

September 18, 2023

EPA-CASAC-23-004

The Honorable Michael S. Regan Administrator U.S. Environmental Protection Agency 1200 Pennsylvania Avenue, N.W. Washington, D.C. 20460

#### Subject: Consultation on the EPA's Integrated Review Plan for the National Ambient Air Quality Standards for Lead. Volume 3: Planning Document for Quantitative Exposure/Risk Analyses (May 2023)

Dear Administrator Regan:

The 2021 Clean Air Scientific Advisory Committee (CASAC) Lead Review Panel, hereafter referred to as the Panel, met on June 29, 2023, to provide a consultation on the EPA's *Integrated Review Plan (IRP)* for the National Ambient Air Quality Standards for Lead. Volume 3: Planning Document for Quantitative Exposure/Risk Analyses (May 2023).

The Science Advisory Board Staff Office has developed the consultation as a mechanism to provide individual expert comments for the EPA's consideration early in the implementation of a project or action. A consultation is conducted under the normal requirements of the Federal Advisory Committee Act (FACA) (5 U.S.C. § 10), which include advance notice of the public meeting in the Federal Register.

No consensus report is provided to the EPA because no consensus advice is given. Individual comments from the Panel are provided in Enclosure A.

We thank the EPA for the opportunity to provide advice early in the review process. The Committee does not expect a formal response from the EPA.

Sincerely,

/s/

Dr. Elizabeth A. (Lianne) Sheppard, Chair Clean Air Scientific Advisory Committee

Enclosure

#### NOTICE

The Clean Air Scientific Advisory Committee (CASAC) is a chartered federal advisory committee, operating under the Federal Advisory Committee Act (FACA; 5 U.S.C. § 10). The committee provides advice to the Administrator of the U.S. Environmental Protection Agency on the scientific and technical bases of the National Ambient Air Quality Standards. The findings and recommendations of the committee do not represent the views of the Agency, and this document does not represent information approved or disseminated by EPA. The CASAC reports are posted on the EPA website at: <a href="https://casac.epa.gov">https://casac.epa.gov</a>.

## U.S. Environmental Protection Agency Clean Air Scientific Advisory Committee Lead Review Panel (2021)

#### CHAIR

**Dr. Elizabeth A. (Lianne) Sheppard,** Rohm and Haas Professor in Public Health Sciences and Professor, Department of Environmental & Occupational Health Sciences and Department of Biostatistics, Hans Rosling Center for Population Health, University of Washington, Seattle, WA

#### MEMBERS

**Mr. George A. Allen**, Chief Scientist, Northeast States for Coordinated Air Use Management (NESCAUM), Boston, MA

**Dr. James Boylan**, Branch Chief, Air Protection Branch, Environmental Protection Division, Georgia Department of Natural Resources, Atlanta, GA

**Dr. Judith C. Chow**, Nazir and Mary Ansari Chair in Entrepreneurialism and Science and Research Professor, Division of Atmospheric Sciences, Desert Research Institute, Reno, NV

**Dr. Deborah Cory-Slechta**, Professor, Department of Environmental Medicine, School of Medicine and Dentistry, University of Rochester, Rochester, NY

**Dr. Christina H. Fuller**, Associate Professor, School of Environmental, Civil, Agricultural and Mechanical (ECAM) Engineering, University of Georgia College of Engineering, Athens, GA

Dr. Philip E. Goodrum, Principal Toxicologist, GSI Environmental Inc., Fayetteville, NY

Mr. Perry Gottesfeld, Executive Director, Occupational Knowledge International, San Francisco, CA

Dr. Daven Henze, Professor, Mechanical Engineering, University of Colorado Boulder, Boulder, CO

**Dr. Howard Hu**, Flora L. Thornton Chair of the Department of Preventive Medicine, Department of Preventive Medicine, Keck School of Medicine, University of Southern California, Los Angeles, CA

**Dr. Chris Johnson**, Professor, Department of Civil and Environmental Engineering, Syracuse University, Syracuse, NY

**Dr. Susan Korrick**, Assistant Professor of Medicine, Department of Medicine, Brigham and Women's Hospital, Channing Division of Network Medicine, Harvard Medical School, Boston, MA

**Dr. Bruce Lanphear**, Professor, Children's Environmental Health, Faculty of Health Sciences, Simon Fraser University, Vancouver, BC.

Dr. Joel G. Pounds, Retired, Linden, MI

**Dr. Brisa Sánchez**, Dornsife Endowed Professor of Biostatistics, Department of Epidemiology and Biostatistics, Dornsife School of Public Health, Drexel University, Philadelphia, PA

**Dr. Brian Schwartz**, Professor, Environmental Health and Engineering, Bloomberg School of Public Health, Johns Hopkins University, Baltimore, MD

**Dr. William Stubblefield**, Professor, Department of Environmental and Molecular Toxicology, Oregon State University, Corvallis, OR

**Dr. Kathleen Vork**, Staff Toxicologist, Office of Environmental Health Hazard Assessment, Air Toxicology and Risk Assessment Section, California Environmental Protection Agency, Oakland, CA

**Dr. Marc Weisskopf**, Cecil K. and Philip Drinker Professor of Environmental Epidemiology and Physiology, Department of Environmental Health and Department of Epidemiology, Harvard T.H. Chan School of Public Health, Boston, MA

### SCIENCE ADVISORY BOARD STAFF

**Mr. Aaron Yeow**, Designated Federal Officer, U.S. Environmental Protection Agency, Science Advisory Board, Washington, DC

## **Enclosure** A

### Individual Comments from Members of the CASAC Lead Review Panel on EPA's Integrated Review Plan for the National Ambient Air Quality Standards for Lead. Volume 3: Planning Document for Quantitative Exposure/Risk Analyses (May 2023)

Mr. George A. Allen	
Dr. James Boylan	
Dr. Judith C. Chow	
Dr. Daven Henze	
Dr. Howard Hu	
Dr. Brian Schwartz	
Dr. Elizabeth A. (Lianne) Sheppard	
Dr. William Stubblefield	
Dr. Kathleen Vork	
Dr. Marc Weisskopf	

## Mr. George A. Allen

Overall the IRP for the REA is well written and summarizes the issues that will be considered in an updated health REA for this review cycle. Table 1-1 provides a timetable for the current review; that table and Pg. 2-1 footnote (and elsewhere) say the REA will be a supplement to the PA doc, not a standalone document. With regard to document review sequencing, since the REA informs the PA, review of a separate REA in advance of a PA may be appropriate if substantial new evidence is available that might support an alternative standard.

**It is critical** that analysis for alternative (lower) standards be conducted in the REA in addition to the current standard. To expand on my comments during day two of the public meeting in June on this draft IRP, if the scientific evidence presented in this ISA could support consideration of alternative standards (level, not form) for the primary NAAQS, EPA needs to include that analysis in the REA. When the REA is combined with the PA and reviewed simultaneously, it is not appropriate for EPA staff to take a chance as to what if any revisions to a NAAQS might be recommended by CASAC, which is essentially what staff said in response to my question on June 14 (https://youtu.be/-IdWFKRy\_kE?t=19781). If the REA were a separate document reviewed and finalized before the review of the PA, this would be less of an issue, but that does not appear to be EPA's intent in this and future reviews. The lack of analysis of any alternative standards was a major issue in the recent failed ozone reconsideration review. In contrast to that REA, for the 2014 review the REA considered four alternative standards to the current (75 ppb) NAAQS, between 55 and 70 ppb. From the final 2014 O3 REA, page 2-4:

"With regard to potential alternative levels for an 8-hour O3 standard, the quantitative risk assessment evaluates the range of levels in 5 ppb increments from 60 to 70 ppb. These levels were selected based on the evaluations of the evidence provided in the PA, which received support from the CASAC in their advisory letter (Frey and Samet, 2012). For a subset of urban study areas, we also evaluated a standard level of 55 ppb, consistent with recommendations from CASAC to also give consideration to evaluating a level somewhat below 60 ppb. Thus, for most areas, we evaluate exposures and risks for potential alternative standard levels of 70, 65, and 60 ppb. Some additional analyses were also included for evaluation of exposures and risks for a potential alternative 8-hour standard level of 55 ppb."

**To repeat for emphasis:** an REA conducted with only a single NAAQS value would not be adequate for its intended purpose when the REA and PA are reviewed in the same meeting. For this Pb review, alternative standards of 100, 75 and possibly (on a limited basis) even 50 ng/m<sup>3</sup> need to be included.

Section 1 is a good overview of the issues in the review of the Pb NAAQS. Trends of Pb in air and blood over the last 40 years are summarized, noting that it is PB air-related multi-media exposure pathways that are the subject of this review, excluding other sources such as Pb in drinking water from pipes and Pb from paint since controlling Pb in air will not have any effect on these non-air sources.

Section 2 opens with helpful descriptions of the purpose of and approach for the health REA. Section 2.1.3 notes the limitations in the estimates of risk attributable to air-related exposure pathways, with lower bounds set by "recent air" exposures and upper bounds by recent plus past air exposures. Section 2.2.1 is a useful summary of newly available information since the 2007 REA. The NAAQS review ending in 2016 did not have an REA, instead relying on the REAs from the review completed in 2008, with a limited assessment for one case study for the existing standard. The introduction to this section

should more clearly note this in Section 2.1 on page 2-5, perhaps by bringing text from footnote 9 into the body text.

Section 2.3, Initial Planning for the Current Review, states that the new information in the ISA since the last review (summarized in Section 2.2) supports development of a new or updated/revised REA for this review. There is a useful summary of the key elements for a REA analytical approach. This section also describes EPA's reliance on the scientific evidence for the 2008 rule, with the REA providing support to the evidence-based framework. This echoes the CASAC's recent advice (in their June 9, 2023 letter on the O3 PA reconsideration) to "better balance the results of the REA with the scientific evidence, such that the REA supplements the scientific evidence, instead of dominating it."

## **Dr. James Boylan**

Page 1-4: In Table 1-1, "Quantitative Exposure/Risk Analyses and Policy Assessment" are listed together under the same "Stage of Review" with one set of "Target Dates". This implies that the Risk and Exposure Assessment (REA) will be included as an appendix in the Policy Assessment. This approach might be acceptable if there are minimal updates to the draft REA. However, if there are significant updates or revisions needed to the draft REA, it would be inappropriate for the CASAC to make any recommendations on the adequacy of the current or alternative standards when questions on the REA have not been fully addressed. It would be much more appropriate for the CASAC to review the draft PA with a final REA in hand to support their policy recommendations. Therefore, the traditional approach of evaluating the REA as separate stand-alone documents prior to the release of the draft PA should be reinstated.

## Dr. Judith C. Chow

The IRP presents of good summary of research studies with some as recent as early 2021. However, the initial plans for the current review presented in Section 3.3 could include more specific actions to be taken to complete the plan.

The Hubbard Brook Experimental Forest along with its recent and historic publications related to lead deposition and surface life times (HBRF, 2023; Johnson and Petras, 1998; Johnson et al., 2004; Richardson et al., 2014; Richardson et al., 2015; Siccama and Smith, 1978; USFS, 2023; Yanai et al., 2004) are worthy of additional study and evaluation, as noted in the first part of Section 3.3. It may be possible to extrapolate these long-term measurements to situations beyond forest soils to estimate how past deposition around other sources (e.g., mines, metal processing plants, etc.) have decreased over time. Additional long-term data sets could be investigated (e.g., Harvard, 2023) to determine the validity of these extrapolations to other areas (Bowers et al., 2014). Much of the lead found in soil probably results from atmospheric deposition, and is therefore relevant to the NAAQS. Long-term deposits in soils and the resulting run-off can also be important non-respirable pathways to human lead ingestion, as noted in the IRP introductory sections.

My prior comments on Appendix 1 of the Lead ISA demonstrate the importance of measurement locations in determining compliance with ambient lead levels. Relocating compliance monitors in Indiana and Ohio resulted in large increases in the lead concentration trends, indicating a large spatial variability in exposures.

The "Executive Summary" and "Integrated Synthesis for Lead" also acknowledge substantial spatial variations in urban- and neighborhood-scales that may not be captured by the national monitoring network (Lines 21-24, Page ES-3 and Lines 1-4, Page IS-12). Table IS-13 summarizes evidence for populations at increased risk to adverse Pb health effects (Page IS-61). This epidemiological evidence further supports the 2013 ISA conclusions regarding positive associations between increased Pb exposure and associated health effects among those in proximity to Pb sources.

More information is needed on spatial variability near source areas, and some of this may be available in the combined lead databases (e.g., compliance, IMPROVE, and CSN) to inform this. Accurate exposure estimates will be needed for a credible risk assessment.

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### Dr. Daven Henze

The exposure analysis in Fig 2-3 and associated text includes modeling several quantitative modeling steps between the ambient air concentrations and blood Pb levels. To what extent can empirical slope factors relating changes in blood Pb [ug/dL] to changes in ambient air concentrations  $[\mu g/m^3]$  (e.g., ISA Fig 2-16) be used instead of modeling these steps? Recognizing there are very large variabilities in the slope-factors as a function of age, or level, or across studies, this is perhaps more of a bounding exercise. But it does seem that it would at least provide a useful cross-check of the proposed model-based approach against observed slope factors. The C-R relationships used in the next analysis step are nonlinear, but absolute levels around which perturbations could be calculated with empirical slope factors could themselves be determined empirically. Such an approach would be analogous to the techniques used in health impacts analysis for e.g. PM<sub>2.5</sub>, wherein epidemiological studies are used to specific relationships between ambient concentrations and health responses, and empirical estimates (from monitors, satellite-derived datasets, or models) are used to estimate the baseline concentration levels around which perturbations are considered.

## Dr. Howard Hu

- Exposures to emissions from the continued use of leaded gasoline in NASCAR racing cars (Bui et al., 2022) (until 2007) and the continued use of leaded aviation fuel (Klemick et al., 2022) should be acknowledged.
- The Appendix ("Cumulative Exposure Estimates for Different Birth Cohorts") contains some extrapolations on racial differences (black v. whites) in cumulative blood lead indices based on NHANES data. The differences between cumulative lead exposure are also seen in studies using direct measures of bone lead (Elmarsafawy et al., 2002; Theppeang et al., 2008; Lin et al., 2004).

#### References

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## Dr. Brian Schwartz

- 1. This was a 104-page PDF dated May 2023. We were instructed that our input on the IRP is a consultation.
- 2. My preliminary conclusions and comments, now finalized:
  - a. As a <u>planning</u> document, volume 3 seems to take a flexible and comprehensive approach to the quantitative exposure and risk analyses that should allow a rigorous product to be developed.
  - b. The bodies of scientific literatures are so extensive and compelling that consideration should be given, based on science alone, to the elimination of new, controllable environmental discharges of lead. The <u>approach</u> in the planning document would seem to support a rigorous process that could lead to such a conclusion. Given that most biases and measurement errors are likely to lead to underestimation of effects, it would seem that the quantitative exposure and risk analyses for policy making may also be likely to underestimate overall impacts. This should be clearly stated.
  - c. EPA should develop case studies from U.S. cities with extensive lead smelting in the past, or older housing undergoing demolition, such as reported from Philadelphia with redevelopment of areas with lead smelters and older homes leading to neighborhood children attaining BLLs as high as 15  $\mu$ g/dL. "Pockets" of lead contamination seem difficult to prevent from distributing lead in dangerous ways, mainly through air contamination pathways. It seems that emissions inventories had not accounted well for legacy lead contamination, and these locations cannot always be identified in advance (ISA Appendix 2 discusses many of these issues).
  - d. Can it be estimated how many children have elevated BLLs (> 2-5  $\mu$ g/dL) from new, allowed emissions annually? That is, how many BLLs above this level would be prevented by ending new lead emissions?
  - e. Table A-2: Do these CBLI values comport with tibia lead measurements in various studies? What is the EPA's view on the relation on CBLI with tibia lead (e.g., tibia lead = [0.05 to 0.10] \* CBLI)?
- 3. Additional comments after June 13-14, 2023 meeting
  - a. The world of lead is SPIKY. It has considerable temporal and spatial variability in new emissions and exposures with occasional large deviations from temporal and spatial averages; there are hidden legacy deposits in many generally small-scale locations; it has important non-linearities in several key relations; there are spiky differences in behaviors that can increase dose; and there are some vulnerable sub-groups, so relying on average slopes with outcomes is a similar problem. I am a little unclear on whether the **generalized local case study** incorporates, and can overcome, these concerns. What are the implications of this?
    - i. We could be missing important impacts.
    - ii. I believe the ISA and IRP are probably underestimating total integrated population-wide impacts. The IRP and ISA should explicitly address this.
    - iii. I believe it is unlikely that changes to the current standard of  $0.15 \,\mu\text{g/m}^3$  of lead in total suspended particles will offer more protection. We must address the key sources. The October 2022 endangerment finding for lead in aviation fuel, and any subsequent regulations, have the potential to be much more effective in

reducing these population health impacts. Such approaches should be considered for other key sources of lead emissions, particularly industrial sources (e.g., smelting and battery manufacturing facilities).

# Dr. Elizabeth A. (Lianne) Sheppard

I wish to highlight several comments made by CASAC panel members:

- Brian Schwartz noted that given the extensive and compelling scientific evidence, consideration should be given to elimination of all controllable environmental discharges of airborne lead. I think EPA should consider an alternative standard that reflects this advice. Further, he suggested more attention be given to areas with historical lead smelting or lead-contaminated housing, as well as to try to determine the number of elevated BLLs that would be avoided by eliminating all controllable airborne environmental discharges.
- Marc Weisskopf asks EPA to explore using models for blood lead that would allow characterization of the relationship between air lead and bone lead.
- I echo George Allen's comments that it is critical that EPA provide analyses of potential alternative standards. This flows directly from the implications of EPA's recent practice of and plan to fold the REA analyses into the PA rather than developing a separate REA for CASAC review, particularly in combination with EPA's plan to produce only a single draft in each review. EPA's recent approach, while valuable with respect to shortening the review schedule, has downsides that have not been fully considered or addressed. As we learned from the recent ozone reconsideration, a REA contained within the PA is particularly problematic when EPA staff have not considered any of the alternative standards that CASAC deems appropriate. Another problematic aspect occurs when the REA analyses rely on assumptions that CASAC doesn't agree with. Given EPA's intent to not develop second drafts of documents for CASAC review, it is essential that EPA make proactive efforts to provide sufficient and appropriate quantitative analyses in the PA that address both a sensible range of alternative standards as well plausible alternative assumptions. Thus, I recommend that the REA analyses routinely consider alternative standards as well as the current standard, particularly in cases where either the recent science suggests the pollutant is more toxic than previously known, or where EPA considered lower alternative standards in past reviews. The consideration of alternative standards should occur even when the staff conclude that the current standard should be retained. The current approach, which only considers alternative standards when the staff conclude that the current standard should not be retained, is far too restrictive. It severely constrains the usefulness of the review, CASAC's ability to provide the best possible advice, and the breadth and depth of evidence provided to the Administrator for making his/her policy decision. Figures 2-1 and 2-2 of Volume 2 of this IRP should be modified to reflect this advice, as should these figures whenever they appear in future documents.

## Dr. William Stubblefield

My comments on the IRP document focus primarily on Section 3 "Quantitative Analysis Planning for the Secondary Standard" as this is more consistent with my area of expertise. I also will note that some of my concerns identified in my review of the ISA document stem from the issues identified in this document.

EPA is incorporating the basic principles of an ecological risk assessment in conducting their characterization of "causality." The basic paradigm for risk assessment involves a characterization of potential effects caused by a contaminant (in this case Pb) and an analysis of potential exposures (see EPA 1992). By relating the two, either qualitatively or quantitatively, an assessment of potential adverse effects (risk characterization) can be made. The ISA goes into great detail describing and categorizing all manners of possible adverse effects resulting from Pb exposure. And it provides a basis upon which an analysis of adverse effects could be conducted to predict matrix specific environmental concentrations that are safe or could result in adverse effects. This addresses one half of the risk assessment paradigm.

Characterization of exposure (the other half of the analysis as defined in the ecological framework document; EPA 1992) "evaluates the interaction of the stressor [Pb in this case] with the ecological component [i.e., receptor organisms]. Exposure can be expressed as co-occurrence or contact depending on the stressor and the ecological component involved. An exposure profile is developed that quantifies the magnitude and spatial and temporal distributions of exposure for the scenarios developed during problem formulation and serves as input to the risk characterization." This requires that an analysis, either a priori (before the release) or a posteriori (after the release), be conducted. In any case, it requires an evaluation of the source(s) of the contaminant. Since this is an evaluation of Air Quality Standards, we assume that the major concern is with Pb that enters the terrestrial or aquatic environment via atmospheric deposition. However, we also must consider the contribution of other sources, e.g., non-point source runoff or point-source discharges, in conducting the evaluation. This evaluation was lacking in the ISA.

The approach described in Section 3 of the IRP document acknowledges that "Unlike most other pollutants for which NAAQS are established, Pb is a multimedia and persistent pollutant." They also note that "Exposure of terrestrial [and aquatic] animals and vegetation to air-related Pb can occur by contact with ambient air or by contact with soil, water or food items that have been contaminated by Pb from ambient air (ISA, section 6.2)." They go on to list a variety of non-air sources that can contribute to the Pb exposures that organisms will likely encounter.

The approach used thus far is described in the document: "More specifically, we focus on 1) the ability of current data sets and tools to characterize exposure of ecosystems to ambient air Pb deposited in association with air quality meeting the existing standard and 2) the availability of new evidence that would allow the current review to develop more robust assessments of associated welfare risk than available in the last review." This approach is flawed in that it requires that an ecosystem's inputs must be in compliance with the air quality standard before an assessment can be made. These are the reasons given for the rejection of studies previously identified in prior assessments, i.e., the Pb concentrations were too high due to contributions from other sources (too near a smelter or too close to a roadway) or non-compliance with the existing air quality standard. In fact, the only study deemed acceptable was the Hubbard Brook Vulnerable Ecosystem Case study, that found minimal Pb exposure (no characterization of atmospheric inputs is discussed in the write-up), because it is located away from most anthropogenic

inputs. The other concern is in the second point and seems to indicate that nothing proactive will be done, i.e., EPA will just wait until new data appears sometime in the future.

This approach to assessing environmental exposures (i.e., set a standard, find a place that is complying with the NAAQS and has no other source(s) or historical inputs, and assess if everything is OK) is not likely to be effective. Based on the statement in the IRP: "Consequently, in the 2016 review, these analyses were not considered informative for predicting effects at the far lower concentrations associated with the current NAAQS." It would appear that EPA agrees.

Alternate "active" approaches must be considered. For example, air quality modelling is commonly used in proposals for new incinerators or other sources of stack emissions. These models provide estimates of atmospheric contaminants and allows for prediction of contaminant concentrations in adjacent areas. These models, in concert with empirical data from existing facilities for validation or training purposes, could be used to estimate matrix concentrations as a result of proposed air quality standards. In any case, a wait and hope that data will come in approach is not likely to be successful. EPA may want to consider a proactive approach to develop/validate existing or new models through new research initiatives.

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# Dr. Kathleen Vork

# Section 3 Quantitative Analysis Planning for the Secondary Standard pertaining to Linking Atmospheric Pb to Non-Air Media Concentrations (3.2.1)

Transfer coefficients, half-lives and other factors developed for the California Hot Spots program (OEHHA 2012) may be useful for linking atmospheric Pb to non-air media concentrations.

This document provides technical support documentation for conducting exposure assessments under the OEHHA Air Toxics Hot Spots program. The purpose of the program is to provide information on the extent of airborne emissions from stationary sources and the potential public health impacts of those emissions. The document includes exposure uptake, absorption and transfer factors for lead, including factors used for assessing exposure to lead through root uptake and dermal absorption from soil-bound lead and lactation, meat, milk and egg transfer coefficients of lead.

For example, in Appendix G "chemical specific soil half-life", the following key information link lead in air and lead in soil. The average concentration of a substance in soil (Csoil) is a function of several different variables, including [air] deposition rate, accumulation period, mixing depth, soil bulk density, and the chemical-specific half-life, as shown in equation G-1.

"As a default estimate, the metal content of soil is assumed to decay with a half-life of  $10^8$  days unless site-specific information is presented showing that soil conditions will result in the loss of soil metal content, i.e., soil aging or leaching. The  $10^8$ -default means that significant loss or removal is not occurring within the risk assessment time frame of interest."

Similarly, fish bioaccumulation factors for lead appears in appendix I, root uptake factors in appendix H, animal product transfer coefficients in appendix K of OEHHA (2012)

## Appendix entitled Cumulative Exposure Estimates for Different Birth Cohorts

Comments in reference to estimated Cumulative CBLI based on NHANES GM estimates for four general population cohorts (Table A-2); pertaining to footnote B - When year is prior to NHANES, the cohort is assigned BLLs from 1st NHANES according to age group.

Two studies conducted prior to NHANES studies support a higher baseline blood lead level in adults than applied in Table A-2 of the appendix to the draft IRP 2023.

The Kehoe Pb balance experiments were carried out from 1937 to 1972. According to the control periods from each experiment, blood lead levels (BLLs) in adult subjects were much greater than 13  $\mu$ g/dL (see copy of Figure 3 from Gross 1981).



FIGURE 3. Control period means for each subject by year of experiment.

The Griffin et al experiments were carried out in the early 1970s (late 1971 – mid 1972) Control BLLs ranged between 13 to 26 ug/dL at the start of each experiment.

#### References

Office of Environmental Health Hazard Assessment (OEHHA). 2012. Technical Support Document for Exposure Assessment and Stochastic Analysis. Office of Environmental Health Hazard Assessment, California Environmental Protection Agency, Sacramento CA. <u>Notice of Adoption of Technical Support</u> Document for Exposure Assessment And Stochastic Analysis Aug 2012 - OEHHA

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## Dr. Marc Weisskopf

1.3.2.2, 1<sup>st</sup> para: Bone lead shouldn't be referred to as reflecting lifetime cumulative lead exposure. First, different types of bone have different averaging times. Second, even the longest—tibia lead—averages over decades, but not an entire lifetime. In particular childhood and early adolescence is a time of more rapid bone turnover so in an adult, it is unlikely bone lead really reflects those periods. So for tibia lead, maybe decades, but not a lifetime. (this may correlate to differing extents with earlier exposure, but they do not directly reflect that)

1.3.2.2, 1<sup>st</sup> para: Similarly, multiple blood lead measures do not necessarily reflect lifetime exposure either. They reflect the exposure over the time period that the serial blood samples were collected. (as for bone lead, this may correlate to differing extents with earlier exposure, but they do not directly reflect that)

1.3.2.2, P 1-13: Remove "illustrated" from first line. And something is missing a little further down "...CBLI estimates presented in 0."

2.2.1, p. 2-21: The reasoning behind the handling of the C-R curve for blood lead and child IQ seems reasonable.

Table 2-4, part C: I understand this issue of higher past lead, and am fine not basing the decisions on adult outcomes that are most strongly associated with bone lead, but at some point couldn't models be built that predict bone lead levels given a certain number of years of blood lead levels at a given level. Those blood lead levels could be related to air lead levels allowing for an estimate of the relation between air lead and bone lead. These could then be explored to see whether they suggest different limit setting based on adult outcomes more related to bone lead.