Preliminary Comments from Members of the CASAC Lead Review Panel on EPA's Integrated Review Plan for the National Ambient Air Quality Standards for Lead

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Comments from Mr. George A. Allen

These comments focus on chapters 5 (risk and exposure) and 6 (monitoring).

Chapter 5: Quantitative risk and exposure assessments

As noted in this chapter, it is very difficult to link typical (near or below the current Pb NAAQS) ambient air Pb concentrations to the bio-indicator of dose (blood Pb levels), since inhalation is not a primary exposure pathway. Thus ambient air concentrations are a poor indicator of potential dose (we can't even talk about exposure in this framework). Pb is a unique primary NAAQS in this respect. These issues are explained well, and make clear the need to better understand and quantify this linkage to the extent that it is relevant in the Pb exposure framework. The disconnect between air Pb and dose is somewhat similar to the NOx-SOx secondary NAAQS that is in the final stages of the review process. In both cases the NAAQS framework is constrained to measurements of the respective pollutants in ambient air, but the endpoints (aquatic acidification index for the NOx-SOx secondary NAAQS) are driven by other mechanisms. For Pb, it is primarily Pb in dirt, and for NOx-SOx it is deposition (primarily wet). Neither NAAQS can directly measure what is most important in terms of health or welfare effects, making a rational health or welfare assessment very difficult.

There are very large spatial variation in elevated air Pb concentrations. High levels are only found near sources. Fine mode lead (from combustion sources such as smelters) disperses rapidly, with minimal local deposition and a limited area of elevated concentrations (driven in part by low background Pb air levels). Coarse (or larger) mode lead particles (from mechanical sources) deposit rapidly, near the source. A complicating factor in exposure assessment is existing (historical) Pb in soils, usually from lead paint from before the late 1970s. Soil Pb becomes airborne usually by wind or vehicle turbulence. However the temporal and spatial patterns of Pb in air from soil are very complex and difficult to measure. Modeling could be done if sufficiently detailed mapping of soil Pb were available, but it is generally not (other than from special studies).

The linkage between ambient air Pb levels and indoor dust Pb from outdoor Pb air concentrations is especially weak, but indoor dust is one of the major (ingestion) exposure pathways for children. For homes with lead paint, this linkage becomes almost impossible to assess and is probably irrelevant. Because of the local soil's Pb "history", this linkage gets even weaker if you consider how the ambient air component of indoor dust Pb levels might decline with a decline in ambient air Pb levels.

I am not aware of significant progress in improving estimates of air-related Pb concentrations that are relevant to human health. Lack of sufficient measurement data that

addresses this issue is the limiting factor, and that has not changed much since the last review.

Chapter 6: Ambient Air Monitoring Considerations

Monitoring methods:
http://replay.web.archive.org/20010619094708/http://rpco.com/cartoons/c199801.htm
http://replay.web.archive.org/20010527041057/http://rpco.com/cartoons/c199904.htm
http://replay.web.archive.org/20010513124050/http://rpco.com/cartoons/c199811.htm
http://replay.web.archive.org/19990830175531/http://rpco.com/cartoons/c199806.htm

The Hi-Volume FRM sampler has long outlived its design lifetime; it was first used in the mid 1940's to sample PM levels from welding fumes. Its fundamental design has not changed. If the Hi-Vol were proposed today as an FRM, it would not get any consideration as a plausible method. Others have pointed out its many shortcomings; I will not repeat them here. I will state clearly that its continued use as an FRM sampler for Pb in the 21st century is indefensible.

There is only limited evidence to suggest that it is important to sample particles larger than 10 um to characterize exposure to Pb from air. However, in some cases Hi-Vol Pb can be somewhat higher than PM10, as presented in previous CASAC and PB NAAQS reviews. If there is sufficient concern about capturing Pb aerosol greater than 10 um, it is practical to design a new “medium-vol” sampler with well characterized performance at reasonable wind speeds and a D50 cutpoint of ~ 18-20 um. Unlike PM2.5 or PM10 FRM samplers, the cutpoint for this method does not have to be sharp -- just well characterized and stable with wind speed and direction.

ORD staff know how to do this, as well as many other aerosol scientists. One simple example as a reasonable starting point: take the existing PM-10 / PM2.5 FRM sampler louvered inlet and mechanically scale it up by a factor of ~2 times. Increase the sample flow to maintain the inlet velocity (~ 100 lpm, compared to the 700 lpm of the Hi-Vol). Wind-tunnel test it (Texas A&M once again has a functioning and appropriate facility for this purpose; EPA does not). The existing FRM louvered inlet has been characterized over the size range of interest, but only at low wind speeds (1 m/s or 2.2 mph). In Figure 7 of Kenny et al., 2005, the D50 is ~ 35 um at this low wind speed; the line of interest is the 3-point open circle line furthest from the origin.

This figure also gives an indication of how size scaling can effect the size cut. To be of use in this round of the Pb NAAQS review process, ORD needs to start development work now. There should be sufficient resources for this effort within ORD’s existing budget.

If deemed essential (and only if), there is an upcoming opportunity to gather additional data on a relative large scale (25 sites nationally) for Pb in fine, coarse, and “TSP” fractions using the upcoming EPA PM-coarse speciation dichot network. If Hi-Vol samplers were added

to some or all of these sites for a year, a robust data set of Pb in these 3 size modes could be generated to assess the extent of "uber-coarse" particles as measured by the Hi-Vol.

Network Design

The existing network design, including the modifications in the Dec. 27, 2010 FR, is sufficient to provide oversight to stationary sources that could contribute to elevated air Pb concentrations, and to track long-term urban lead trends (urban NCore sites). This new network design is not sufficient to allow estimation of spatial gradients; it never will be given resource constraints and the large spatial variability of Pb in air.

Although I support EPA's efforts to remove Pb from AvGas as a long term goal, I do not agree with EPA that general aviation airports are a substantial source of elevated Pb in "ambient" air near airports. However, EPA counsel has defined ambient air to include the air on the tarmac at the location of maximum concentration. With this siting criteria, it is likely that elevated Pb levels will be monitored, and these Hi-Vol monitors would become "permanent".

Ambient air Pb exposures to populations living near or adjacent to airports has been shown to be similar or slightly elevated compared to relevant background levels, and not a substantial health issue. If the EPA airport sampler siting does show exceedances of the "never to be exceeded" 3-month Pb NAAQS, there is very little a local air agency could do to reduce monitored Pb concentrations. Any effort to do so would have minimal to no benefit to human health, given that no one stays at the (hot spot) location of the sampler for 3 months (e.g., the sampler does not reflect a NAAQS-relevant Pb exposure to anyone).

The Dec. 27, 2010 regulation requires Pb monitoring at all airports with estimated annual emissions of 1 ton or more, a reasonable approach. There are only a handful of such airports in this country. The same regulation requires a 1-year pilot study at 15 additional specific airports with estimated Pb emissions between ½ and 1 ton per year; Hi-Vols (with break-away stands) are required for those sites. Especially in these difficult economic times, large-scale GA airport monitoring is not an appropriate use of very limited local air agency resources; there is more important (non-Pb) monitoring to do that is much more health-relevant.

Reference:

Kenny et al., 2005. Aspiration and sampling efficiencies of the TSP and louvered particulate matter inlets. *J. Environ. Monit.*, Volume 7, 481-487.

Comments from Dr. Herbert Allen

Some of my comments may actually duplicate the intent of points in the review document. However, the document is frequently so generic in nature that it becomes impossible to determine the actual intent of the writers. Some of my comments relate to items not in Chapter 3.

Should biomarkers of exposure/effects be considered? There is a large and expanding literature on reactive oxygen species (ROS). Biological effects are well-documented. A quick look revealed hundreds, if not thousands, of citations.

If stress proteins are considered, should multiple metal (and other toxicant) exposures also be considered?

The document has not considered EPA 120/R-07/001 Framework for Metals Risk Assessment at all. This indicates that the chemistry of metals is of paramount importance. This is well-known in aquatic toxicology and in soil contamination. To reduce bioavailability of lead in contaminated soil, phosphate is added to form pyromorphite, a lead-containing mineral with a reduced solubility in ingested soil. All chemical species containing lead do not have equal bioaccessibility. This is ignored in assessment and analysis where the only consideration to differentiation of lead forms is by size.

In some routes of exposure there are multiple Pb sources, some of which may have originated in air whereas others are not airborne. Effects in organisms depend on exposure not the material source. Lead in vegetables grown in urban gardens may have originated from deposition of airborne lead onto the soil. If a person eating those vegetables is also exposed to lead in drinking water resulting from corrosion of lead pipe, there are two sources that must be considered in the risk assessment. The lead from the plumbing cannot be ignored. In aquatic toxicology both water and food as sources of metals are being considered more frequently. For another example, a child may be exposed to lead from paint and from dust.

The Primary and Secondary Standards are on a “not-to-be-exceeded” basis. Such a basis is not sound. Concentrations of all substances in the environment vary. There is a finite probability that any value will be exceeded. The revised means of averaging will lower the probability, but will not reduce it to zero. The question that should be addressed is what remedial action should be triggered by an exceedance?

Comments from Dr. Richard Canfield

I wish to commend the EPA for producing a very strong draft integrated review plan for evaluating the National Ambient Air Quality Standards for Lead. After a close review of the Science Assessment section I found it to be well organized, clearly written, and quite comprehensive. I have a few comments, most of a fairly specific nature.

Specific Comments

p. 4-5 line 1 - It might add clarity and focus to point 4 by including the criterion of "validity" to the criteria "meaningful and reliable." Validity is a more specific term than meaningful in that it refers to whether a given health effect measurement measures what it is intended or claimed to measure (internal validity).

p. 4-5 lines 28-33 - The text suggests but does not explicitly state that studies conducted on U.S. populations will, given acceptable quality, be considered as among the most informative. Also, the issue of how to incorporate results from studies conducted on non U.S. populations can require subtle judgments that depend on how one construes the phrase "the corresponding U.S. population." If a general population from a study in a non U.S. sample has a higher mean blood Pb than the general U.S. population then it could still be that the results of the study are relevant to a well-defined subpopulation in the U.S. that experiences higher than average exposures. It would be helpful to provide a little more detail on how such judgments will be made. Precisely this sort of detail is provided when discussing research with laboratory animals (p. 4-6 lines 4-7).

p. 4-6, 4-7 section 4.2.4 Quality Assurance - Reference sources describing the "Agency-wide Quality Management System" should be added.

p. 4-8 line 27 (and throughout document) - In some places it is unclear whether "ambient Pb" is meant to refer only to "ambient *air* Pb."

p. 4-9 lines 30-35 (point 6) - I found this paragraph difficult to parse. Can it be clarified what "this relationship" refers to (line32)? The word "relationship" is used three times and in combination with "variation" and "changes" and so I'm getting lost trying to think about variations in relationships of relationships.

Comments from Dr. Cliff Davidson

I only have a few comments on the Science Assessment section, Chapter 4. On page 4-4, it is not clear to me who does the reviews and makes the decisions on which studies to include (lines 20-21).

I am not sure why the Criteria for Study Selection (section 4.2.3) only address health and welfare effects. Should any of the topics in Section 4.3 Content and Organization of the ISA have criteria listed for studies to be included in the ISA?

Lastly, there will not be a huge number of studies since 2006, and it takes a long time to get studies published. Is there a mechanism for including studies that may be relevant but have not yet been published? (e.g., are in the middle of peer review)

Comments from Dr. Susan Korrick

Overall the draft IRP is well-written and provides a thoughtful and thorough overview of the key scientific questions and policy-relevant issues that will be considered in the current review of the NAAQS for Pb. I have some general comments:

(1) Some of the plan appears to be predicated on the implicit assumption that children and IQ represent, respectively, the key population and health effect of concern whereas elsewhere it is acknowledged that other populations and health outcomes may be important. The plan needs to incorporate breadth and flexibility to comprehensively and consistently assess the latter possibility.

(2) As an extension of comment #1, it would be useful at this planning phase to be more specific about other populations and/or health outcomes of potential interest. E.g., childhood behavioral outcomes (ADHD-like behavior) may be even more sensitive to Pb exposure than global cognition measures such as IQ. The potential role of Pb as a risk factor for diabetes or metabolic syndrome is also an area of public health importance not explicitly acknowledged here.

(3) It is not clear how the review might address the potential for temporal issues (differences in the timing and duration of exposure) to affect health risk. E.g., health risks may vary by when exposures occur (prenatal vs. childhood vs. adult), exposure rate (episodic high-level vs. chronic low-level), exposure duration (short- vs. long-term), and exposure latency (recent vs. past). These issues may be increasingly important as overall background Pb levels decline.

(4) Because a relatively short time has elapsed since the last review, the scientific literature available at the last review (pre-2006) will likely still be relatively central to this new review. New literature that can address items #3 & #5 will be of particular value.

(5) Also, because a relatively short time has elapsed since the last substantial revision of the NAAQS for Pb (from 1.5 $\mu g/m^3$ since 1978 to 0.15 $\mu g/m^3$ as of 2008), it is unclear how well available population exposure data (and associated health risk), e.g., reflect the 2008 standard. Some discussion of how the review might address this fundamental uncertainty would be useful.

(6) With the last Pb standard revision, there was some controversy re. use of an "Air-related IQ Loss Evidence-based Framework" as the analytic framework from which to set the primary Pb standard. It would be helpful to know if this framework is going to be used in this new review.

(7) Is there an opportunity to discuss how (or if) the recently revised Pb monitoring network requirements might impact this review?

(8) Are there important limitations in the resources available for this review (see page 5-2, 1st paragraph)?

Comments from Dr. Michael Kosnett

The following are preliminary comments on the Integrated Review Plan (IRP) for the National Ambient Air Quality Standards for Lead (External Review Draft, March 2011). They may be subject to revision in the future pending further review, discussion and analysis.

Overall, the IRP presents an approach to developing the Integrated Scientific Assessment and Risk/Exposure Assessment that is quite comprehensive. There is appropriate attention to key issues of uncertainty and variability identified in the last reviews conducted for the lead NAAQS.

I. Comments related to Chapter 5 (Quantitative Risk and Exposure Assessments)

1. The narrative appropriately notes the value of reviewing datasets that have examined the impact of housing age on interior dust lead, and the concurrent contribution of housing age (as a surrogate for lead paint) and interior lead dust on blood lead in children. The relatively recent availability of a large dataset examining the inter-relationship of housing age, interior lead dust, and childhood blood lead in a subset of the NHANES 1999 – 2004 investigations (Gaitens et al, 2009; Dixon et al, 2009) may be informative in this regard.

2. In like manner, the recent NHANES studies incorporating data on house dust lead and childhood blood lead (Dixon et al, 2009), and data from other investigations such as the HUD National Risk Assessment Study (Wilson et al, 2007) and low blood lead subsets extracted from the pooled dust lead analysis by Lanphear et al (Lanphear et al, 1998), might offer a means of examining empiric relationships between low levels of interior lead dust, soil lead (available in some of the studies), and blood lead. The findings from this empiric data could be productively compared to the results yielded by the IEUBK model.

3. Certain studies conducted at Superfund sites in the past decade are likely to offer information on the inter-relationships between lead in various media (i.e. exterior soil, interior dust, ambient air) that could be useful in the upcoming lead NAAQS review. For example, the Baseline Risk Assessment for the Vasquez Boulevard/Interstate 70 Superfund site in Denver, CO contained empiric data on the relationship between outdoor soil lead and indoor lead dust in an urban residential community unaffected by recent lead emissions from a point source. Datasets such as this might assist EPA in refining the hybrid indoor dust lead model it utilized in the last NAAQS review. In like manner, it may be valuable for EPA to examine recent empiric datasets in evaluating the fs parameter (fraction of total soil/dust mass ingested daily by a child that comes from soil), a term that has substantial impact on the output of IEUBK modeling.

4. A few recently published studies (e.g. Manton et al, 2005; Gulson et al, 2006) have utilized measurement of stable lead isotopes to examine the inter-relationships of lead in various

media (air, dust, diet). These studies might contribute useful information to the lead exposure pathway analyses that will be examined by EPA in the ISA and REA documents.

II. Comments related to chapter 4 (Science Assessment)

1. The narrative describes EPA's intent to review the recent literature pertaining to the impact of lead of multiple health endpoints. In the prior NAAQS review documents, the impact of lead on childhood IQ emerged as a primary endpoint of concern, and that is likely to remain the case in the current review. However, it is possible that the current NAAQS may be able to include an expanded discussion of the impact of lead on the risk of cardiovascular morbidity and mortality, particularly in light of recent studies (e.g. Menke et al, 2006; Weisskopf et al, 2009;). In addition, the potential contribution of ambient lead particulate in different size fractions to the oxidant stress exerted by ultrafine and fine ambient air pollution may be of interest, given the considerable public health concern that exists regarding the effect of such pollution on cardiovascular disease (Brook et al, 2010).

2. In like manner, studies published since the last NAAQS review may now permit an expanded examination of the impact of low levels of prenatal and postnatal lead exposure on childhood growth and stature, and certain endocrinological endpoints (e.g. Selevan et al, 2003; Min et al, 2009).

References

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Selevan SG, Rice DC, Hogan KA et al. Blood lead concentration and delayed puberty in girls. New Engl J Med 348:1527-1536; 2003

Weisskopf MG, Jain N, Nie H et al. A prospective study of bone lead concentration and death from all causes, cardiovascular diseases, and cancer in the Department of Veteran Affairs Normative Aging Study. Circulation 120:1056-104; 2009

Wilson J, Dixon S, Galke W, McLaine P.. An investigation of dust lead sampling locations and children's blood lead levels. J Expo Sci Environ Epidemiol 17:2–12; 2007

Comments from Dr. Roman Lanno

Here are my comments on the IRP document from a terrestrial ecotoxicology perspective on Chapter 4. Since this is a planning document, I didn't find much to comment on, as I felt major angles were covered.

Page 4-8: Line 6 – What is specifically meant here by the "organisms' biochemical characteristics"?

Bioavailability is affected the physical, chemical, and biological nature of the interaction between the organism, Pb, and components of the environmental medium in which it resides. This should be clearly defined.

Page 4-12: It's unclear to me why both < 10 μg/dL or < 5 μg/dL are stated – seems redundant

Page 4-14: Lines 13-14 – This probably should explicitly state "specific exposure levels related to aerial Pb". The focus is on either dry or wet aerial deposition of Pb, which should be distinct from other Pb sources

Also under point 3: What are the effects of aging on Pb in soils that results from aerial deposition?

Comments from Mr. Richard Poirot

Overall, the Draft Pb Review Plan looks quite good. The Plan exhibits a very clear and in-depth familiarity with the details of the 2008 Pb NAAQS review process, and provides a sharp focus on a number of policy-relevant issues, which represented key decision points in the last review and which were also characterized by relatively high levels of uncertainty. The plan aims to reduce these areas of uncertainty by posing a series of specific questions which might be clarified by newly available information. This is a logical framework in which key uncertainties in the last review provide the basis for a focused literature review in the current cycle.

However, while there is a long list of good questions that begin with "Does the newly available information indicate…" or "To what extent is there new information to support", there are no examples provided that there is any such new information that will illuminate these questions. It feels like a very short time since the 2008 NAAQS review – or conversely that the pace of new research for air lead causes and effects may proceed more slowly than for pollutants like PM or ozone. I question the extent that there will really be a lot of new information to address all of these questions. This leads to a suggestion that it might be useful to provide a few examples of recent publications (or potential modeling or data analysis activities) which could help reduce uncertainties for some of these key issues. Another possibility would be to start with your recent literature review – presumably not complete but surely in progress – and consider what kinds of new insights the new information you've seen so far can provide. Combining a "questions first" approach with a "literature first" perspective might lead to a more efficient focus on key questions that can be answered (and the ones for which new research, measurements, modeling or data analyses is most needed).

Ambient Air Monitoring Considerations

Among the problems associated with the 30-year failure to revise the Pb NAAQS between 1978 and 2008 is the quaint historical persistence of antique high-volume TSP sampling technology as the basis for the Pb FRM (and for some 24 FEMs). Following the 2008 review, an option was provided to utilize the more modern and precise low volume PM_{10} sampler in situations where expected 3-month mean concentrations are below 0.1 $\mu g/m^3$ (2/3 of standard) and where a substantial majority of Pb is in the PM_{10} size fraction.

Section 6.1 (sampling and analysis) of the Plan poses the question: "Are new TSP samplers available and adequately characterized for use in PB-TSP sampling?" Presumably such new samplers would not exhibit the sampling biases with wind speed and sampler orientation that characterized the old hi-vol TSP samplers – and there have been indications that EPA is developing a medium volume "TSP" sampler that would be superior in all respects to the old hi-vols. While this should certainly be given a high priority, it's not entirely clear what "TSP" means in this case, or more importantly: what should be the particle cut size characteristics of a

sampler (or samplers) used to determine compliance with the Pb NAAQS? Some prefacing questions might be:

- What are the averages and ranges of absolute concentrations (and percentages) of current Blood Lead which originates as current air lead? Lets call this BL(a).
- What are averages and ranges of ratios between current BL(a) and current Air Lead (AL)?
- (How) do these BL(a):AL ratios vary for Air Lead in different particle size ranges (<2.5, 2.5-10, 10-20, >20µm, etc.)?
- What fractions of BL(a) result from direct inhalation vs. aural ingestion of deposited AL?

I'm not sure these kinds of questions have clear answers in the literature, but perhaps could be addressed in some sort of dosimetry modeling. The point being that it would be useful to have some apriori indication of the ideal size distribution & cut point characteristics of Pb samplers that would best reflect human exposures. It would also be useful to consider:

- What are the particle size characteristics of Pb emissions from major Pb sources?
- What spatial scales of population exposure near Pb sources, and how would these be represented by Pb samplers with alternative cut sizes?
- (What) is (there) an upper particle cut size (which may contribute to deposited and ingested Pb but) shouldn't be considered as airborne Pb that can be effectively controlled by NAAQS?
- What would be potential applications for a new "TSP" sampler other than Pb NAAQS?
- For sources exceeding standards would adding something like a dichotomous sampler provide additional useful information on emissions characteristics and population exposures?

Given the inherent physical difficulties of achieving sharp cut points in the ≥10 µm size range, it seems likely that a compromise will be required between what's desirable and what's possible. Still, it should be relatively easy to improve considerably on and replace the hi-vol sampler, which would stand no chance of being designated FRM if it were being considered anew today.

Section 6.2 (monitoring network requirements) raises the question of whether current source-oriented monitoring thresholds (0.5 tons/yr for industrial sources and 1 ton/yr for airports are appropriate for determining compliance with current or alternative NAAQS. Given inconsistencies (or changes from one draft to the next) in the identification and ranking of major source categories encountered during the last Pb NAAQS review cycle, it seems important to evaluate (from new monitor data or revised emissions estimates) how reasonable these source-related monitoring requirements are. Useful results along these lines should also be coming in from a "pilot network" of about 15 smaller (0.5 to 1.0 ton) airport sites. Since airport emissions

are fuel-combustion related (fine particle mode), and since there would obviously be strong directional influences and typically relatively high wind speeds at airports, the requirement to use antique, directionally and wind speed-biased hi-vols for such sampling seems questionable.

Given that there are likely to be fairly extreme spatial gradients in concentrations and population exposures around major Pb emission sources (especially for those with significant coarse-mode emissions), it would seem important to pay more attention to the details of siting characteristics for source oriented monitoring, and to better evaluate how these relate to exposures of populations at risk.

Comments from Dr. Ian von Lindern

Overview

The draft Integrated Review Plan (IRP) is generally well organized, comprehensive, and addresses the main issues to be considered in the National Ambient Air Quality Standards (NAAQS) review. The document provides a concise summary of the previous NAAQS review effort and the uncertainties and difficulties encountered in developing the current Air Quality Criteria Document (AQCD) and subsequent NAAQS. The underlying strategy seems to focus on new information since the last review that will determine whether any addenda are required. The document implies that additional action regarding the NAAQS may be curtailed based on the determination of the relevancy of the new material.

Taking advantage of the lessons learned from the 2006-7 revision should facilitate the Agency in responsibly meeting the 5 year review requirements. This is in contrast to the last review, when decades of information was allowed to accumulate across orders of magnitude changes in ambient concentrations, absorption, blood lead levels, internal exposures and identified health effects; in addition to monitoring and analytical capabilities, control technologies, and market applications for lead.

It is appropriate for the Agency to concentrate on new additions to the knowledge base and evaluate the degree to which the new information informs the analyses completed in 2007. This should streamline the process. However, the EPA should not confine the review and revision of the AQCD to this narrow period of lead regulatory history. There were challenges encountered in the previous review that indicated significant gaps in the knowledge base. These information deficiencies introduced uncertainties into the process that should be revisited. The EPA should learn from and evaluate the effectiveness of the NAAQS in the context of the longer history of lead regulation.

Historic Perspective

It was clear long before the 2006-7 review that the 1970's standard had become largely irrelevant throughout most of the country. The Agency was remiss in failing to update the NAAQS, as recommended in 1991, and it effectively stopped monitoring concurrent ambient air lead emissions and related absorption metrics for nearly fifteen years. In finally reassessing the NAAQS in 2007, the EPA struggled with whether to develop a relevant standard, or eliminate lead as a criteria pollutant. In deference to its responsibility to protect the public health, the EPA retained lead as a criteria pollutant and adopted a standard reduced by an order of magnitude. The last AQCD showed that EPA had, in maintaining the irrelevant standard for so long, "lost track" of key parameters necessary to effectively assess the health and ecological risks of airborne lead in the U.S. Relatively few data were available in several key areas for performing

a responsible risk assessment.

Uncertainties in the Current NAAQS

Development of effective exposure estimates was the weakest point in the Agency's analyses that supported the current NAAQS. This was due to the lack of monitoring data available to assess contemporary exposures in the U.S., or to support the modeling analyses relied upon in subsequent development of the NAAQS. As the current AQCD points out, previously undetected deleterious health effects were occurring at lower blood lead levels, and potentially at the environmental concentrations the Agency had failed to monitor.

As a result, in the last review the EPA was challenged in effectively estimating the extent of potential damage in the general population; the relationship between air lead levels, emissions and absorption; safe air lead concentrations; or the number of citizens exposed to potentially dangerous levels. There were insufficient data to characterize active emissions and emission rates, ambient concentrations and the degree, extent and severity of ongoing redistribution of residual lead in the nation's environment. As a result, EPA relied on modeling and decades-old empirical relationships to quantify exposures.

This weakness was identified in the AQCD; and subsequently the Office of Air Quality Planning and Standards (OAQPS) made the best of a poorly characterized situation in developing the NAAQS. This resulted in considerable uncertainty inherent in the overall process.

It is important in this revision that the AQCD address these uncertainties. Frank discussions of the unknowns and lack of certainty in the existing analysis are found on pages 5-3, 5-9 and 5-10 of the IRP regarding the modeling approach. The subsequent policy analyses should examine whether relevant databases are being developed, both internal and external to the EPA. A determination should be made as to whether it is possible to move from the near total reliance on modeling to observational and empirical analysis of contemporaneous data.

Several questions should be answered with respect to monitoring and surveillance. What data base is accumulating with respect to compliance with the new standard? Is a network established, is it adequate and effective, and are there a detectable blood lead levels associated with any gradient in exposure? Have there been excursions? Certain U.S. sub-populations (e.g., immigrants and inner city children) are at substantially greater risk of exposure due to co-factors associated with different cultures, climates, dietary and nutritional regimes, as are being encountered in the global lead poisoning epidemic. Is there monitoring in these venues?

If indeed these types of data are becoming available, then it seems incumbent upon the Agency to undertake the necessary analyses to reduce the level of uncertainty inherent in the current regulatory scheme and respond accordingly. If no such data are being accumulated, the EPA should explain why.

Data Sources

A major concern in the last review was that EPA limited the information search to *"… where information is available in the peer-reviewed literature."* Unfortunately, the best sources of production data, emission information, industry transition and economic indicators are more likely found in the trade literature and government agency records. Much of the practical knowledge that has been developed in applying scientific findings and methods to remedial and regulatory activities is generated and housed in programmatic activities within EPA and the States. It would not be prudent to limit the combined analyses to the relatively obscure and less-representative studies that have reached the peer-reviewed journals.

The Data Quality Objectives (DQOs) have apparently been expanded somewhat to *"peer-reviewed journal articles, books, and government reports"*. This expansion is more inclusive of the recognition that much of the information to develop a nation-wide assessment of lead exposures is unlikely to be found in peer-reviewed journals. The CASAC urged the Agency to mine these data sources in the last review, but was told that there was insufficient time to effectively exploit these resources in the context of the ongoing litigation and budgetary constraints. Perhaps in the current effort, sufficient resources could be allocated to better characterize sources, emissions, ambient concentrations, transport and transformation, and effective control technologies through broader examination of programmatic successes and failures. In the event that EPA is restricted from utilizing this extensive experience in crafting effective regulations, the scarcity and short-comings of information available from journal articles should be noted.

Policy Implications

The demand for and consumption of lead in the U.S. has increased markedly in this century, accompanied by substantial price increases in the domestic and world market (see Figure 1). The IRP seems heavily weighted toward assessing and characterizing new information regarding health risk assessments and health effects. As noted above, other general exposure considerations related to market and use factors (i.e., emission sources, commercial applications, waste, recovery, recycling, and disposition and fate of lead) in the U.S. today are poorly understood, nor have exposure parameters been quantified. Several other issues not mentioned include advancements in pollution control capacity, best available technologies and best practices for source control, monitoring protocols, detection limits, and analytical methods; and assessment methodologies particularly with regard to health and ecological effects.

Although demand has increased, domestic production and recycling and recovery of many discarded lead products have been diverted to developing countries. Much of this diversion results from EPA policies.

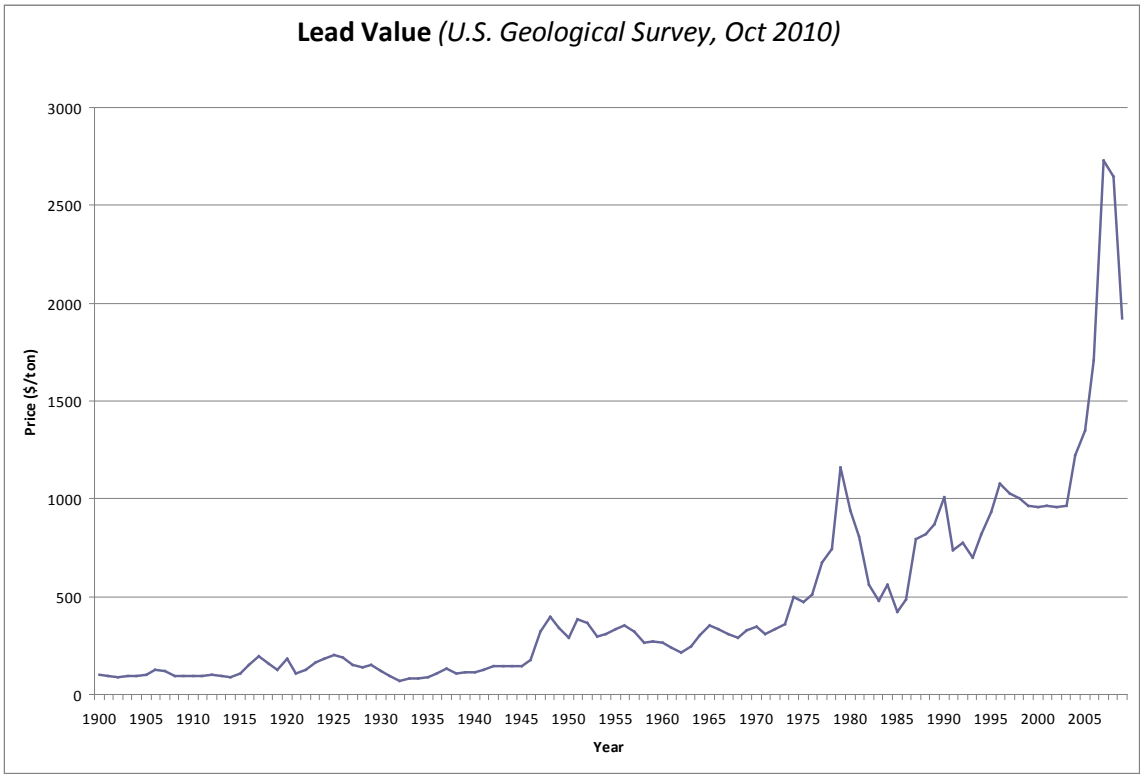
Price increases noted during the early and mid-1970s indirectly accounted for the lead poisoning epidemics noted around production facilities that ultimately played a significant role in the development of the NAAQS in 1977-80. Excessive and irresponsible emissions from smelters at Bunker Hill in Idaho, Broken Hill in Zambia and Australia, and Kosovo, (former Yugoslavia) resulted in severe poisoning, disease and some death during the run up in prices. These problems were documented and aired in the earlier AQCD, which played no small role in bringing about substantial reductions in both emissions and irresponsible operations.

On the international scene, the increased price and demand observed in the last five years (see Figure 1) has had devastating effects, substantially more severe than those observed in the 1970s. Environmental exposures and lead poisoning are increasing with several incidences of severe morbidity and substantial mortality associated with the increased demand and high price of metals. Hundreds of children have died at some sites and thousands suffer irreversible health effects that will leave them a burden on their families and communities for decades.

Although these factors may have little direct impact on air lead levels in the U.S., the implications for regulation of lead releases and the impact of U.S. policies in the global environment and human health can be substantial. The Agency also has an obligation to export the scientific knowledge base, consequences of irresponsible practices, and information regarding mitigation of adverse effects. Regardless of the statutory requirements, the 1977, 1986 and 2007 AQCD revisions and addenda have served as seminal documents. The AQCD are utilized, referenced, critiqued and practically applied on an almost daily basis throughout the world and provide an invaluable framework for society, industry and the scientific community to develop and implement strategies to meet public health and environmental needs. The subsequent regulatory policies when implemented have ramifications, not only beyond ambient air lead levels, but throughout the world. These issues should be developed in the IRP.

Finally, there are two major lessons from the last 40 years of implementing lead control policies that should be applied. First, lead remains and must always be evaluated in a multimedia context. The need to disentangle the air component from global exposure is more a function of fractured media-based regulatory policy than of science or public health protection. The EPA should continue to apply, refine, develop, improve and learn from multi-media integrated exposure models. Second, the implementation of lead reduction rules has lowered ambient levels, and subsequently absorption and blood lead levels. This provided a population base for further research that allowed detection, and ultimately mitigation of adverse health effects previously unknown or unproven. In the interest of advancement of science, health effects reviews should consider assessing co-exposures with other metals and toxins; and to the extent possible this approach should be extended to the ecological risk assessments.

Figure 1.


Lead Value (U.S. Geological Survey, Oct 2010)
Price ($/ton)
3000
2500
2000
1500
1000
500
0
1900 1905 1910 1915 1920 1925 1930 1935 1940 1945 1950 1955 1960 1965 1970 1975 1980 1985 1990 1995 2000 2005
Year