Review of Pb NAAQS Uncertainties

Presented by

Teresa S. Bowers, Ph.D.

Gradient Corporation

October 2, 2008

Data Gaps and Major Sources of Uncertainty

- Uncertainties in best estimates of blood lead – IQ concentration-response (C-R) functions
- Magnitude of risk associated with short-term exposures is unknown
- Extrapolation of long-term to short-term risks is uncertain, but can be done

Uncertainty in the Blood Lead – IQ C-R Function at Low Blood Lead Levels

- Unresolved potential math errors in Lanphear *et al.* (2005)
- Limited number of children at low blood lead levels in Lanphear *et al.* (2005) study
- Several recent studies do not support extreme end of the C-R function range

How Non-Linear is the C-R Function?

- Lanphear *et al*. (2005) found C-R to be steeply non-linear at low blood lead levels
- Tellez-Rojo *et al*. (2006) found no statistical difference in slopes of the C-R function between blood lead categories below 5 μg/dL and between 5 and 10 μg/dL.
- Jusko *et al*. (2007), in a categorical analysis, found no statistically significant non-linearity in the function
- Surkan *et al*. (2007) found no relationship between blood lead and IQ below 4 μg/dL

Is the C-R Function Truly Non-Linear?

- CDC (2005) analysis on the effect of unidentified confounders suggested that this could explain apparent non-linearities
- Bowers and Beck (2006, 2007) analysis on the impact of statistical and distributional factors on the shape of the C-R function also could explain apparent non-linearities
- Both possibilities suggest that a biological basis for non-linearity may not be necessary

Risks Associated with Short-Term Exposures are Lower than Risks Associated with Long-Term Exposures

- Blood lead levels increase with length of exposure: elevated exposure for 12 months will lead to a higher blood lead level than will the same elevated exposure for 1 month.
- A 1 month exposure will increase blood lead, but blood lead will decrease after the exposure ceases.
- Hypothetically, if 1 month of exposure and 12 months of exposure led to the same risk, then the blood lead – IQ C-R curve would be flat. This is contradicted by the epidemiology studies.
- Further, Superfund and lead paint remediation programs, as well as CDC intervention guidelines are premised on the foundation that reducing exposure reduces risk. Otherwise, why would we remediate?

There is No Basis for the Assumption that Short- and Long-Term Excursions in Ambient Air Lead Levels Have the Same Effect on IQ

- CASAC members have provided citations to support their position that "Pb exposures and associated toxic effects are expressed quite rapidly in time," thus advocating for a monthly averaging period.
- None of the publications cited by CASAC refer to neurotoxic effects measured within months after new exposures to lead, rather they discuss either severe acute toxicity requiring hospitalization, or biochemical changes in blood and/or urine with little or no overt symptoms.
- Even if short-term exposures result in effects on IQ, the magnitude of these effects is less than the effect of long-term exposure.

EPA Acknowledges that the Effect of Short-term Exposures on IQ is Unknown

- EPA's March 28, 2008 document entitled, "The approach used for estimating changes in children's IQ from lead dust generated during renovation, repair, and painting in residences and child-occupied facilities," in support of the Final Rule, Lead: Renovation, Repair, and Painting Program states:

  > "The relationship between IQ changes and shorter-term fluctuations in blood Pb is not known. By its nature, the Lanphear *et al.* (2005) study could not quantify such effects." (page 97)

- As a result, the analysis in support of the Lead Paint Rule estimated IQ decrements based on life-time average blood lead levels (ages 0-6 years), where single or multiple renovations leading to exposure were modeled to occur on a short-term basis

Extrapolation from Long-Term to Short-Term Risks can be done with the Adjustment Factor

- Air lead levels vary with time, with the result that annual averaged air lead levels are always lower than the highest quarterly or monthly average
- EPA's Risk Assessment was based on exposure to annual average air lead levels and developed factors to convert between monthly or quarterly averaged NAAQS and annual averages
- The adjustment factor provides a method to extrapolate uncertain long-term risks to unknown short-term risks.

Factors Relating Monthly, Quarterly, and Annual Air Lead Levels

		Max Quarterly/Annual (3 years)		2nd Max Monthly/Annual (3 years)	
Monitors	**Number**	**Mean**	**95th**	**Mean**	**95th**
All Monitors	171	1.7	3.1	1.9	3.5
Urban Monitors	122	1.7	2.6	2.0	3.9
Chicago and LA	18	1.6	2.3	1.6	2.3
Primary and Secondary Smelters	27	1.5	2.1	2.9	4.7

EPA's Risk Assessment Estimates of IQ Loss for a Population

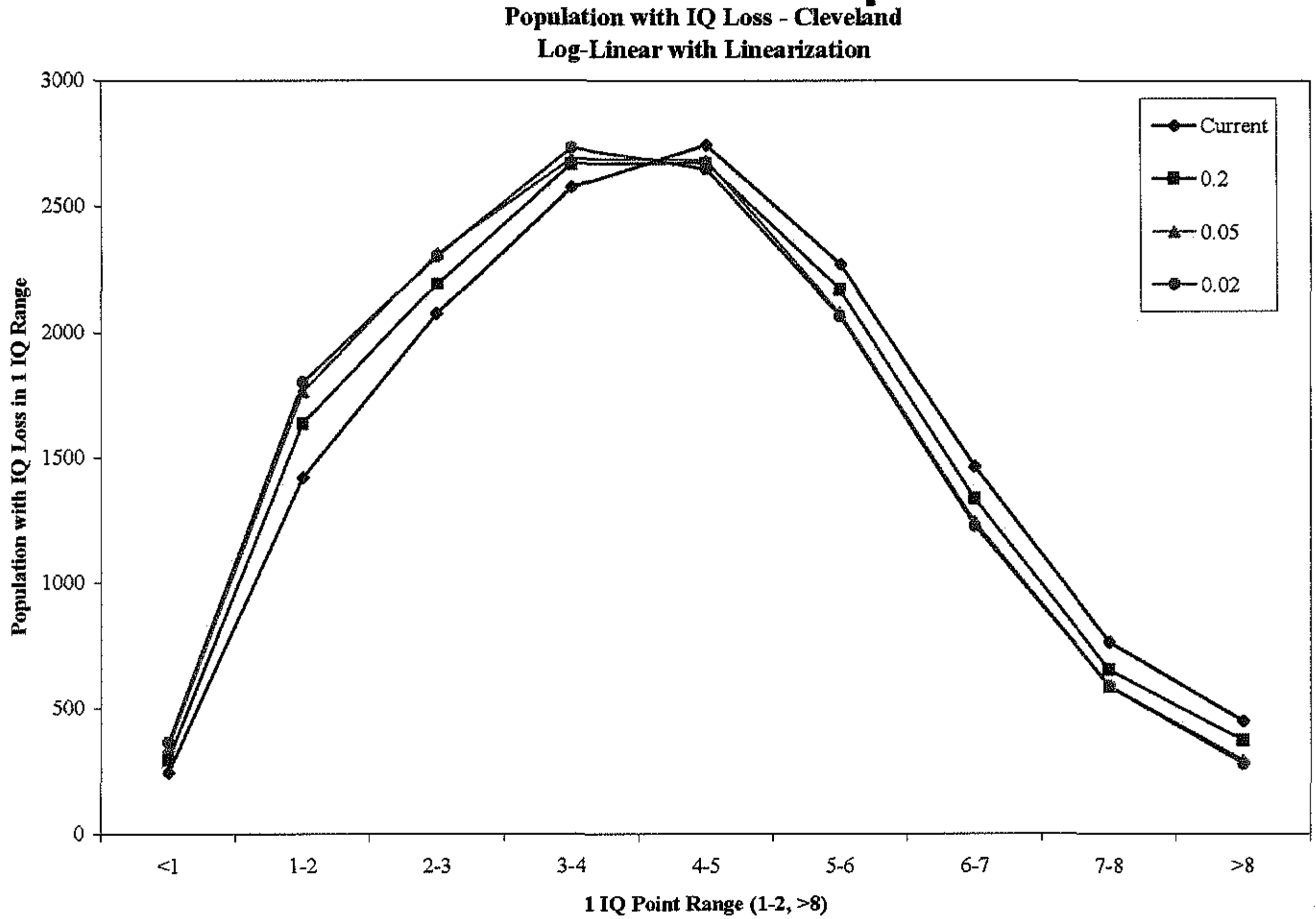

Figure drawn from calculations presented in EPA Risk Assessment Appendix O.

Centers for Disease Control Editorial in *Environmental Health Perspectives* (February, 2008)

- "Responding to Blood Lead Levels < 10 µg/dL" by Mary Jean Brown, Chief of the Lead Poisoning Prevention Branch at the Centers for Disease Control (CDC), and George Rhoads, Chair of the CDC Advisory Committee on Childhood Lead Poisoning

> "…the entire population of U.S. children 1-5 years of age enjoyed a decline in geometric mean BLLs from about 15 µg/dL in the late 1970s to less than 2 µg/dL in 2002 (CDC, 2005a), but there is no agreement that IQs have increased by 7 points."

Comparison of Facility Air Lead Monitoring Data to Potential Ambient Air Lead Standards

Facility Code	E	Monitor Distance (miles)	3 year period	2nd Highest Max Monthly Avg (µg/m3)	Max Quarterly Avg (µg/m3)	Number of Months or Quarters With Exceedences, in a 3-yr Period: 0.1 µg/m3 Monthly	0.1 µg/m3 Quarterly	0.15 µg/m3 Monthly	0.15 µg/m3 Quarterly	0.2 µg/m3 Monthly	0.2 µg/m3 Quarterly	0.25 µg/m3 Monthly	0.25 µg/m3 Quarterly	0.3 µg/m3 Monthly	0.3 µg/m3 Quarterly
1		0.5	2005 - 2007	1.54	1.41	28	10	27	10	25	10	24	10	22	10
2	E	<0.1	2005 - 2007	0.86	0.95	30	11	30	11	27	10	25	10	20	7
3	E	<0.1	2004 - 2006	0.88	0.90	33	12	33	12	33	12	33	12	30	12
4		0.15	2005 - 2007	1.54	1.65	33	12	31	12	28	11	25	11	21	11
5	E	0.2	2005 - 2007	1.39	1.39	36	12	35	12	35	12	35	12	35	12
6	E	0.43	2005 - 2007	0.05	0.03	0	0	0	0	0	0	0	0	0	0
8	E	0.15	2005 - 2007	0.67	0.69	21	8	17	8	14	6	12	5	8	5
8	E	0.15	2004 - 2006	0.32	0.32	14	6	11	4	7	2	5	1	2	1
9		0.6	2005 - 2007	1.87	1.31	36	12	35	12	35	12	35	12	34	12
11	E	0.26	2005 - 2007	0.09	0.11	0	1	0	0	0	0	0	0	0	0
12	E	0.6	2005 - 2007	0.23	0.17	20	11	8	2	1	0	0	0	0	0
13		0.25	2005 - 2007	0.57	0.39	34	12	22	11	19	7	10	5	7	4
15		0.45	2005 - 2007	1.09	0.77	35	12	34	12	33	12	30	12	29	12
16		0.15	2005 - 2007	2.38	1.93	36	12	36	12	36	12	36	12	36	12

Notes:
E = Facility smelting operations are enclosed.
Comparison was done for most recent 3 calendar year period for which data were available.
The highest monthly maximum for each monitor within the 3-year period was excluded from the "Monthly" evaluation.
Air monitoring data were obtained from EPA AQS database, except for the two facilities in CA.
Shaded values indicate zero exceedences in the 3-year period.

Proportional Rollback

- EPA Risk Assessment computes "benefits" using the assumption that all monitors in an urban area will "improve" by the same proportion of improvement necessary to bring the highest monitor into attainment.
- This assumption is unfounded and is really an assertion that serves to inflate the apparent benefits of NAAQS reduction.
- ABR review of EPA monitoring data history identified no instances of such proportional improvement occurring in response to SIP implementation.

Proportional Rollback

- ABR presented two specific case studies in ANPR comments.
- Cleveland
  - Post-1997 improvement at maximum monitor was 88% reduction after completion of remediation activities.
  - One other monitor in Cleveland reduced by 20%
  - Two other monitors unchanged
  - Two increased.
- Memphis
  - Post-1998 improvement at maximum monitor was 68% reduction after shut down of Exide smelter.
  - Other monitor in Memphis increased.