

Draft Response to Risk and Exposure Assessment (REA)
Planning Document (Consultation)
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Health Risk Assessment:

1. The overview of the previous health risk assessment and presentation of results from the last review of the lead NAAQS.

Section 2-1 provides a clear, comprehensive review of the limitations and uncertainties in modeling risk and exposure modeling done for the last NAAQS review. However, some specifics were unclear. Clarification would be useful to addressing the planned approach for the current review: (1) How (if at all) does indoor air inhalation factor into the risk models? Is indoor air inhalation included in the ambient air category? It is identified as a direct source in Figure 2-1 but not Figure 2-2. (2) it was unclear why 'high' air Pb exposures (near the standard) in the general urban case study seems to be modeled as comparable to the 'high' air Pb exposures in the smelter case study. Also, the smelter case study was not included in the final risk assessment because of uncertainties in estimates but, as it seems this case models an important component of air Pb emission regulation, it is unfortunate that it could not be included in some form. (3) Pb exposure pathways tied to atmospheric deposition (e.g., outdoor dust/soil ingestion) were assigned to a 'past air' category (page 2-14); how far back in time does atmospheric deposition represent? (4) what are the dual linear models? Are these comparable to piecewise linear regression? If so, how is the inflection point determined?

2. The staff evaluation of elements of the risk assessment that were considered in determining the need for an updated quantitative risk assessment (e.g., advances in methods for modeling exposure including estimation of air-related pathways of exposure, prediction of blood Pb, updated/refined concentration-response functions for IQ loss).

Section 2-2 provides a tabular overview of the limitations and uncertainties of the previous risk assessment, new data/techniques relevant to those limitations and then a summary of whether that new information is sufficient to improve past limitations. (1) In several instances, it was unclear why the new information was not considered applicable. E.g., (page 2-22): new studies assessing the relation of dust Pb with blood Pb were not considered sufficient to do performance assessment on the models of the relation of ambient air Pb with indoor dust P and blood Pb, in turn. Wouldn't it be useful to do performance assessment at least on the last association (dust to blood) using the new data? (2) Re. the issue of modeling other endpoints, ADHD and ADHD-related behaviors was not included in the summary of new data. Recent data suggesting associations of very low blood Pb levels with ADHD risk (e.g., from NHANES) have important public health implications. However, it seems that the IEUBK model does not work above age 7 (ADHD outcomes encompass older ages) assessing this outcome is probably not an option. As there are not other acceptable models (besides the IEUBK) that could be used for a new risk assessment; perhaps a goal for the future might include

development of models that could be applied to other health outcomes and be appropriate in older children. (3) on page 2-28, the summary describes 2 studies showing associations of childhood blood Pb with delayed puberty. It's useful to keep in mind the two cited publications are only one study. The two papers studied Russian boys using the exact same study/study population with the earlier publication reporting a cross sectional analysis and the later one a longitudinal analysis as more data were available.

3. The decision to rely on the quantitative health risk assessment from the previous review, interpreted within the context of newly available evidence and information.

Overall, the decision to rely on the quantitative health risk assessment from the previous review seems carefully considered and justified; the REA provides a point-by-point review of the limitations of the previous risk assessment and the reasons new information will not substantially improve upon the previous work. However, sometimes it's not clear whether incorporation of new information does not provide at least some benefit. See comment under item #2 above. Also, e.g., using newer data regarding blood Pb variability could improve GSD estimates used in the previous review. Because there is ongoing uncertainty re. exposure pathway contributions to total risk and correlations among pathways (page 2-31), the authors argue there is no substantial benefit to using improved blood Pb GSD estimates. As a non-risk assessor, it would be helpful to have more information about why improving the GSD estimates is not still valuable, caveats about pathway uncertainties notwithstanding.