

# Summary of Public Comments and Responses



**Air Resources Board**



**Office of Environmental  
Health Hazard Assessment**

---

**California Environmental Protection Agency**

# Six Major Comment Topics

- Method and process of standard review
- Form and attainability of the proposed standards
- Natural background concentration
- Adequacy of the scientific evidence supporting the recommendations
- Justification for the recommendations
- Health benefits analysis is flawed

# Method and Process of Standard Review

- The federal process for standard review should be followed
  - Does not apply to state regulations
  - State law requires process defined in the Administrative Procedure Act
  - We have followed the applicable State laws
- No risk assessment conducted
  - State law requires that standards be health based

# Form of the Proposed Standards

- Form of the standards is too stringent/  
CA should adopt the federal form  
allowing several exceedences
  - California ambient air quality standards are historically “not to be exceeded”
  - The federal form is not required since this is a state regulation

# Attainment Designations

- The attainment designation process should be changed
  - Not part of standard setting in CA
  - Attainment designation process unrelated to the standards

# Background Ozone - 1

- Proposed standards overlap natural background (several air quality measurements presented to support claim)
  - ARB analysis shows anthropogenic contributions

# Background Ozone - 2

- Tropopause Folding Events (stratospheric intrusion) will lead to standard exceedences
  - Only one documented tropopause folding event event in California (1972 in Santa Rosa)
  - Policies and procedures already exist to handle such events

# Adequacy of the Scientific Evidence

- Definition of adverse health effects
- Issues with controlled human studies
- Flawed epidemiologic studies

# Definition of Adverse Health Effects

- Effects attributed to ozone do not qualify as adverse
  - Applied guidelines published by the American Thoracic Society
    - Effects large or significant enough to reduce physiological function, or ability to work or exercise were judged to be adverse in controlled human studies
    - Endpoints from epi studies clearly adverse
      - Hospitalization and ER visits
      - Mortality
      - School absenteeism, work loss days

# Issues with Controlled Exposure Studies - 1

- Unrealistic protocols not applicable to the general public
  - Protocols standardized for over 30 years
  - Protocols simulate real-world activity patterns

# Issues with Controlled Exposure Studies - 2

- Possible subject response bias
  - Precluded by pulmonary function test protocols
  - Bronchoscopy and bronchochallenge results are not controllable by the subject
  - Presence of cough and difficulty breathing are evident to an observer

# Issues with Controlled Exposure Studies - 3

- Responses should be compared between background and the standard, not filtered air and the standard
  - Responses are related to the inhaled dose of ozone and the dose-rate, not the change in ozone concentration

# Issues with Epidemiological Studies - 1

- Statistical modeling issues not fully acknowledged
  - Modeling issues discussed for each type of epidemiological study
  - Some additional issues and uncertainties cited in comments will be added

# Issues with Epidemiological Studies - 2

- Inconsistent results between studies
  - Heterogeneity acknowledged in report
  - Likely due to different model specifications, monitor locations, characteristics of sample, and random variation
  - Model specifications have greater effect when RR is small
  - Body of evidence too large and health endpoints too important to ignore

# Issues with Epidemiological Studies - 3

- Concern about use of studies focused primarily on PM
  - Recent increase in ozone-specific studies
  - Agree that more sensitivity analysis needed in primary studies
- Publication bias
  - Ozone results bolster PM conclusions, thus unlikely to be suppressed

# Ozone Benefits Assessment

- Epi studies don't prove causality - should use chamber studies
- Ozone mortality should include zero and may not be quantifiable
- Methodological issues on exposure estimation, rollback and averaging-time conversion factors

# Comment 1. Epi studies don't prove causality - should use chamber studies

- Results from chamber studies difficult to apply on population basis; limited outcomes studied
- Epi studies meet many of the criteria for causality
- Human and animal exposure data support causal relationship
- Our methods similar to those used in EPA report to Congress, RIAs, published articles

## Comment 2: Ozone mortality should not be quantified or should include zero

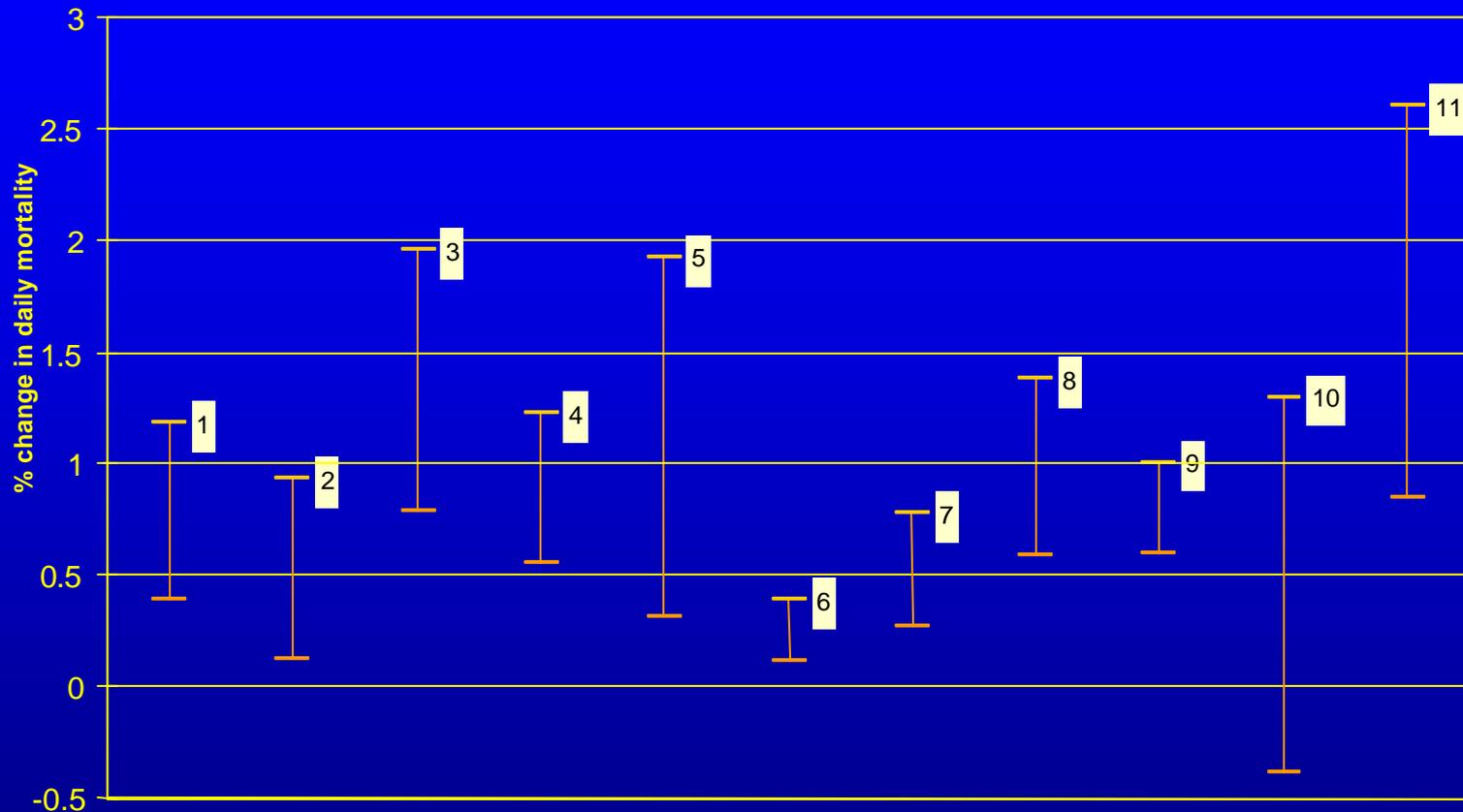
- New NMMAPS and meta-analyses by Levy, WHO and others show association
- Association exists for full year and summer only
- Uncertainty remains but doesn't imply zero effect
- Heterogeneity in response not unlikely

# Recent Reanalysis of Mortality and Ozone from NMMAPS

(Bell et al., 2004)

- Involves 95 cities, 1987-2000
- Associations with total and cardiopulmonary mortality
- Similar effects for 55 cities with full years of data, warm season and all 95 cities
- Robust to inclusion of PM10 in the model and exclusion of high temperature days
- Similar effects among ages < 65, 65-74, 75+

# Percent Change in Mortality Associated with Ozone (10 ppb, 24-hr ave)



1. WHO (2004)

5. Stieb et al. (2003)

9. Levy et al. (2001)

2. WHO (2004)

6. Bell et al. (2004)

10. Gryparis et al. (2004)

3. Thurston & Ito (2001)

7. Bell et al. (2004)

11. Gryparis et al. (2004)

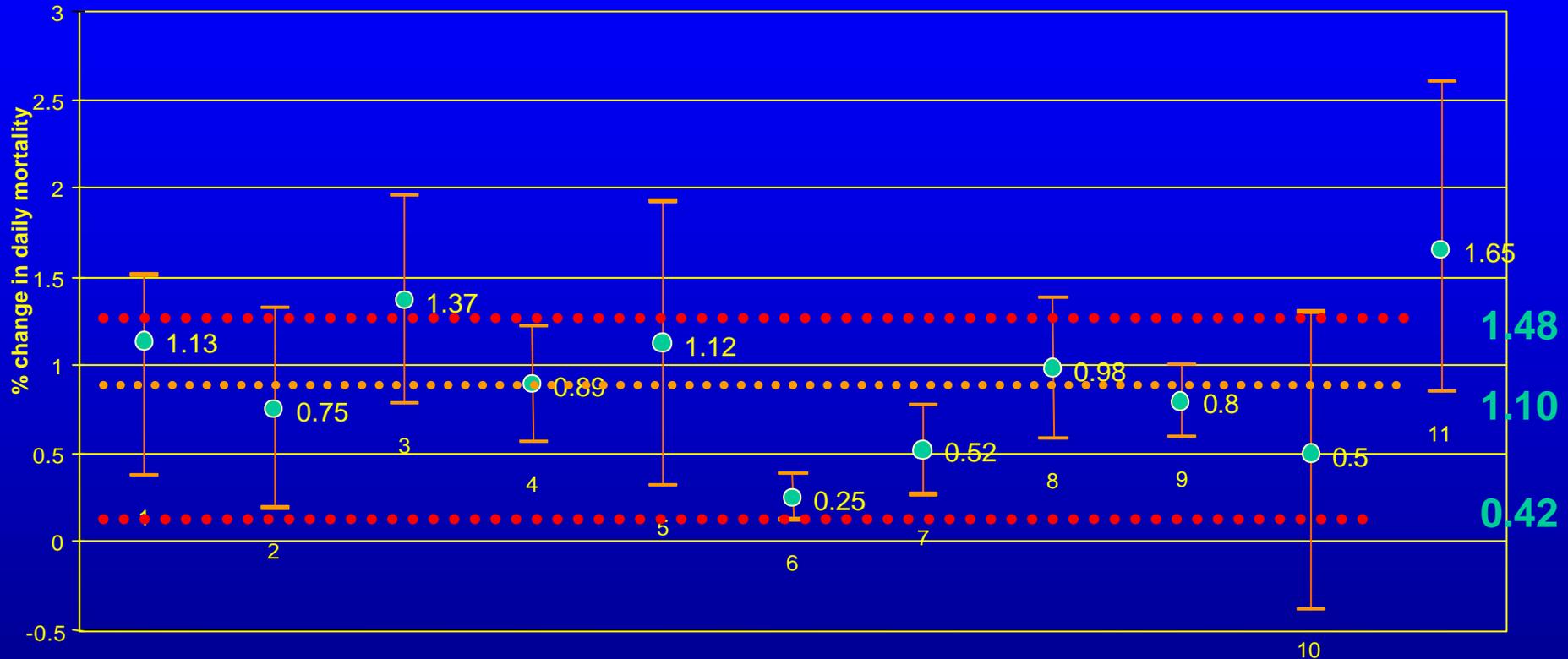
4. Thurston & Ito (2001)

8. Levy et al. (2001)

# Ozone Study Details

	<b>Author</b>	<b># of studies</b>	<b>comment</b>
1	WHO(2004)	15	European
2	WHO(2004)	20	Euro, corr for poss pub bias
3	Thurston+lto (2001)	7	non-linear temp
4	Thurston+lto (2001)	19	all studies
5	Stieb et al. (2003)	109	mixed models
6	Bell et. al. (2004)	95	NMMAPS, unlagged
7	Bell et. al. (2004)	95	NMMAPS,lag06
8	Levy et al. (2001)	4	tight criteria
9	Levy et al. (2001)	15	loose criteria
10	Gryparis et al.(2004)	23	all year Europe

# Percent Change in Mortality Associated with Ozone (per 10 ppb, 24-hr ave)



1. WHO (2004)

5. Stieb et al. (2003)

9. Levy et al. (2001)

2. WHO (2004)

6. Bell et al. (2004)

10. Gryparis et al. (2004)

3. Thurston & Ito (2001)

7. Bell et al. (2004)

11. Gryparis et al. (2004)

4. Thurston & Ito (2001)

8. Levy et al. (2001)

## Comment 3: Methodological issues on exposure estimation, rollback and averaging-time conversion factors

- Attempt to mimic exposure scenario of original studies by assigning population to monitors
- Conducting sensitivity analysis of method
- Proportional rollback scheme consistent with air quality plans and historical trends in ozone reduction
- National average of ratios between 1-hr, 8-hr, and 24-hr averages consistent with California ratios

# Other Health-Related Issues -1

- Responses of potentially susceptible populations not adequately discussed
  - All available information was reviewed
- No discussion of reduced ozone impacts due to historical reductions
  - Data addressing “interventions” are not available for ozone

# Other Health-Related Issues -2

- Indoor contributions to ozone exposure are not adequately considered
  - Ambient air quality standards are for outdoor air
  - Few indoor sources of ozone
  - Epi studies demonstrate impacts concurrent with changes recorded in outdoor monitors

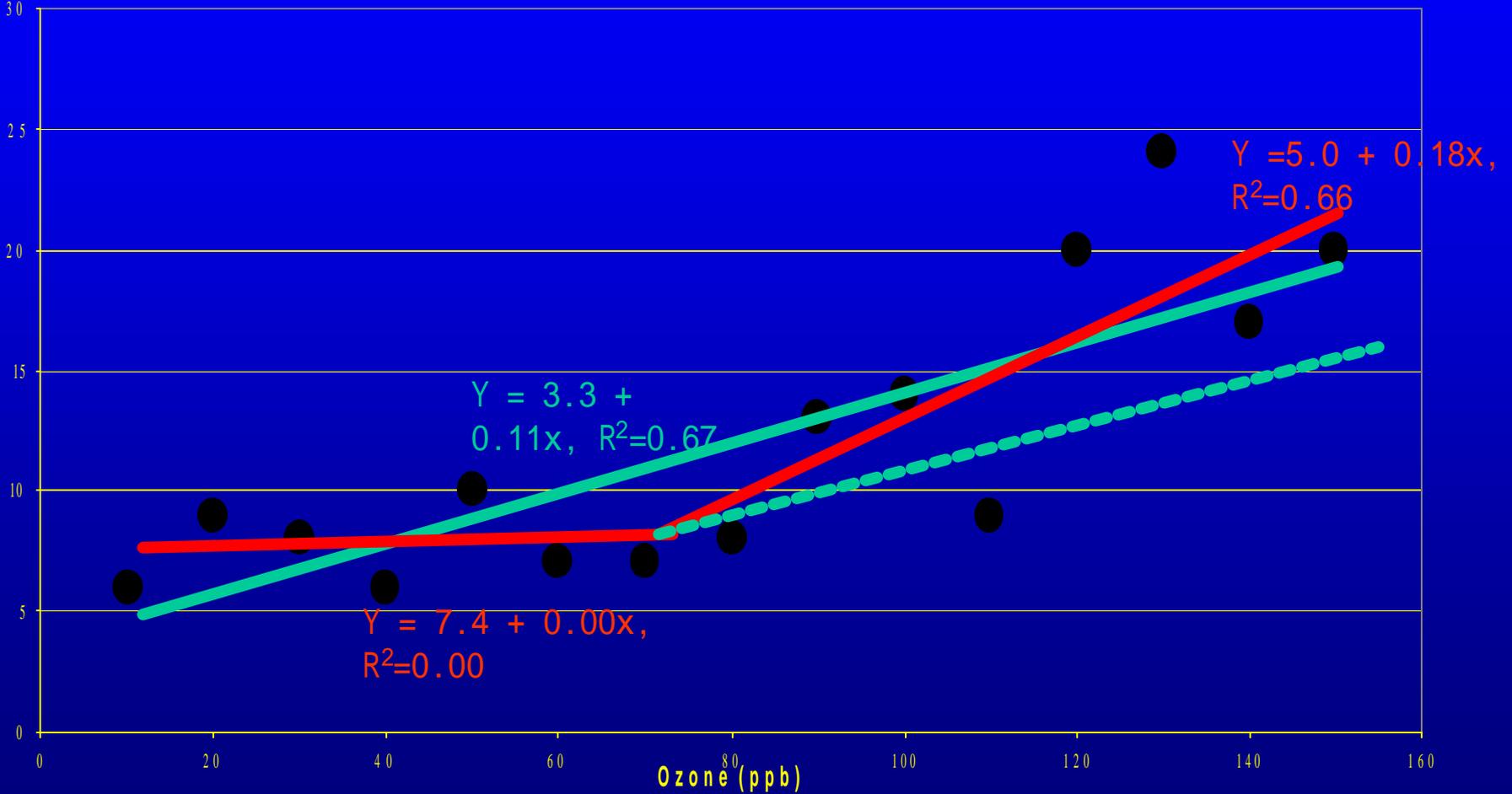


# Comment : Threshold issue and question about effects below chamber study concentrations

- Most studies suggest linear CR function
- No population threshold may exist given heterogeneity of individual thresholds
- All epi studies include concentrations below the effect level from chamber studies (0.8 8-hr and 0.12 ppm for 1-hr)
- Sensitivity analysis will be conducted with adjustment for CR slope

# Effects of Imposing Threshold

Number of cases



# Effects of Imposing Threshold

Number of cases

