

05-05-11 Preliminary Draft Comments from Clean Air Scientific Advisory Committee (CASAC) Lead Review Panel. These preliminary pre-meeting comments are from individual members of the Panel and do not represent CASAC consensus comments nor EPA policy. Do not cite or quote.

Preliminary Comments from Dr. Philip Goodrum

Chapter 5. Quantitative Risk and Exposure Assessment

In general, the draft Integrated Review Plan is well conceived and clearly presented. The focus of the updated ISA and REA is to determine if more recent empirical data and modeling approaches provide sufficient evidence to warrant changes to the existing NAAQS. The multi-media, multi-pathway exposure component of a lead risk assessment presents challenges, particularly as the emphasis increasingly shifts to quantifying the contribution of air-borne lead to the dose-response relationship at lower cumulative doses.

A logical starting point for the re-assessment is to build from the uncertainty analysis that was conducted in the previous review. I would encourage EPA staff to carefully evaluate the previous work and subsequent literature to consider whether sufficient evidence is available to distinguish between outcomes of the uncertainty analysis in low-dose versus high-dose regions of the dose-response relationship. Uncertainty in estimates of exposures via inhalation, diet and water ingestion, for example, may be more critical at the low dose region, especially if the risk metric is defined by an “absolute” blood lead concentration threshold (e.g., probability of exceeding 5 or 10 $\mu\text{g}/\text{dL}$). At some point, it may become impractical to expect to isolate the relative contribution of one exposure medium (e.g., air) when the distribution of blood leads at low doses is heavily dependent on a suite of factors.

EPA intends to continue evaluating variability and uncertainty using a probabilistic approach (Monte Carlo analysis). This is particularly useful for understanding relative contributions of various exposure factors to the estimate of an average daily dose (uptake). Previously, the limitation of PRA for lead risk assessment has been the limited information available to incorporate probabilistic methods in the biokinetic component of the model; therefore, the distribution of blood lead concentrations was interpreted as underestimating the likely variance in an exposed population. To advance the methods used to inform the previous risk assessment, literature reviews should focus on understanding the likely magnitude of variance in blood lead that can be attributed to biokinetics.

The list of limitation, assumptions, and uncertainties given on pages 5-3 and 5-4 captures the key factors well, and should help to focus the reassessment effort. Care should be taken to try to distinguish between estimates of variability and estimates of uncertainty.

For the ecological risk assessment, in addition to focusing on specific case studies, databases developed from site assessments should be considered – particularly to understand how conditions at sites within the same watershed may vary.

Pages 5-9 and 5-10. EPA staff should consider the evaluations of NHANES data as an additional resource for matched PbB/ dietary lead levels.

p. 5-10. There is discussion of the use of empirical data to estimate the GSD parameter. EPA staff should be careful to control for variability in media concentrations if these new data are to be used to derive a plausible range of GSD for modeling purposes.