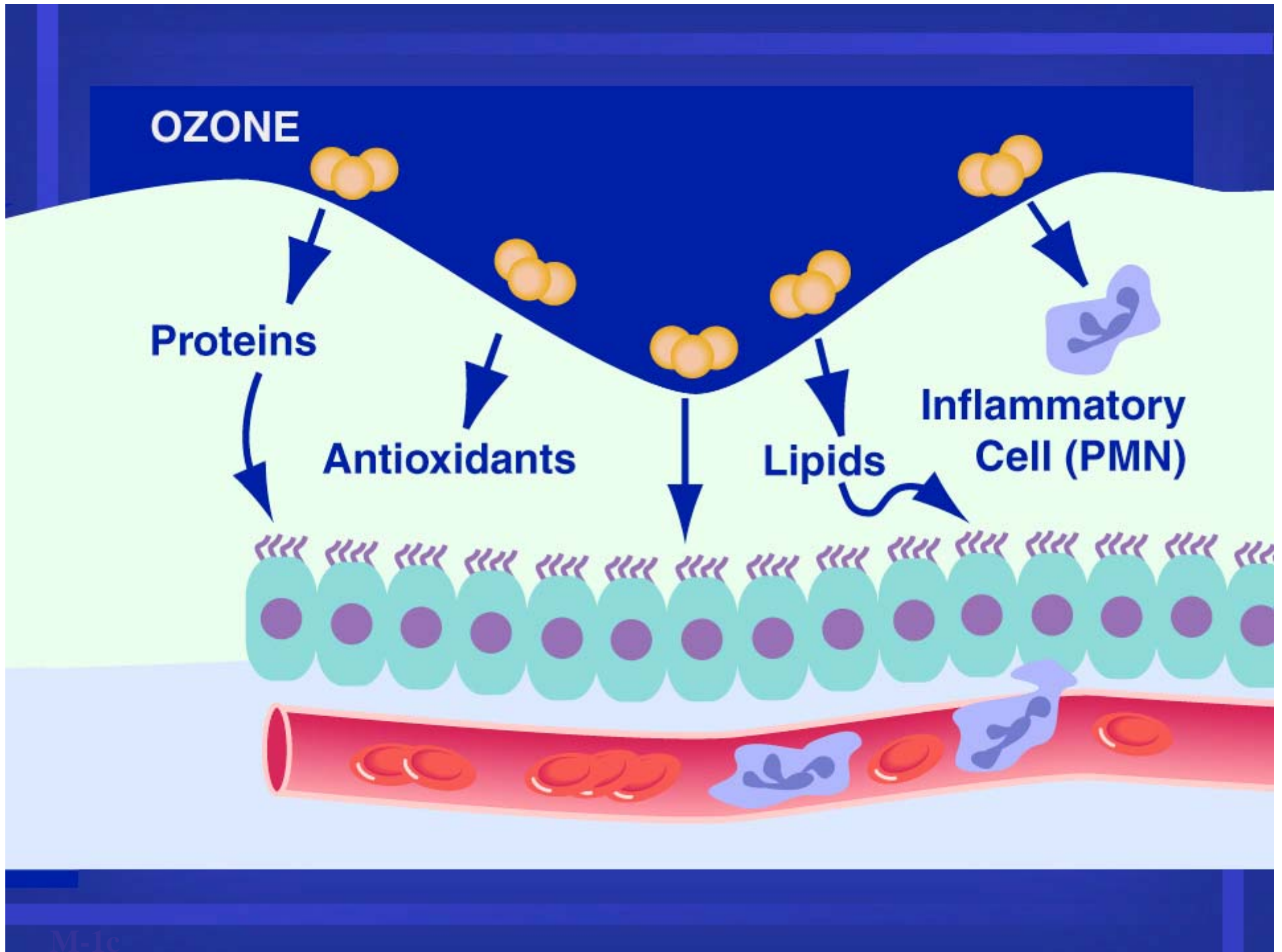
- Symptoms
  - Cough
  - Sore or scratchy throat
  - Pain with deep breath
  - Fatigue
- Rapid onset
- Similar symptoms - people with and without asthma



## Ozone Reduces Lung Function

*Exposure to 0.22 ppm O<sub>3</sub> (Frampton et al., 1997)*





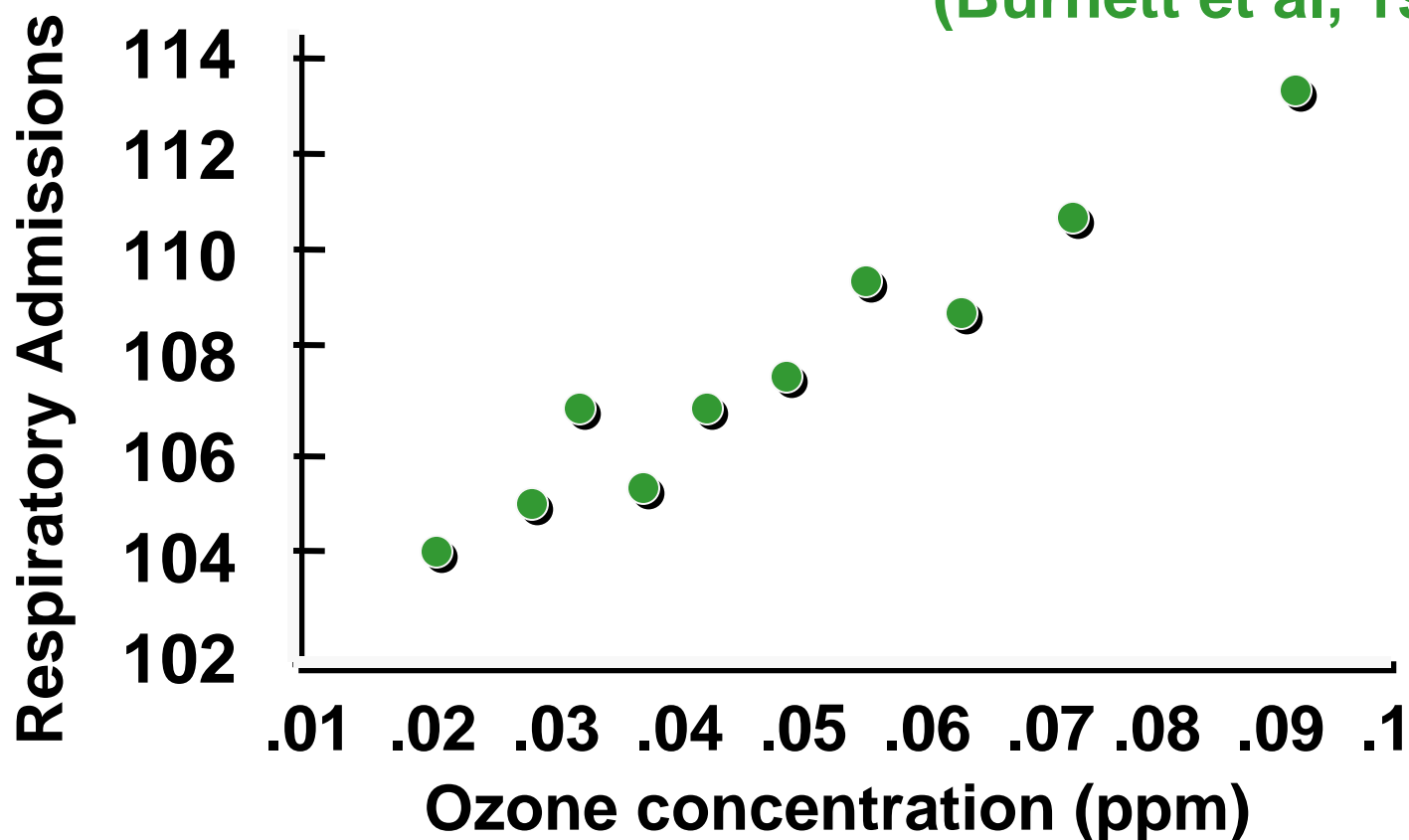


## *Ozone Causes Inflammation*

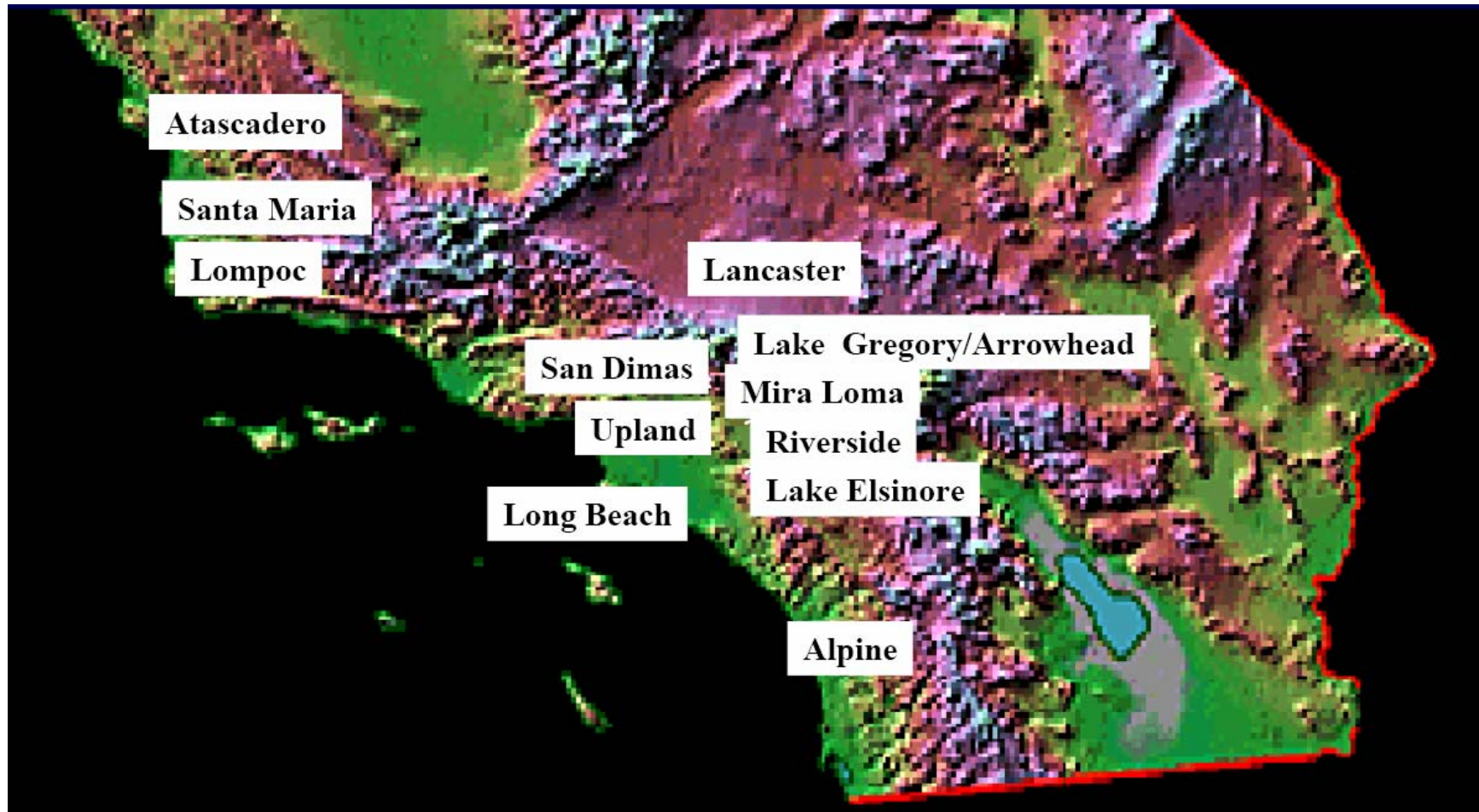
- Ozone reacts completely in surface layer - forms reactive oxygen molecules
- Influx of white blood cells
- Damages cells that line the airways
- Effect is greater 24 hours after exposure
- Increases airway reactivity
- Inflammation and increased airway reactivity responses greater in people with asthma
- Concern about repeated exposures

## *Respiratory Hospital Admissions by Daily Maximum Ozone Level, Lagged One Day*

(Burnett et al, 1994)



# California Children's Health Study



## *CHS: School Absences*

- 20 ppb increase in O<sub>3</sub> 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*

<u>Sports</u>	<u>Low O<sub>3</sub> Towns</u>		<u>High O<sub>3</sub> Towns</u>	
	#	RR	#	RR
0	58	1.00	46	1.00
1	50	1.28	40	1.28
2	20	0.82	16	1.28
≥3	9	0.79	<b>20</b>	<b>3.31</b>

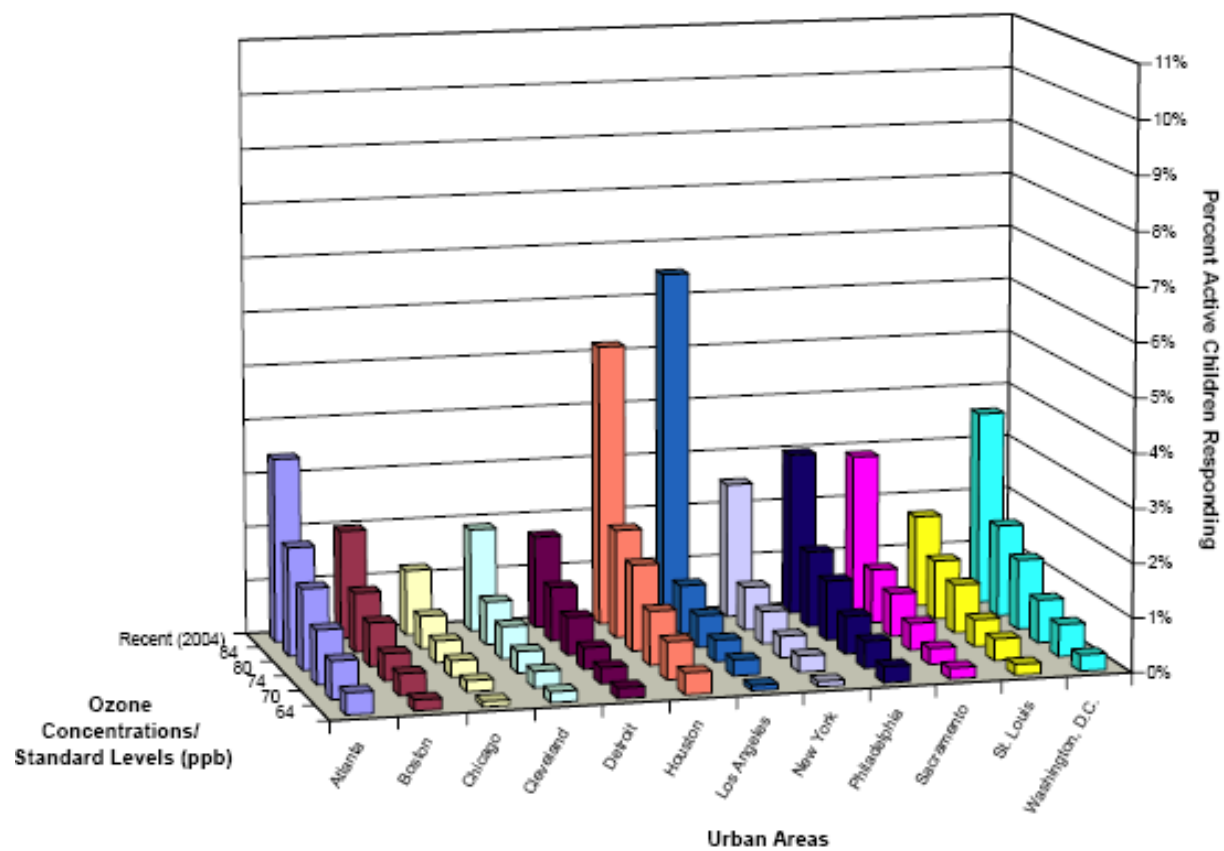
## *What's New?*

- 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 O<sub>3</sub> with total (non-accidental) and cardiorespiratory mortality

## *Sensitive Groups for Ozone*

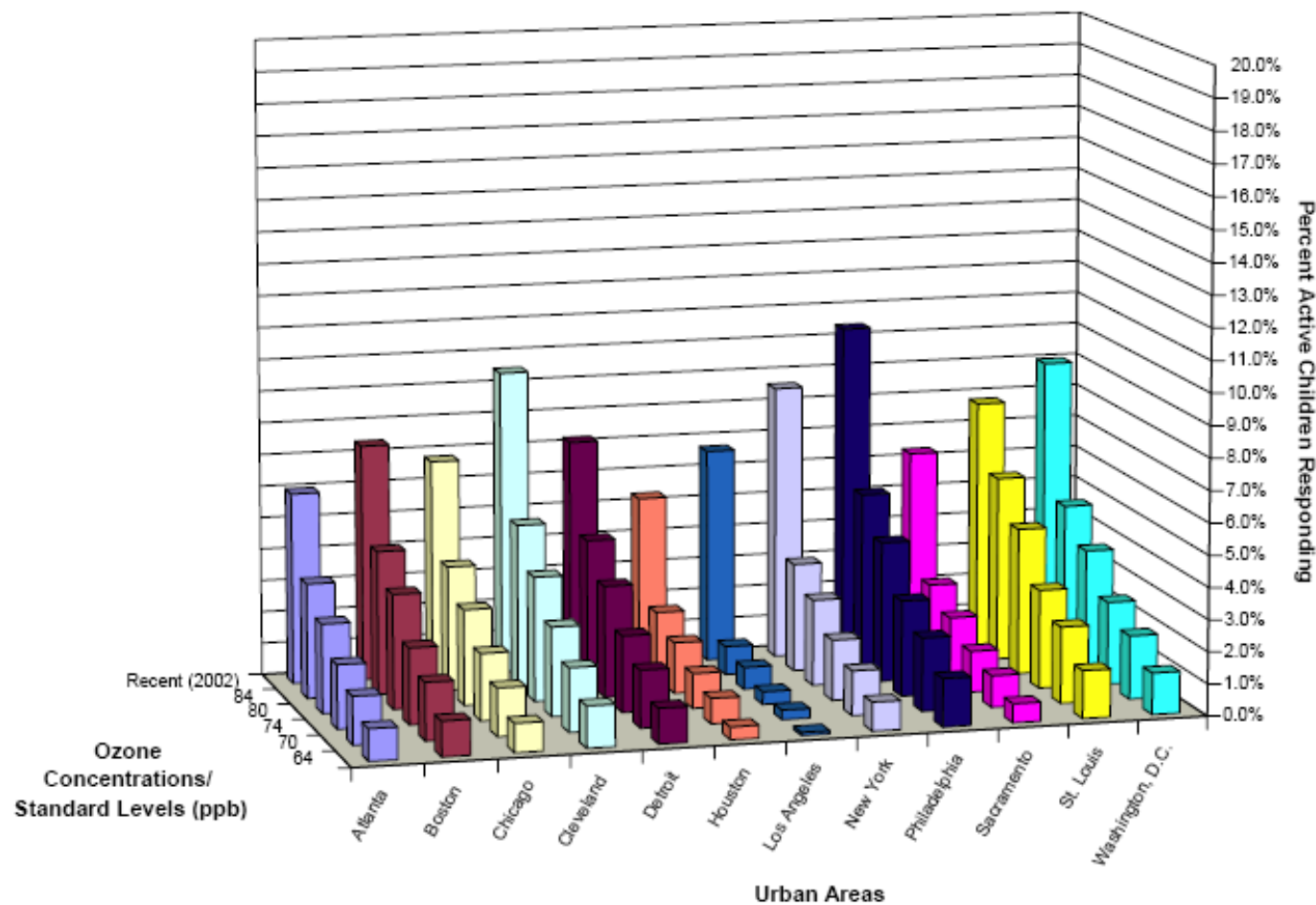
- People with lung disease
- Children
- Older adults
- People who are active outdoors

**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<sub>1</sub> ≥ 15%) Associated with Exposure to O<sub>3</sub> Concentrations That Just Meet the Current and Alternative Average 4<sup>th</sup> Daily Maximum 8-Hour Standards, for Location-Specific O<sub>3</sub> Seasons (Based on Adjusting 2004 Air Quality)**

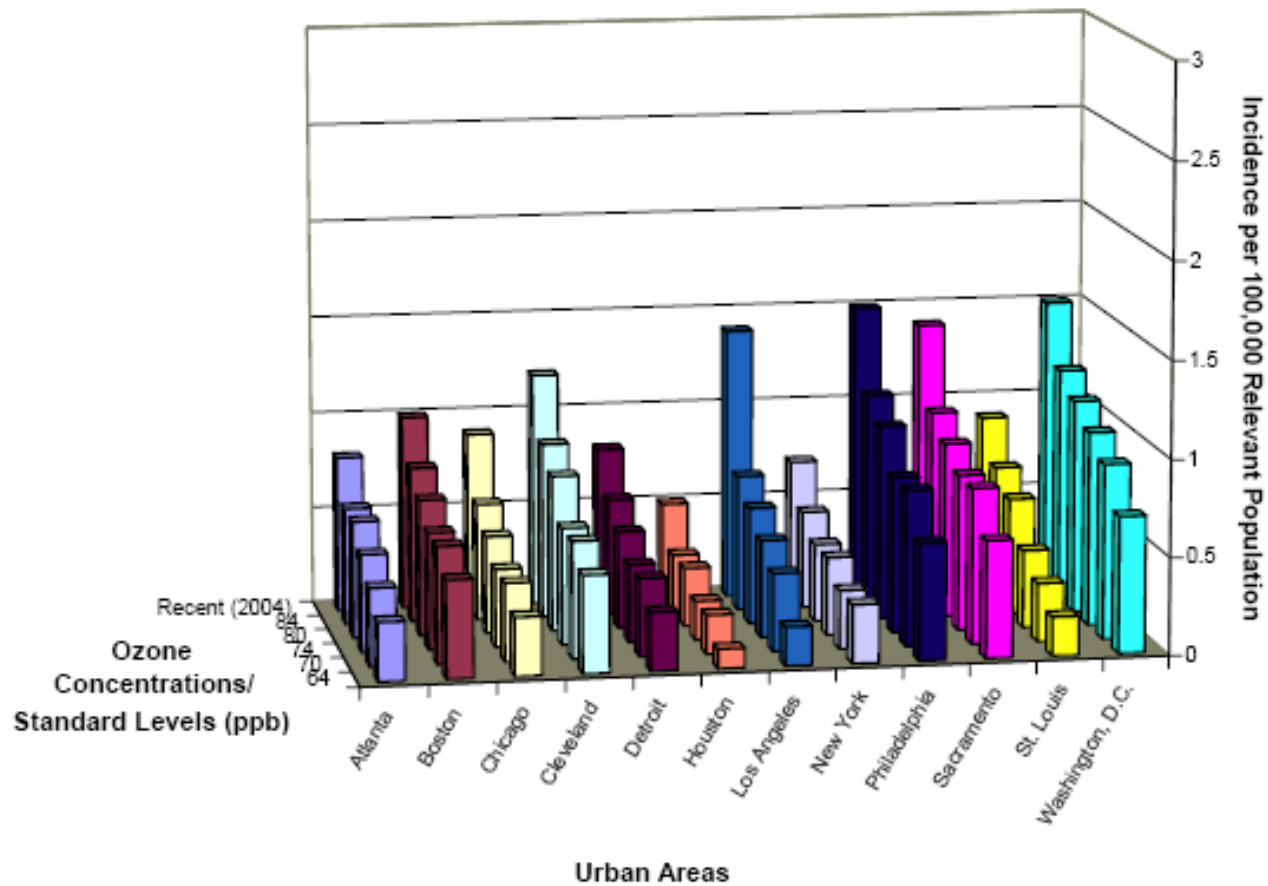




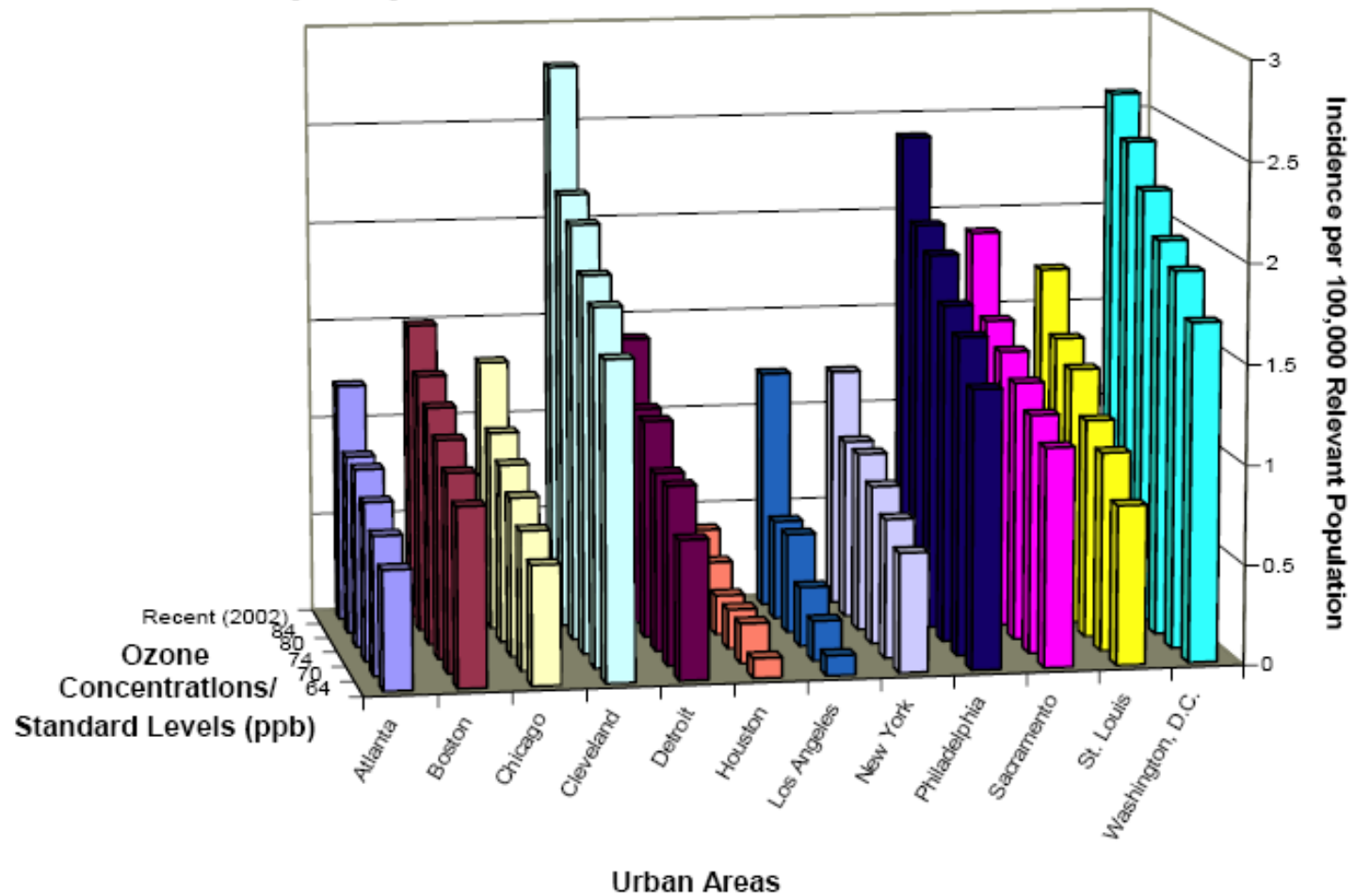
**Figure 5C-1. Percent of Active Children (Ages 5-18) Engaged in Moderate Exertion Estimated to Experience At Least One Lung Function Response (Decrement in FEV<sub>1</sub> ≥ 15 %) Associated with Exposure to O<sub>3</sub> Concentrations That Just Meet the Current and Alternative Average 4<sup>th</sup> Daily Maximum 8-Hour Standards, for Location-Specific O<sub>3</sub> Seasons: Based on Adjusting 2002 O<sub>3</sub> 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 4<sup>th</sup> 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 O<sub>3</sub> Concentrations and with O<sub>3</sub> Concentrations that Just Meet the Current and Alternative Average 4<sup>th</sup> 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 O<sub>3</sub>, based on:
    - Consideration of the uncertainties in lung function responses at levels below 0.08 ppm O<sub>3</sub>
    - 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 O<sub>3</sub>, 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 O<sub>3</sub> 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 O<sub>3</sub> levels below the current standard

## *CASAC Panel Conclusions*

- 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”

## ***CASAC Panel Conclusions (continued)***

- 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*

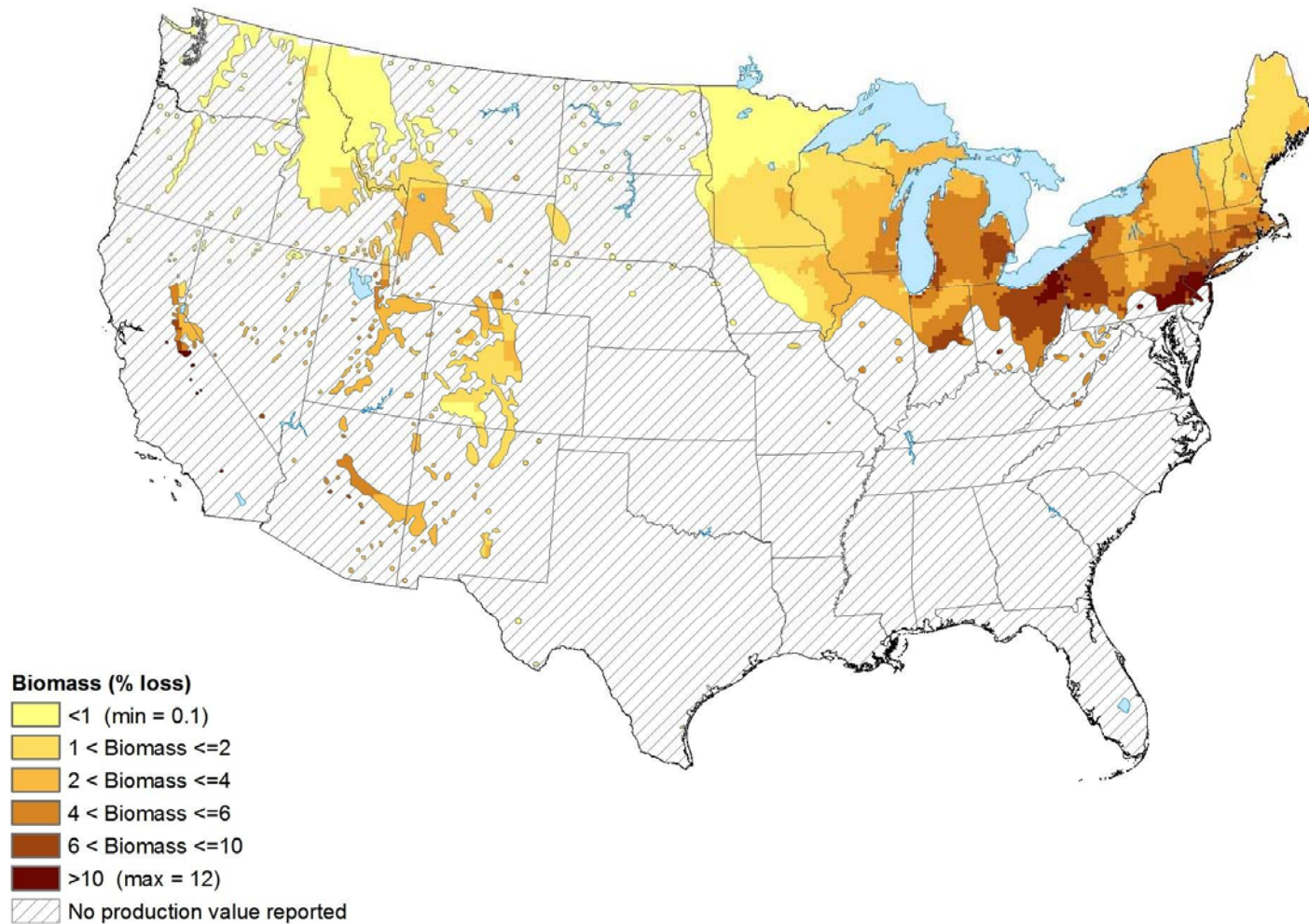
- Sensitivity analyses of policy relevant background (PRB) ozone concentrations
- Extended lung function and mortality risk analyses to include estimates based on 2003 air quality for 5 of the 12 urban areas
- Sensitivity analysis of model form (linear vs. logistic) for lung function decrement risk estimates
- 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<sub>3</sub> 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<sub>3</sub> exposure is widespread across U.S., as documented at US Forest Service bio-monitoring network field sites
  - O<sub>3</sub> 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

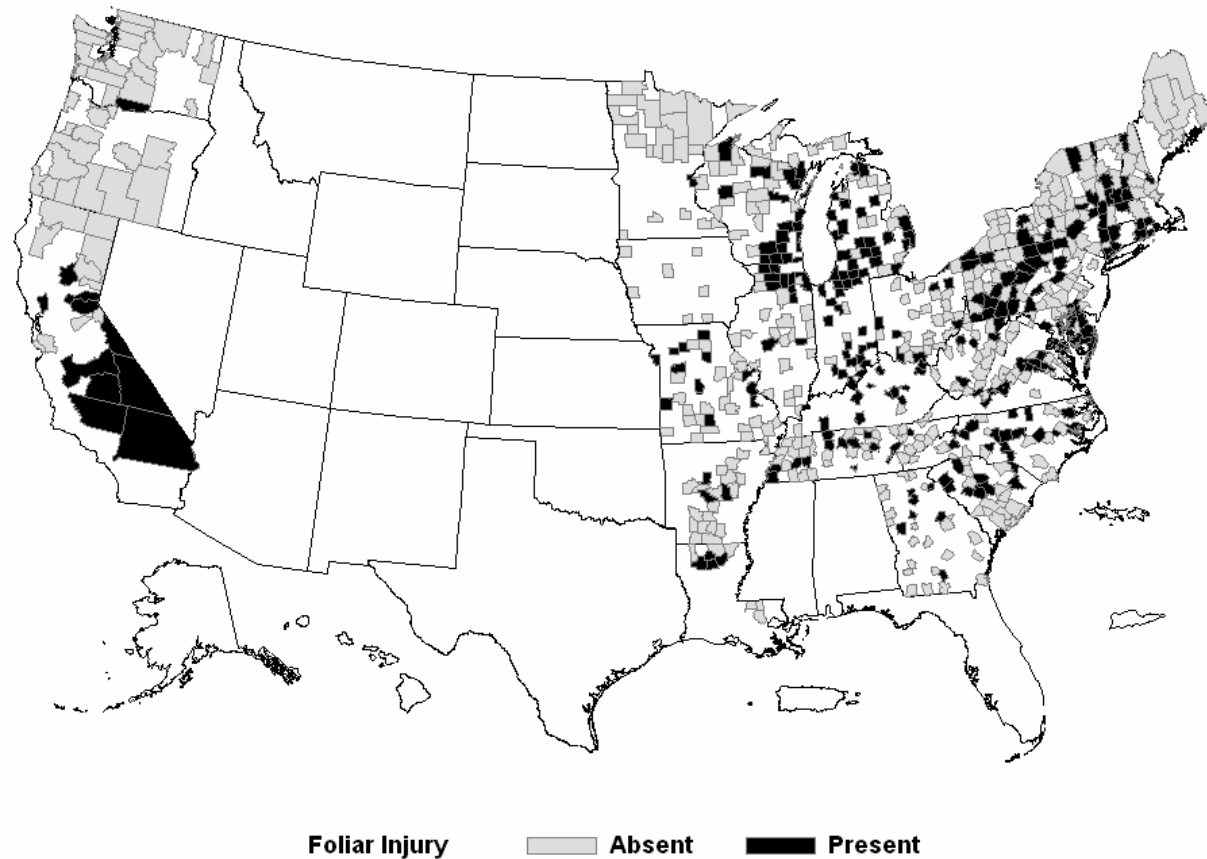


## 2001 Estimated Aspen Seedling Annual Biomass Loss



## 2001 County-Level Incidence of Visible Foliar Injury

Is Foliar Injury Present or Absent?, 2001



## *Findings Second Draft Staff Paper*

- Secondary NAAQS
  - Options analyzed:
    - Current standard of 8 hr. avg. of 0.084 ppm, 4<sup>th</sup> max
    - 8 hr., 0.070 ppm 4<sup>th</sup> 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<sub>3</sub>
  - Preferred the W126 metric over the SUM06 metric
- For more information contact Dr. Jeffrey Herrick; [herrick.jeffrey@epa.gov](mailto: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