Comments on the NAAQS for Lead: Proposed Rule

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I begin by stating generally that I fully support the proposal to significantly reduce the NAAQS for lead in light of accumulating scientific evidence that detrimental effects occur at exposures below 1.5 μg/m^3, continuing to be reasonably well documented below 1 μg/m^3 in sensitive subpopulations. I believe the EPA has followed both internal staff advice and CASAC advice (in previous reviews) in this regard. My personal preference would be for a standard at the upper end of the proposed range (i.e. at 0.3 μg/m^3 rather than 0.1 μg/m^3) because I remain unconvinced by the evidence below 0.3 μg/m^3. However, I could be convinced of a NAAQS value as low as 0.2 μg/m^3 if an argument related to margins of safety were to be applied (the reason I signed on initially to a CASAC recommendation that the new NAAQS be 0.2 or below). I don't believe the current document makes a strong case for any particular margin of safety, or quantifies a margin that would be consistent with other Agency decisions on other pollutants, and so I would lean towards a NAAQS of 0.3 μg/m^3. I realize, however, that it is up to the EPA administrators in the end to select the appropriate standard.

I also realize that the recommendation of CASAC was that the new NAAQS not exceed 0.2 μg/m^3, and that this seems inconsistent with the range of 0.1 to 0.3 suggested by the Administrator. I don't, however, believe consideration of such a range is inappropriate. While CASAC is an essential part of the process of developing a NAAQS, I continue to believe that it is only an advisory body and only one of several sources of input into the process of decision-making. I am comfortable that the range of 0.1 to 0.3 μg/m^3 includes the upper limit value recommended by the CASAC, and still represents a significant reduction in the NAAQS even at its upper end.

As to the averaging time, I believe the decision between a monthly (second highest) or quarterly (highest) average is more political and economic than scientific. I don't believe the current state of science can specify reliably which of these two is more appropriate or even more protective. While the CASAC may have views on this issue,

it seems to me one that is beyond the temporal resolution of the data, because I don't believe those data demonstrate that spikes in exposure of as low as one month duration do or do not yield significant adverse effects. My personal preference would be for the quarterly averaging to simplify analysis and reporting.

I continue to support the used of blood lead levels as the primary means of establishing the NAAQS for airborne lead. The ratios (air to blood) used in the current analysis are reasonable central tendency values over the quite wide range found in the literature. However, I believe the conclusion of CASAC was that a ratio of up to 10 would be appropriate for the levels of exposure considered here, as suggested by the epidemiological literature. 10 appears to me to be the upper bound estimate of this ratio, so I would be comfortable with anything between 5 and 10. This issue is particularly important for the results in Table 7, and hence for the evidence-based justifications provided in that section.

As with the previous documents, I am less comfortable with the analysis of Potential Public Health Impacts, starting on Page 23. I don't believe this is really an analysis of the impacts, but rather an analysis of the number of people likely to live in areas above a given NAAQS and the fraction of the population that might be considered sensitive or susceptible. These to me are not analyses of public health impacts, potential or otherwise. The analysis may suggest that the number of people exposed is high – I agree with this conclusion – but this is not to suggest that they will have adverse effects, which is what should be meant by public health impacts.

I note here also (since I can find no more convenient place to make the point) that the document still does not provide evidence that lowering the NAAQS will reduce public health impacts of exposure to lead. This could be a moot point, because the intent of the NAAQS is to establish a concentration that would, in and of itself, be protective of health if maintained over an infinite time so equilibrium is reached in all environmental media. This is not the same, however, as the belief that reducing the NAAQS to 0.3 or 0.1 $\mu g/m^3$ will bring about the improvements in health status used as justification for the new standard, since it is not clear that the emissions control measures that would be taken in light of such a new standard would have a significant impact on the sum of policy and non-policy relevant exposures. The results in Table 2

and in other, related, tables (3, 4, 5 and 6), suggest that a greatly reduced NAAQS may have much less of an effect as a policy tool than would be expected from a simple ratio of potential NAAQS values (i.e. a decrease in the NAAQS by a factor of 2 may have significantly less than a two-fold decrease in adverse health effects). Having said this, I still support the reduced NAAQS in establishing a TARGET concentration of airborne lead even if the public health effectiveness of actual control measures that might be taken is being overstated (or over-implied).

I support the conclusion of a non-linear exposure-response curve, with steeper slope as exposures decrease to blood lead levels of below 10 µg/dL. The implication of such a steeper slope in identifying an appropriate NAAQS is not, however, clear to me in the document. The tendency in the document is to assume that an increasing slope at lower exposures indicates things get worse incrementally at these lower exposures, which in turn argues for an even lower NAAQS. However, an exposure-response curve with a threshold would also have the property of increasing slope at lower exposures, and there is nothing in the document that explores the existence of, or implications, of a threshold. So I just don't see how the "increasing slope" argument is playing a role anywhere in the selection of a NAAQS, other than being used to select a higher slope for the analysis of number of people with IQ losses of 1 and 7 points (perhaps this is all the steeper slope argument is needed for).

I am not sure what to make of the calculations of numbers of children with IQ loses above 1 or above 7. It is interesting to see the values to develop a sense of the numbers of people that might be impacted by any NAAQS, but the document does not provide an explanation of how large these numbers would need to be to warrant regulatory action. I suppose one could argue that ANY number of affected children (other than zero) is too large, but that would be too facile as it is not required by the initial rulings on regulatory limits by the EPA - rulings that clearly established that the EPA need not set standards that protect 100% of the population against all risks above zero. And I am not sure that a decrement in IQ of 1 point is either meaningful or measurable. A decrement of 7 points does seem to me significant. I am not arguing that these decrements should not be of public health concern, but rather that I remain unclear as to what reduction in the number of people with such decrements would

justify more stringent regulatory controls. It seems to me this document should lay out the case better, making it more transparent.

My personal preference would be to use Pb-10 rather than TSP-Pb, although I realize the latter would make maximal use of the existing monitoring network. Particles above 10 microns in diameter just don't seem to me relevant here, either from the perspective of particles entering the lungs or from particles that might be taken out by the nose and then swallowed after drainage (both of which seem to me significant pathways for exposure to lead).

On page 29242, the Administrator mentions a population-mean IQ loss of 1.5 points, which is then compared to the CASAC recommendation that a loss of between 1 and 2 points should be considered adverse. I don't understand this comparison. A population-mean loss does not seem to me relevant here, as it is a mean of a very wide and skewed distribution of values in the population. The CASAC was not saying that a population-mean loss of 1 to 2 points was significant. What is more important is the fraction of the population above some particular IQ loss (presumably the purpose of calculating the number of people with losses above 1 point and above 7 points). I realize this leaves unresolved the issue of what will count as an unacceptably large fraction or number of people above a given decrement in IQ, but I see no way around such an approach, and the mention of a population average strikes me as a meaningless compromise.