Comments on EPA National Ambient Air Quality Standards for Lead; Proposed Rule (Fed. Reg. 5/20/08) R. Poirot

Note: page # references are based on the initially available (451-page double spaced PDF) version of the proposed rule before it was reformatted for the Fed. Reg.

The 5/20/08 Lead NAAQS Proposed Rule is an improvement over the 12/17/07 Lead ANPR, with a more focused proposed range of levels for a revised primary standard between 0.1 to 0.3 $\mu g/m^3$, with monthly (or calendar quarterly) averaging time, second highest (month in 3 years) or highest (quarter in 3 years) form, and TSP (or TSP and PM_{10} or PM_{10}) indicator(s). While the range has been tightened from the open-ended (zero to infinity) public opinion survey of the ANPR, the proposal still covers a very wide range of relative health protection, as a 1 month, not to be exceeded TSP indicator of 0.1 $\mu g/m^3$ would be substantially more protective than a calendar quarter PM_{10} indicator of 0.3 $\mu g/m^3$. In addition, the NPR continues to seek comment on levels as high as 0.5 $\mu g/m^3$ and below 0.1 $\mu g/m^3$, providing minimally useful information about the Agency's actual intentions for this rulemaking very late in the process.

In a manner consistent with recent NAAQS revisions for PM and Ozone, the proposed 0.3 $\mu g/m^3$ upper bound level for the revised Pb NAAQS lies above the upper bound of levels recommended by EPA Staff and by the CASAC Review Panel. The NPR indicates (p. 27) that three general sets of recommendations were taken into account in developing this proposal: "(1) staff assessments …upon which staff recommendations for revisions to the primary Pb standard are based, (2) CASAC advice and recommendations…and (3) public comments…" and further states (p. 232) that "among the many public comments the Agency has received in this review regarding the level of the standard, the overwhelming majority recommended appreciable reductions in the level, e.g., setting it at 0.2 $\mu g/m^3$ or less…" So if the overwhelming majority of public comments, the EPA staff paper recommendations and underlying risk and exposure analyses, and the CASAC Lead Panel's unanimous recommendations all advocated a maximum level of less than 0.2 $\mu g/m^3$, its not clear where, exactly, the idea for a higher 0.3 $\mu g/m^3$ level of the Pb standard originated, and why is it now necessary to seek additional public comment on a level as high as 0.5 $\mu g/m^3$?

Air-related IQ Loss Evidence-based Framework: This proposed range, and especially the upper bound of 0.3 $\mu g/m^3$ (possibly extending as high as 0.5 $\mu g/m^3$), appears to be almost entirely based on a single new meta-analysis, entitled the "Air-related IQ Loss Evidence-based Framework." The following comments are focused primarily on this new analysis.

1. **Timing:** It seems late in the process to introduce a set of new and controlling risk calculations. These analyses could have much more productively been included as part of the risk/exposure assessment, further integrated with other analyses in the Staff paper(s), or at the very least aired for open public review in the ANPR. I'm concerned that this last minute change may be an example of the Agency's intended standard operating procedures under the new NAAQS review process.

2. **Exclusivity:** All other previous analyses, risk/exposure assessments, staff, CASAC and public recommendations appear to have been discarded, with this single new analysis used as the exclusive basis for the proposed NAAQS level. The range of proposed standards appears

to be predominantly driven by alternative assumptions of the appropriate C-R function(s) to relate IQ score point reductions to blood Pb concentrations, combined with a policy judgment that a mean population loss of up to two IQ points is the desired health outcome of a revised Pb NAAQS. Aside from this new 'air-related IQ loss evidence-based framework', no other analyses are presented which support a level as high as 0.3 (or 0.5) $\mu g/m^3$.

3. **Air-to-blood Pb ratios:** The analysis results are constrained to an assumed range of air-to-blood ratios of 1:3 to 1:7, which is described (p. 55) as being consistent "with the results and observations drawn from the exposure assessment, including related uncertainties". This is only true if we discard the many estimated ratios that fall above this range, ignore the clear indications that the blood Pb: air Pb ratio increases as air & blood Pb decrease, and if we further assume that the related "uncertainties" are directionally biased and somehow justify use of lower ratios, more representative of much higher air and blood Pb levels in the 1970s and 80s. By contrast, the current (2007) staff paper noted that while "there is uncertainty and variability in the absolute value of an air-to-blood relationship, the current evidence indicates a notably greater ratio… e.g., on the order of 1:3 to 1:10" (not 1.3 to 1:7).

   Even from the (22 year old) 1986 CD, the cited Brunekreef et al. (1983) analysis indicated a ratio of 1:8.5. The more recent Schwartz & Pitcher analyses suggest a ratio of 1:9 or 1:10. Results from Hayes (1994) suggested a range from about 1:6 (at high air Pb levels near 1 $\mu g/m^3$) to 1:16 (at ambient air Pb of about 0.25 $\mu g/m^3$ – near the range currently being considered for the NAAQS). In the EPA risk/exposure assessment, estimated ratios ranged from 1:2 to 1:9 across the range of alternative standards considered for the urban case study and from 1:10 to 1:19 across the range of alternative standards considered for the primary smelter. The NPR discredits these risk assessment calculations by noting (without attribution of authorship) that "some have suggested, however, that the regression modeling … could produce air-to-blood Pb ratios that are biased high" (p. 55) although it later notes (p. 132) that the ratios used in the risk assessment "reflect a subset of air-related pathways related to inhalation and ingestion of indoor dust [and that] inclusion of the remaining pathways would be expected to yield higher ratios." The lower end of the proposed range (1:3) reflects the much higher air and blood levels encountered decades ago, while the upper end of the range (1:7) fails to account for the higher ratios expected at lower current and future air and blood Pb levels, especially when multiple air-related Pb exposure pathways are considered.

4. **C-R Functions:** The critical C-R functions used in this meta-analysis represent the estimated slope of the relationship between IQ point decrements and blood Pb concentration. As summarized in Table 1, p. 80, the analysis identifies 2 groups of C-R functions – one with steeper slopes (ranging from -1.71 to – 2.94 IQ points per ug/dl blood Pb) and one with shallower slopes (ranging from -0.4 to -1.79 IQ points per ug/dl blood Pb). The median value of the shallow-sloped group (-0.90) is subsequently used (as the "2nd group of C-R functions") in the summary Table 7 "Estimates of air-related population mean IQ loss for children exposed at the level of the standard" on page 223. Like the lowest Air-to-Blood Pb ratio (1:3), the shallow-slope C-R function (-0.9) is based on analyses of populations exposed to much higher air lead concentrations and exhibiting much higher blood lead levels than is appropriate for current US populations and the levels under consideration for a revised NAAQS.

For example, the median BLL for children 1 to 5 years of age from the NHANES survey dropped from 3.5 µg/dl in 1988-91 to 1.9 µg/dl in 2003-04 (at which time the 90th percentile BLL was 3.5 µg/dl. However, all 8 of the "shallow slope" C-R functions presented in Table 1 had geometric mean BLL s greater than 3.3 µg/dl, and the 4 studies with slopes below the median value of -0.9 IQ points / µg/dl BLL, had mean blood levels ranging between 4.3 and 9.7 µg/dl. Within the shallow slope group, the only studies with mean BLL levels less than 4 µg/dl (which were the only studies in that group based entirely on US population groups) had slopes of -1.6 and -1.8 respectively. It is only the combination of the lowest C-R slopes and lowest air-to-blood PB ratios – both representative of much higher exposure conditions of 30 years ago - that provides any basis for considering a standard as high as 0.3 µg/m^3.

In questioning the validity of the higher slope C-R functions (typically based on lower Pb blood level population subsets of larger population studies), the NPR (p. 104) first notes that "these analyses are quite suitable for the purpose of investigating whether the slope at lower concentration levels is greater compared to higher concentration levels", but then cautions that the "use of such coefficients as the primary C-R function in a risk analysis such as this may be inappropriate." The NPR further notes that while a subset of children with maximal blood Pb levels below 7.5 µg/dl "may better represent current blood Pb levels, not fitting a single model using all available data may lead to bias." So its OK to learn that slope steepens at lower concentration so long as that information is disregarded in the risk analysis, where use of slopes and BLL representative of current levels would tend to "bias" the results. These are not especially convincing arguments.

5. **Target IQ Decrements:** The air-related IQ loss framework proposes a target IQ decrement of roughly 1 to 2 points as a level of damage which the proposed standard is intended to protect against. This target level is attributed in part to CASAC recommendations. The use of this target level is inappropriate for several reasons. First, the initial CASAC advice (Henderson Letter to Administrator Johnson 3/27/07 on (CASAC) Review of the 1st Draft Lead Staff Paper and Draft Lead Exposure and Risk Assessments) indicated that "*a population loss of 1-2 IQ points is highly significant from a public health perspective (22). Therefore, the primary lead standard should be set so as to protect 99.5% of the population from exceeding that IQ loss.*"

   Note that this comment refers to 1-2 IQ points as a "highly significant" loss to be prevented (not as a desired national damage level goal that a standard should be set to assure) and note also that the recommendation is that IQ decrements as large as this should be prevented in all but a small percentile of the population (not accepted as a reasonable change in <u>mean</u> IQ scores across the entire population). If a loss of 1 IQ point (rather than losses of up to 3.9 points) in mean IQ levels were considered a significant loss to be prevented, this analysis would point to a range of standards between 0.05 and 0.2 µg/m^3, with the lower end of that range being more consistent with the higher C-R slopes and higher air-to-blood ratios representative of current US ambient air and blood lead concentrations. But by combining the lowest air-to blood Pb ratios (1:3), shallowest C-R slope (-0.9) and high acceptable IQ decrement endpoint (>1 IQ point) the NPR subsequently goes on to suggest (p. 241) that a standard as high as 0.5 µg/m^3 would be adequate to protect public health, although at higher

air-to-blood ratios and steeper C-R slopes - both more representative of current US exposures - this standard would allow losses of 5 IQ points or more.

Pb NAAQS Indicator: In several rounds of previous comments, the CASAC Lead panel recommended that a revised (and substantially lowered) Pb NAAQS should be accompanied by a transition of the sampling indicator from TSP to Low Volume PM_{10}. In comments on the Pb ANPR (Henderson letter to Administrator Johnson, 1/22/08), the CASAC Lead Panel "unanimously supported the selection of an [PM_{10}] indicator that can be more robustly measured and thus would be more representative of actual population exposures" and also noted that "a more accurate and precise Pb-PM_{10} indicator would provide a more stable determination of compliance with the new lower Lead NAAQS". In regard to concerns over potential loss of ultra-coarse lead particles by PM_{10} samplers, the Lead Panel further noted that "it would be well within EPA's range of discretionary options to accept a slight loss of ultra-coarse lead at some monitoring sites by selecting an appropriately conservative level for the revised Pb NAAQS." In a subsequent review by the CASAC AAMM Committee, a majority of the members of that committee also recommended transition from TSP to low volume PM_{10} sampling for lead.

These recommendations were based, in part, on an assumption that the level of the primary Pb NAAQS would be "substantially" lowered to the EPA Staff-recommended range (with an TSP indicator) of between 0.1 to 0.2 $\mu g/m^3$ as an upper bound and 0.02 to 0.05 $\mu g/m^3$ as a lower bound (with the added consideration that the selection be made somewhat "conservatively" within this range to accommodate the potential loss of ultra-coarse Pb with a PM_{10} Pb indicator). For example at most population-orientated monitoring sites, levels of PM_{10} Pb are essentially the same as TSP Pb, but at source-oriented monitoring sites with high coarse mode particulate lead emissions, TSP Pb was roughly twice as high as PM_{10} Pb. This factor of 2 difference is small compared to the factor of 10 to 100 of the recommended reduction in the level of the standard, and could be readily accommodated by considering a slightly more conservative upper bound of 0.1 $\mu g/m^3$ rather than 0.2 $\mu g/m^3$.

However, since the Agency now appears to disagree with previous staff (and CASAC and the "overwhelming majority" of the public) recommendations and is considering an upper bound of 0.3 $\mu g/m^3$ and possibly as high as 0.5 $\mu g/m^3$, a transition from TSP to PM_{10} at these much less protective upper levels of the proposed range could represent a critical weakening of the standard. A particulate lead emissions standard at 0.5 $\mu g/m^3$ could potentially allow TSP Pb levels as high as 1 $\mu g/m^3$ at sites near large sources with coarse-mode particulate lead emissions. If the level of the standard is set toward the upper end of the range the Agency is now considering, the current TSP indicator should not be revised in a way which would allow a potential weakening of the NAAQS. As recommended previously, a transition to PM_{10} indicator would be preferable, but only at a level of 0.1 $\mu g/m^3$ or lower.

Pb NAAQS Averaging Time and Form: The NPR proposes consideration of a monthly averaging time with a "second highest month in 3 years" form, but also seeks comment on retaining the current calendar quarter not to be exceeded form. There is no logic for averaging only by "calendar" quarter, as there is nothing unique about effects that may occur exclusively during the 4 calendar seasons. A rolling 3 month or rolling 90 day average would be more logical. A monthly average (at the same level) would be more protective, even with a second

highest month in 3 years form, and would better reflect the time period over which adverse effects may occur.

Previous CASAC Lead Panel recommendations (in the current review and also in the previous 1980s Pb NAAQS review cycle) advocated reducing the averaging time of the Pb NAAQS from Calendar quarter to monthly. The rationale was that adverse effects could result from exposures over as few as 30 days duration. The NPR proposes consideration of a monthly averaging time with a "second highest month in 3 years" form. The "second high" form would promote a more "stable" standard (less flipping into and out of attainment), and a source would not be penalized for a single bad month in a 3-year period. A child's cognitive development , however, could be irreversibly penalized for exposures to elevated Pb concentrations during that single bad month, and the Agency should also consider a more protective monthly standard with a "not to be exceeded" form. Further guidance could be developed to accommodate "exceptional events" to assure that non-compliance would not be caused by extraordinary meteorological events, etc.

It should be recognized that a monthly average will require a sampling frequency of at least every 3 days – except for sites that are well below the level of the NAAQS – and that this requirement if combined with a TSP indicator, will be especially burdensome on state monitoring agencies. Sequential TSP samplers are not available, and installing multiple TSP samplers will be precluded by space limitations at many sites since high volume samplers require 2 meter separation from other samplers.