

**“Risk Assessment and Risk
Management in a Regulatory
Framework”
Focus on Ozone**

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Outline

- What Are:
 - Risk Assessment?
 - Risk Management?
- How Do They Come Together?
- Regulatory Framework
- Ozone RIA
- Local Implications

Risk Assessment & Management

■ Risk Assessment

- Hazard Identification:
Causal Link
- Dose-Response:
Magnitude of
Relationship
- Exposure
Assessment:
Extent of Exposure
- Risk Characterization:
Nature & Magnitude &
Uncertainty

■ Risk Management

- Decisions & Actions
- Tradeoffs & Balances
Who, What, How, How
Much, How Long
- Factors
 - Risk Magnitude
 - Feasibility
 - Benefits - Costs
 - Political
 - Social
 - Institutional

Risk Assessment

Hazard Identification

**“Chemicals of
Concern”**

**Dose-Response
Assessment**

“Damage Function”

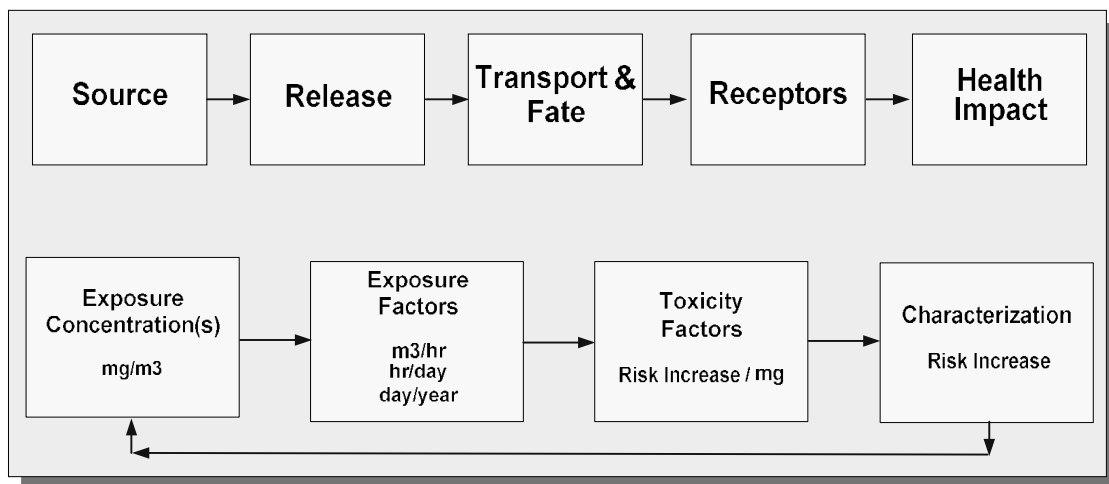
**Exposure
Assessment**

**“Who, When, Where,
How Much”**

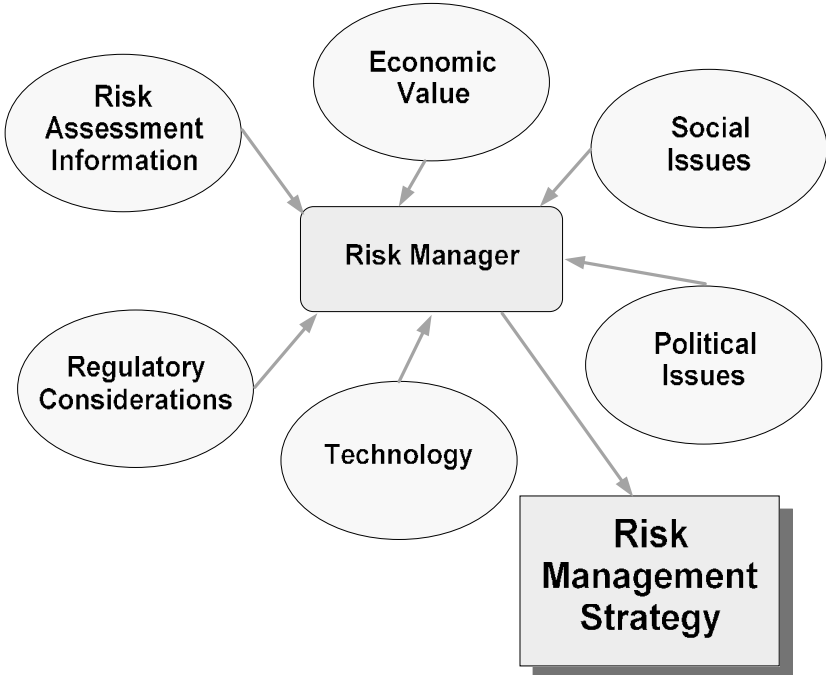
Characterization

**“Likelihood & Nature
of Damage”**

Risk Assessment Models



Risk Management



Pending Ozone Changes

O₃ NAAQS Chronology

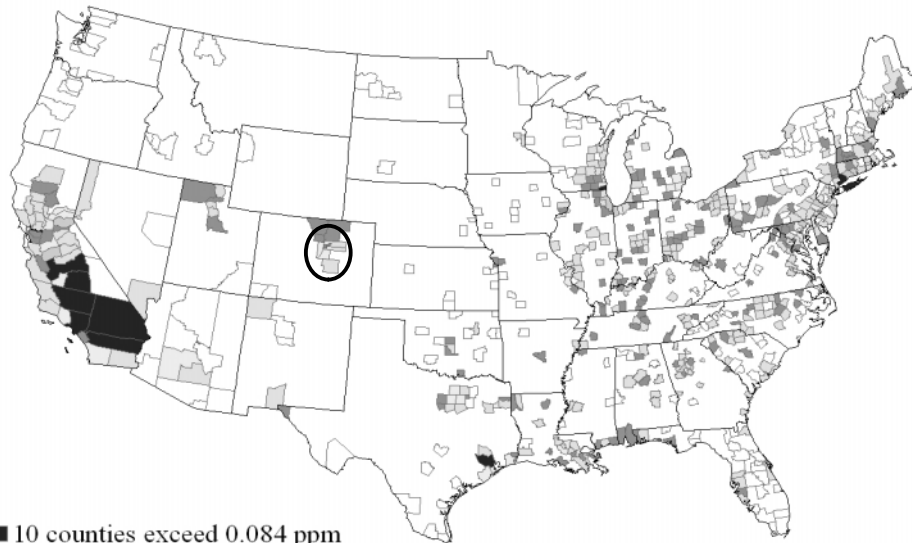
- 1971 1' & 2' Stds. 08 ppm
1 hr. yr.
- 1979 1-hr max. 1 day
average 0.12 ppm
- 1997 8-hr max. 3-yr.
average, 4th highest 0.08
ppm (80 ppb)
- 2008 8-hr max. 3-yr.
average, 4th highest
< 0.08 ppm (0.07 to
0.075?)

Criteria Document (CD)

- Risk Assessment Basis
- Premature Mortality*
- Respiratory Symptoms*
- Hospital Admissions
Emergency Dept. (ED)
Visits

* New Information Since
1997

Ozone Nationally & Locally



- 10 counties exceed 0.084 ppm
- 19 additional counties exceed 0.079 ppm for a total of 29
- 53 additional counties exceed 0.075 ppm for a total of 82
- 150 additional counties exceed 0.070 ppm for a total of 203
- 210 additional counties exceed 0.065 ppm for a total of 360
- 131 counties meet .065 ppm standard for a total of 491
- monitored in 2003 - 2005 but not projected

Revising NAAQS

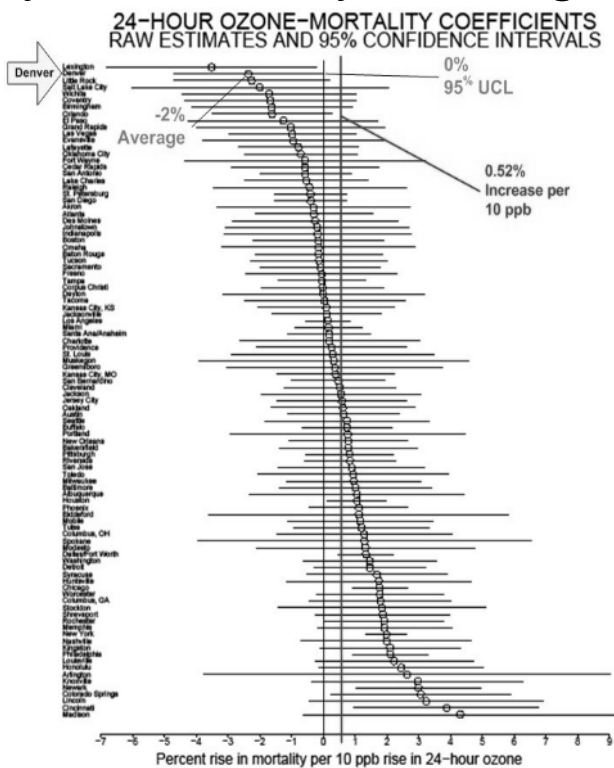
How Much Uncertainty -Two Views

- NAAQS “..protective with adequate margin of safety..”
- New Information Suggests Need for Lower NAAQS
- Uncertainty “ ..Err On Side of Safety..”
Precautionary Principal
- NAAQS Requisite to Protect
- No Compelling New Information Since 1997 - Inconclusive
- Overall Air Quality is Improving
- Too Much Uncertainty EPA Cannot Engage in “*Sheer Guesswork*”

Main Issues

- The Epidemiology is “Observational” and Does Not Establish Causality for Acute Mortality - Issues of combining multi-city, 24 hr vs. 8 hour exposure data, PM_{2.5} effects and other confounders, monitor vs. “personal exposure” data, Bayesian and Meta Analysis – (Bell NMMAPS)
- Respiratory Symptoms at Low Concentration Inconclusive (tests @ 40, 60, 80 ppb - Adams Clinical Studies). A small study found a small but no *statistical* difference between 60 and 80 ppb; EPA re-worked statistics and found *statistical* difference.

Uncertainty in Mortality Damage Function



Main Issues, contd.

- Policy Relevant Background (PRB) EPA uses a coarse scale model to estimate PRB. Benefits can only accrue above BG. PRB is thought to be “too low” (well below 40ppb).
- Linearity at low dose and the “Rollback” technique across numerous (dose response near BG not linear).

Background O₃?

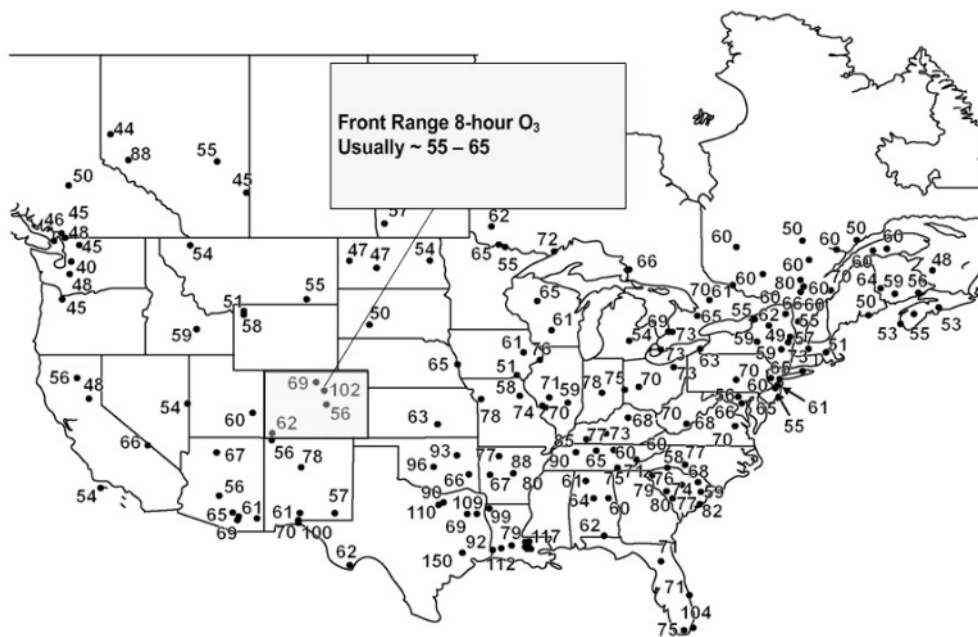
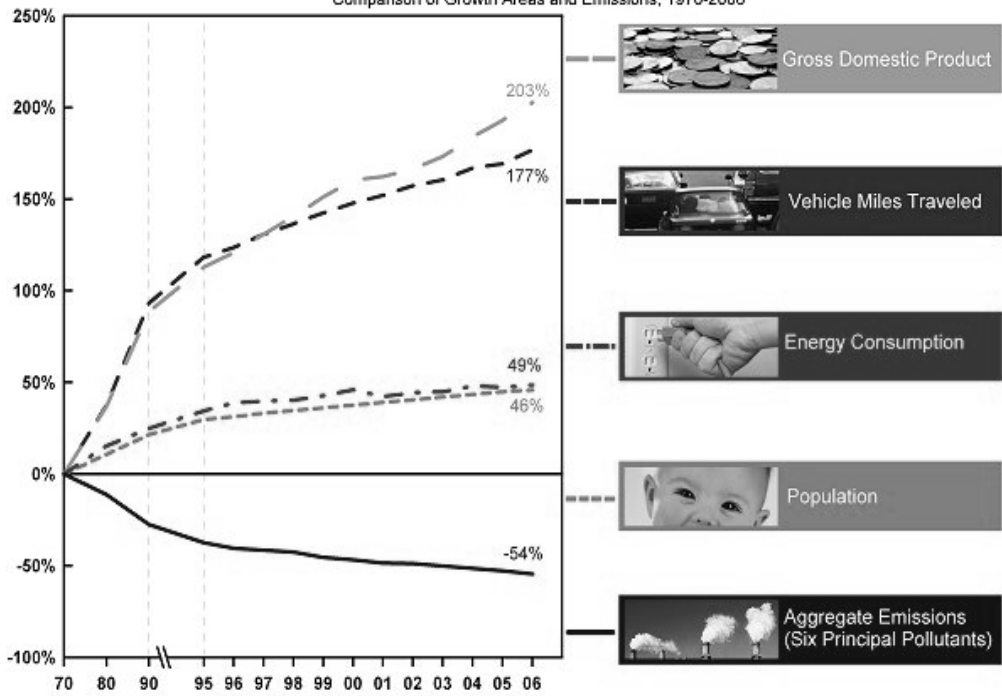


Figure AX3-78 Maximum hourly average O₃ concentrations at rural monitoring sites in Canada and the United States in February from 1980 to 1998.

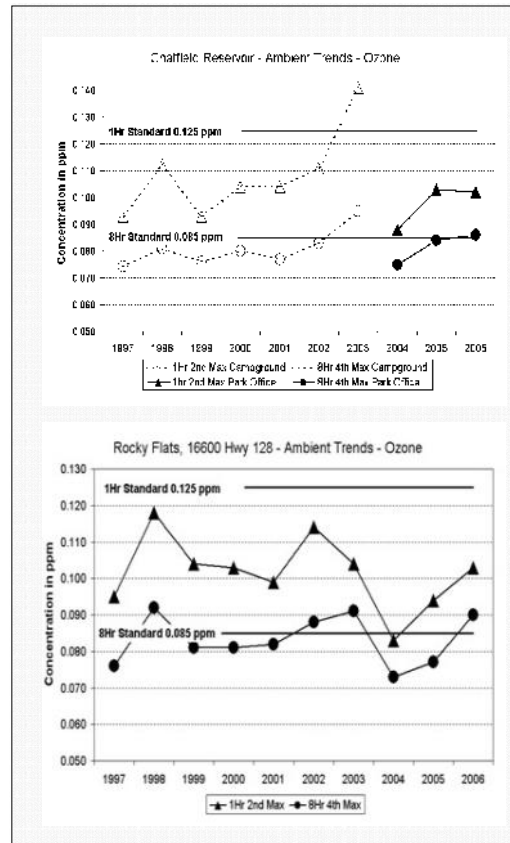
Big Picture

Comparison of Growth Areas and Emissions, 1970-2006



Locally

- Some Recent Increases
- Non Attainment Designation
- State Implementation Plan (SIP) Revisions Forthcoming



Benefits & Cost of SIP

- Widely Used in Regulatory Impact Analysis (RIA)
- Risk Management Economic Value “A Consideration”
- How Well Do Benefits Stack Up to Costs?

Benefits ~ Costs?

Benefits

Cost

Costs ~ Benefits

Allocate Costs
According to
Contribution?

National Annual Health Effects Reduce O₃ to Achieve 8-hr. Std (84 ppb)

<u>Endpoint</u>	<u>Cases Prevented</u>	<u>Remark</u>
Premature Mortality	750	Non Accidental
Hospital Admissions	2,000	Adults 65
Hospital Admissions	1,900	Children < 2
ED Visits	460	Asthma

Data Hubbell, EHP 13, 1

Means using percentage rollback

**Annual Health Effects 6 Metro Counties
Reduce O₃ ~ 10 ppb**

<u>Endpoint</u>	<u>Cases Expected</u>	<u>Cases Prevented</u>	<u>% Reduction</u>
Premature Mortality	15,720	6	0.04%
Hosp Admits Resp.>65	27,000	25	0.1%
Hosp Admits Resp. <2	3,265	8	0.3%
ED Visits	15,500	4	0.03%
Adams, Arapahoe, Boulder, Denver, Douglas, Jefferson: Population ~ 2.4M (2000)			

**Annual Health Benefits 6 Metro Counties
Reduce O₃ ~ 10 ppb**

<u>Endpoint</u>	<u>Cases</u>	<u>Value \$ / Case</u>	<u>Value \$</u>	<u>%</u>
Premature Mortality	6	\$6.5M	\$39M	98
Hosp Admits Resp.>65	25	\$18,353	\$460,000	1
Hosp Admits Resp. <2	8	\$7,741	\$62,000	<1
ED Visits	4	\$286	\$1,144	<<1
Total			~ \$40M	
Adams, Arapahoe, Boulder, Denver, Douglas, Jefferson: Population ~ 2.4M (2000)				

**Annual Health Benefits 6 Metro Counties
Reduce O3 ~ 10 ppb**

<u>Endpoint</u>	<u>Cases</u>	<u>Value \$ / Case</u>	<u>Value \$</u>	<u>%</u>
Premature Mortality	6	\$3M ^a	\$18M	97
Hosp Admits Resp.>65	25	\$18,353	\$460,000	2
Hosp Admits Resp. <2	8	\$7,741	\$62,000	<1
ED Visits	4	\$286	\$1,144	<<1
Total Adams, Arapahoe, Boulder, Denver, Douglas, Jefferson: Population ~ 2.4M (2000) ^a More typical			~ 18.5M	

**Annual Health Benefits 6 Metro Counties
Reduce O3 ~ 10 ppb**

<u>Endpoint</u>	<u>Cases</u>	<u>Value \$ / Case</u>	<u>Value \$</u>	<u>%</u>
Premature Mortality	0	0	0	0
Hosp Admits Resp.>65	25	\$18,353	\$460,000	80
Hosp Admits Resp. <2	8	\$7,741	\$62,000	14
ED Visits	4	\$286	\$1,144	1
Total			\$523,000	
Adams, Arapahoe, Boulder, Denver, Douglas, Jefferson: Population ~ 2.4M (2000)				

Regulatory Impact Analysis (In the SIP process?)

Regulatory Impact Analysis Addresses

- Need for the Action
- Examining Alternative Approaches
- Quantifying Benefits & Costs & Valuing in \$ Terms (where feasible)
- Evaluating Findings on Benefits & Costs in a Risk Management Framework
- Communication

Views of:

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