PRE-TELECONFERENCE COMMENTS ON EPA'S PROPOSED LEAD NAAQS

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I have a number of comments on the Pb NAAQS notice of proposed rulemaking (NPR) released by EPA May 1, 2008. These are provided in connection with any unsolicited review of the Pb NAAQS NPR by the Pb NAAQS CASAC Panel. Comments that include citations for page numbers in the NPR refer to locations in the Federal Register notice **[73 FR 29184-29291, May 20, 2008]**.

I. THE NUMERICAL VALUE OF THE PB NAAQS STANDARD

A. The Proposed Numerical Value(s) of the Air Pb Standard in the NPR

One of my principal concerns is the proposed numerical range for the air lead standard. The NPR proposes an air Pb value that is "within" the range of 0.10 to 0.30 μg/m^3. Other language within this portion of the text defines "within" to include the specific bracketing figures 0.10 and 0.30 μg/m^3.

In arriving at this proposed range of air Pb values, the Administrator notes he not only took notice of the OAQPS Staff Paper and its recommendations, but public comments and the CASAC Panel's conclusions and recommendations. Part of the CASAC Panel's work, spelled out in Attachments to the March 27, 2007 CASAC Chair's Letter to the Administrator, involved the presentation of illustrative methodologies based on Pb-B/air Pb ratios.

The Administrator noted in **Section II.E.3, "level for a Pb NAAQS with a Pb-TSP Indicator" [73 FR 29236-29245]**, his arguments and conclusions for arriving at the proposed air Pb values of 0.10 to 0.30 μg/m^3 and for rejecting other selections. The rationales for the selection are specifically given in **Subsection (d) "Administrator's Proposed Conclusion Concerning Level" [73 FR 29241-29245]**. The selected value is stated to be the Administrator's interpretation of the available evidence. Air Pb values < 0.10 μg/m^3 are deemed to offer little added protection over the proposed figures while they require tighter, i.e., more expensive, control of ambient Pb emissions. Furthermore, values > 0.30 μg/m^3 up to 0.50 μg/m^3 would result in an unacceptably high loss of IQ points in exposed children.

B. The CASAC Pb NAAQS Panel's Recommendations to the Administrator About An Appropriate Air Pb Standard

The proposed numerical size of the Pb standard deviates in some significant ways from the consensus recommendations of the CASAC Pb NAAQS Panel numerical values in its three Letters to the Administrator: March 27, 2007; September 27, 2007; January 22, 2008.

For example**,** the Panel's **Letter to the Administrator of September 27, 2007 [EPA-CASAC 07-007]** states on **p. 2, at item 2** that:"...EPA needs to substantially lower the level of the primary NAAQS for Lead, to 0.2 μg/m^3 or less. In the unanimous opinion of the Lead Panel, EPA has not presented any rigorous analyses or other information in its 2nd Draft Lead Exposure and Risk Assessments document that leads the CASAC to reconsider its previous recommendation to you that the upper limit the Agency should consider in revising the Pb NAAQS should be 0.2 μg/m^3 on a monthly average."

The Panel's **Letter to the Administrator of January 22, 2008 [EPA-CASAC-08-007], on p. 1, at ¶ 2**, states that:

> "...The Committee unanimously and fully supports Agency staff's scientific analyses in recommending the need to substantially lower the level of the primary (public-health based) Lead NAAQS, to an upper bound of no higher than 0.2 μg/m^3 with a monthly averaging time."

The last-cited Administrator's Letter not only recapitulated the core of the Panel's recommendations in the first two communications but it equally endorsed the conclusions of the EPA OAQPS Staff in its Staff Paper. OAQPS Staff essentially came to the same set of conclusions in this specific matter that the Panel did. This set of parallel conclusions for evidence-based evaluations by Agency and Panel argues that the evidence for specific air Pb reductions is both compelling and transparent when viewed through either regulatory or independent lenses.

C. How do the Panel's unanimous statements regarding choice of a primary air Pb standard address the requirement stated in the CAA to protect public (child) health with an adequate margin of safety?

The Panel's unanimous recommendations as to a choice of air Pb values for consideration based on the current evidence explicitly said two things. First, they said that the absolute upper bound should be 0.2 μg/m^3 but also that the value should be less than this upper bound figure. Otherwise, there would be no reason to include values less than 0.2 μg/m^3. Put in statistical terms, an upper bound is not a "best estimate". Put in terms of the requirement of the

CAA, a value < 0.2 μg/m^3 is implicitly judged through the recommendations to be the "best estimate" for providing protection of child health with an adequate margin of safety.

The range of values as a proposed selection for a Pb standard in the NPR include potential selections which would be unacceptable on their face, given the CASAC Pb Panel and the EPA OAQPS Staff recommendations. Values of 0.25 and 0.30 μg/m^3, which are within the NPR range being proposed, would at the same time clearly exceed even the absolute upper bound value of 0.20 μg/m^3 indicated in the Panel's recommendations. They would exceed the upper bound recommendation figure by 25 and 50% respectively. These exceedences are not trivial in their consequences, given that we are dealing with a nationwide ambient air Pb standard, and a standard intended for protection of the health of the entire country with an adequate margin of safety.

Selection by EPA of the air Pb value of 0.20 μg/m^3, the midpoint of the NPR range of 0.10 to 0.30 units, would be the absolute upper bound to the Panel's recommendations and would be, by definition, a problematic value for providing an adequate margin of safety compared to values below this level of 0.20 units.

Selection by EPA in its final rulemaking of a figure of 0.10 μg/m^3 would, however, be within its own range of levels for consideration and an approximate "best estimate" midpoint within the range of the Panel's recommended air Pb levels, 0.02 to 0.20 μg/m^3.

D. What did the CASAC Panel's illustrative methodology using Pb-B/air Pb relationships say about arriving at a new Pb NAAQS and what role should that illustrative methodology play in the Administrator's evaluations of the overall evidence?

The 3/27/2007 Letter to the Administrator spelled out several illustrative methodologies using the basic "ratio" approach of relating changes in national Pb-B values to corresponding changes in national air Pb values. In various places in the text of the 5/1/08 Pb NAAQS NPR, e.g., the section referred to above, the ratios advanced by the Panel as illustrative appear to have been factored to some extent into the Administrator's selection.

The Administrator referred to Pb-B/air Pb ratios in the range of 3 to 7, with a midpoint of 5, this being the Agency's sense of the CASAC Panel's presentation of this suggested illustrative methodology. That is misleading and clearly incomplete. The best documentable ratio, and one that is relatively current, is the one based on actual epidemiological data showing that declines in U.S. national Pb-Bs from NHANES surveys tracked declines in EPA- and State-monitored air Pb levels over the same time periods. This ratio is 10. As discussed by members in their comments attached to the 3/27/07 CASAC Panel Letter, the epidemiological evidence supports a ratio of 10. Specifically, the national picture of Pb-B declines with air Pb declines

showed that during the period the national Pb-B declined 10 units, the corresponding air Pb national value declined about 1.0 μg/m^3, yielding a ratio of 10. See the 3/27/2007 Letter to the Administrator, Appendix D: Approach B, p. D-2.

To the extent that the Administrator substantively factors in the ratios posed by CASAC's Letter in coming up with his ultimate choice for a numerical standard, the ratio of 10 should be given preference for reliability, based on epidemiological data.

The use of a ratio of 10 translates, via the language employed by the Administrator in Subsection (d) and the ratio methodology in the Panel's Letter: Appendix D, to an air Pb of 0.10 μg/m^3 or somewhat less as an option for selection.

E. ***Taken together, the above comments argue for a new air Pb standard of 0.10 μg/m^3 or somewhat less, especially if one takes into account the epidemiologically based Pb-B/air-Pb ratio of 10.***

II. THE AVERAGING TIME OF THE STANDARD

A. The Choice of Averaging Time in the Pb NAAQS NPR

The NPR indicates two options for the averaging time selection: retention of the quarterly averaging time or changing to a monthly averaging time. The respective forms of the standard would be: the maximum quarterly average across a 3-year time span, and the second-highest monthly average across a 3-year span, **Sec. 11.E.2. Averaging Time and Form [73 FR 29234-29236]**. The Administrator does not indicate a preference for one over the other.

B. The CASAC Pb NAAQS Panel's Recommendations to the Administrator of an Appropriate Averaging time for the Air Pb Standard

The CASAC Panel recommended a monthly, rather than the current quarterly, averaging time. The evidence marshaled for the CASAC Panel's arguments for a monthly time interval strongly indicated that, toxicokinetically, young children respond more rapidly in time to changes in Pb exposure, such as a fugitive emission from a facility to a neighboring home, than was assumed for the current standard. Specifically, changes in exposures and associated Pb-B levels can occur around a month’s time frame, well within a calendar quarter. Responses to exposure changes upward by increases in Pb-B and subsequent declines in exposure and Pb-B level around a month's time would be invisible to a quarterly averaging time.

The CASAC Pb Panel's recommendation of a monthly averaging time was not subsequently refuted by anything in the text of this Subsection and the Panel's recommendations for a monthly averaging time would still argue for a selection of this option.

C. What should the CASAC Panel offer in the way of advice for coupling the averaging time and form to the proposed numerical standard range?

EPA in this Subsection also appears to imply linkage is necessary between the proposed numerical values of the standard and any selected averaging time and form option. No explanation as to the computational, regulatory or public health basis for this is presented in this portion of the NPR. I would note that an earlier document, the OAQPS Staff Paper reviewed by the Panel, also linked the two sets of parameters in inverse directions without explaining why this is necessary. Specifically, there is little basis in the text for this that would argue that change in the averaging time to a shorter period calls for an adjustment upwards in the numerical value of the proposed NAAQS. And vice-versa. That is, a standard of X $\mu g/m^3$ coupled to a quarterly averaging time and maximum quarterly average as to the form would have to be lower than a numerical value of the standard, Y $\mu g/m^3$, when using a one-month averaging time and a form of second-highest monthly average.

On its face, the two parameters discussed here, i.e., numerical value of the standard and the averaging time/form for that standard both address the issue of protection of child health with an adequate margin of safety. Given that the evidence before the Administrator argues strongly for a low-as-possible standard and a short-as-feasible averaging time for public health protection, why is there any inverse linkage of the parameters that provide for a de-facto zero-sum process? Both are found from the scientific body of data to be independently in the same direction. Furthermore, if the combination of lower values for a NAAQS and shorter averaging time provide for increased regulatory burdens on the regulated stakeholders, that is not the principal concern of a public health and ecological health advisory body like the CASAC Pb Panel.

I believe the Panel should take up the Administrator on his invitation to interested parties to offer comment on this specific point. EPA **[at 73 FR 29236]** invites comment such that:

> "...Based on the considerations discussed above, EPA requests comment on whether a level for a NAAQS with a monthly averaging time and a second-highest monthly average form should be based on an adjustment to a higher level than the level for a NAAQS with a quarterly averaging time and a not-to-be exceeded form, and, if so, on the magnitude of the adjustment that would be appropriate."

III. INVITATION TO COMMENT ON A PB NAAQS OF ZERO

The Administrator, at **[73 FR 29245]**, invites comment on

"...when, if ever, it would be appropriate to set a NAAQS for Pb at a level of zero. Comments on this question might address issues such as: the level of scientific certainty

> required...; the level of harm...and size of affected population... and whether there are normative or quantitative criteria that could be applied...to set a standard at zero. EPA invites..."

At first blush, this matter would appear to be of interest and concern for this Pb Panel. However, I am not sure what exactly the Administrator is inviting, without his providing the means for some understanding among Panel members as to what are the Administrator's elements of reliance on statutory definitions, and boundaries to those definitions, to a "zero" proposal. Specifically, what room is made in the Clean Air Act for either the implementation or the pursuit of a "zero" Pb NAAQS?

It might be informative to contrast ambient air Pb to drinking water Pb with reference to "zero" as a regulatory option in standard-setting. The Safe Drinking Water Act calls for setting of primary drinking water standards as Maximum Contaminant Levels (MCLs) and concurrent with this, Maximum Contaminant Level Goals (MCLGs). MCLs are set at some derived and measurable concentration in drinking water based on the evidence while the MCLGs are typically set at zero. The reference point with the water regulations is the MCLG, in that

> "...Each maximum contaminant level goal established under this subsection shall be set at a level at which no known or anticipated adverse effects on the health of persons occurs and which allows an adequate margin of safety. Each national primary drinking water regulation for a contaminant [MCL] for which a maximum contaminant level goal is established under this subsection shall specify a maximum level for such contaminant which is as close to the maximum contaminant level goal as is feasible" **[NATIONAL DRINKING WATER REGULATIONS, Sec. 1412(b)(4)]**.

In practice, many of the MCLGs are set to zero.

What the Administrator seems to be inviting comment upon is more-or-less a NAAQS "Goal" of -0- for ambient air Pb. Such a NAAQS "goal" for Pb being as close to -0- as feasible necessarily places a premium on an Agency rationale that emphasizes choice of a Pb standard "at which no known or anticipated adverse effects…and which allow an adequate margin of safety", versus selection of a standard below which neurotoxic harm has not been conclusively documented.

Failing any identification by the Panel of the Administrator's intentions to the contrary in the present text, the water regulations seem to provide guidance for a precautionary rationale, i.e., the first rationale mentioned in the previous paragraph, in regulatory scientific terms.