Risk Assessment in the Trenches: The Importance of Getting it Right

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Conservatism

• Regulatory risk assessment – tendency towards conservatism
  – Upper bound values
  – Compounding of conservative values
  – Precautionary principle

• New Value
  – “Is it more conservative?” vs “Is it more scientifically supported?”

• All well and good, but there are consequences...
Allocation of Resources

- Example - 2015 Ozone Standard
- EPA sets National Ambient Air Quality Standards (NAAQS) for 6 pollutants (ozone, NOx, PM, SO$_2$, Pb, CO)
- Required to review these standards every 5 years – First set in 1971

<table>
<thead>
<tr>
<th>Year</th>
<th>Period</th>
<th>Pollutant</th>
<th>Duration</th>
<th>Concentration</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>2008</td>
<td>Primary and Secondary</td>
<td>O$_3$</td>
<td>8 hours</td>
<td>0.075 ppm</td>
<td>Annual fourth-highest daily maximum 8-hr concentration, averaged over 3 years</td>
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<tr>
<td></td>
<td>73 FR 16483 Mar 27, 2008</td>
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<td>80 FR 65292 Oct 26, 2015</td>
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</table>
- Photochemical product, not directly emitted
- $O_3$ is a highly-reactive, poorly water soluble gas at room temperature, and is a respiratory irritant
- $O_3$ reacts with indoor surfaces and ventilation, scavenging it from indoor air: $O_3$ is effectively an outdoor pollutant
- Inhaled $O_3$:
  - Is scavenged by antioxidants in the respiratory tract
  - When antioxidants are depleted, it causes a neural reaction that decreases FEV1, in addition to other responses such as inflammation
  - Decreased FEV1 – Basis for lowering standard
Human Controlled Exposure Studies

- Healthy volunteers are exposed to ambient or near-ambient concentrations of O₃ while exercising at moderate to vigorous exertion for 50 min/hr for 6.6 hours; face mask or chamber
- Averaged 33 L/min ventilation rate; resting rate ~6 L/min
- These studies measure primarily forced expiratory volume in 1 second (FEV₁)
- FEV₁ decreases with increasing air toxicant
- Mild, reversible effect (within minutes to hours)
Clinical Data – 6.6 hr exposure with moderate to vigorous exercise

10-20% defined as “moderate” decrement (US EPA, 2007)

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<tr>
<th>Study</th>
<th>Sample Size</th>
<th>Exposure</th>
<th>O₃ Conc. (ppb)</th>
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<tr>
<td>Adams (2006)</td>
<td>30</td>
<td>CH-TRI</td>
<td>40</td>
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<td>Adams (2002)</td>
<td>30</td>
<td>FM-SQR</td>
<td>40</td>
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<tr>
<td>Kim et al. (2011)</td>
<td>59</td>
<td>CH-SQR</td>
<td>60</td>
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<td>CH-TRI</td>
<td>63</td>
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<td>31</td>
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<td>88</td>
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<td>Adams (2002)</td>
<td>30</td>
<td>FM-SQR</td>
<td>120</td>
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<td>30</td>
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Adapted from Goodman et al. (2013)

Schelegle 72 ppb Exposure - 6 of 31 individuals had > 10% decreases and 5 of 31 individuals had increases in FEV₁. Lung function returned to normal within 1-4 hours.
Characteristics of Human Exposure Studies - Exercise

- Vigorous Exercise, 33 L/min
- Light Exercise, 20 L/min

Range of normal human variation

% Change in Lung Function

Time (hrs)

Adams et al, 1997

120 ppb O₃
Ozone dose (based on EPA-derived exposure patterns) changes very little with a changing ozone standard.
What’s the Big Deal?

- 75 ppb vs. 70 ppb doesn’t sound like a big change
- We’ll get to that but first some more background info...
Calculating Ozone Design Value

The design value is the three-year average of each year’s fourth highest reading.

**Monitor A** with three complete years of data.

**Year 1:** 2012
- 91
- 87
- 81
- **78**

**Year 2:** 2013
- 90
- 85
- **82**
- **79**

**Year 3:** 2014
- 88
- **79**
- 75
- 74

Take the 4th highest peak hour-ozone from each year

“Design Value” for 2014:

**77**

Find three-year average of each year’s fourth highest reading.
Calculating Design Values

- Values are not averaged across monitors
- Highest monitor in the area is the design value
- If only 1 monitor design value exceeds the standard: nonattainment
The standard dropped from here to here.
State of Texas Effort

- $66M to $150M state funds (TERP) per year for 20+ years on ozone by TCEQ alone
- By far largest expenditure for any single pollutant
- By far largest use of staff resources for any single pollutant
- ~1 ppb reduction per year in design value
- FCAA – can’t consider costs
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<th>Remediation, Reimbursement and Grant Contracts</th>
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<tr>
<td>Air Quality and Monitoring Grants</td>
<td>$ 6,177,833</td>
</tr>
<tr>
<td>Drinking Water Quality and Standards Grants</td>
<td>3,349,880</td>
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<tr>
<td>Dry Cleaning Facilities</td>
<td>3,342,584</td>
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<tr>
<td>Estuary Programs</td>
<td>1,300,304</td>
</tr>
<tr>
<td>Local Air Grants - Federal</td>
<td>862,500</td>
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<tr>
<td>Local Air Grants - State</td>
<td>1,751,863</td>
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<tr>
<td>Low Income Vehicle Repair Program</td>
<td>48,043,825</td>
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<td>Misc RRG Contracts</td>
<td>859,270</td>
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<tr>
<td>Other Remediation</td>
<td>2,546,691</td>
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<td>Petroleum Storage Tank Program</td>
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<td>Solid Waste Management Grants</td>
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<td>Superfund</td>
<td>9,418,639</td>
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<tr>
<td>Texas Emission Reduction Plan Grants</td>
<td>109,212,630</td>
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<td>Water Quality and Monitoring Grants</td>
<td>7,311,659</td>
</tr>
<tr>
<td>Water Quality Clean Rivers</td>
<td>4,250,290</td>
</tr>
<tr>
<td><strong>Agency Total</strong></td>
<td><strong>$ 218,798,917</strong></td>
</tr>
</tbody>
</table>
Second Point

- Rules can have unintended consequences
Lead NAAQS

- Inhalation insignificant (~1% of total exposure)
- Oral exposure predominates (food, paint, toys, soil, etc.)
- EPA considered eliminating the 1.5 ug/m$^3$ standard
- Instead, lowered to 0.15 ug/m$^3$ in November, 2008
- In a nutshell - no threshold, other media/sources predominate, therefore should lower exposure as much as possible
Lead in Frisco
Lead in Frisco

Rolling 3-Month Average Lead Concentration in Frisco

Change in Standard from 1.5 µg/m^3 Quarterly to 0.15 µg/m^3 3-month rolling average
Community Concern

Get the LEAD Out of Frisco!
A Community Partnership for a Lead-Free Frisco

- Brain or Nerve Damage
- Hearing Problems
- Digestive Issues
- Stunted Growth

Breaking News: CDC Advisory Committee Report: Low Level Lead

Community Concern

Lead-Free Frisco

Lead-Free Frisco is on Facebook.
To connect with Lead-Free Frisco, sign up for Facebook today.

MUST LISTEN TO SERIES OF INTERVIEWS WITH DR. HOWARD MELKIS: ABOUT THE REAL DANGERS OF LEAD IN SOIL.

“We have air pollution laws and water pollution laws but we don’t have any soil pollution laws,” says Dr. Melkie.

Next event: Interview with Dr. Melkie.

Like one or more others on Lead-Free Frisco.
TDSHS Blood Lead Screening

- 608 blood samples
  - 1-5 yrs n=69
  - 6-11 yrs n=98
  - 12-19 yrs n=54
  - 20+ yrs n=387
- 575 (95%) non-detect (<2 ug/dL)
- 594 (98%) consistent with NHANES
- 2 adults > 10 ug/dL, but less than 15 ug/dL
- Frisco children had levels less than Texas children in general
Path Forward

- SIP Order to come into compliance – June 2011
- Plant closed – November 2012
- Facility demolished
Figure 6: The US Monthly Exports of ULAB

Notes: Each dot in the figure above indicates the amount of ULAB exported from the US to Mexico (in green) and Canada (in orange). The corresponding lines indicate smoothed local polynomial trends with the bandwidth of three months. The trend for Mexico does not consider May and June, 2008, as these two deviate from the trend due to the announcement of the NAAQS revision.

Data source: The US ITC with corrections provided by the US Census Bureau Foreign Trade Division
Good Policy Decision?

Take Home

- It is important that we as risk assessors accurately assess risk
- Decisions made by risk managers can impact resource allocation, have unintended consequences, etc.

Questions?