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July 25, 2008

Stephen L. Johnson, Administrator
U.S. Environmental Protection Agency
Mail Code 6102 T
1200 Pennsylvania Avenue, NW
Washington, DC 20460

Attention: Docket ID No. EPA-HQ-OAR-2006-0735

Re: *National Ambient Air Quality Standards for Lead – Proposed Rule*

Dear Administrator Johnson:

The Northeast States for Coordinated Air Use Management (NESCAUM) offer the following comments on the U.S. Environmental Protection Agency's (EPA's) Notice of Proposed Rulemaking (NPR), published on May 20, 2008 in the Federal Register, entitled *National Ambient Air Quality Standards for Lead* (73 FR 29184 - 29291). NESCAUM is the regional association of air pollution control agencies representing Connecticut, Maine, Massachusetts, New Hampshire, New Jersey, New York, Rhode Island, and Vermont.

There are a number of ways to achieve improved public health protection through the revised lead National Ambient Air Quality Standard (NAAQS). A recent assessment by New York (see Appendix A) concludes that the ambient air concentration for lead should be no greater than 0.15 micrograms per cubic meter ($\mu g/m^3$). We also note that values below this may be well justified. In an ideal world, lead should be measured with accurate and reliable Total Suspended Particulate (TSP) monitors in a comprehensive network designed to capture both hotspots near known sources and neighborhoods where the accumulation of sources could result in nonattainment. We recognize that this ideal may be unachievable in the next few years. However, it is imperative that EPA moves forward quickly to reduce lead exposures among our nation's children. We therefore recommend three alternatives for the revised NAAQS (in order of preference) that will move the country in the right direction pending development of improved TSP monitors and an expanded monitoring network, all of which will help inform the next lead NAAQS review:

1. Set the revised lead NAAQS at a level no greater than 0.15 $\mu g/m^3$, based on the concentration of lead in TSP using relatively straightforward, easy to implement improved technology.[1]

[1] Examples of such improvements include the existing particulate matter (PM) Federal Reference Method PM-10 sampler louvered inlet without any further size fractionation. This method would require a water trap in order to ensure that water that might get into the inlet does not get on to the filter and void the sample. Testing of this method would be required before widespread use.

2. Set the revised lead NAAQS at a level no greater than 0.15 µg/m^3, based on the concentration of lead in TSP using current TSP technology, supplemented with PM-10 sampling data at sites well below the NAAQS.
3. Set the revised lead NAAQS at a level no greater than 0.050 µg/m^3, based on the concentration of lead in PM-10.

Need for a More Stringent Lead NAAQS

NESCAUM agrees with the EPA Administrator, EPA staff and the Clean Air Scientific Advisory Committee (CASAC) determinations that the primary lead NAAQS must be substantially lowered to provide adequate public health protection. In 1978, EPA issued the current primary lead NAAQS of 1.5 µg/m^3. Over the past 30 years, a wealth of new health-based scientific information has become available that clearly documents the adverse health effects of lead at levels well below the current NAAQS.

The air pathway is a route of general population exposure to lead. Lead exposure is associated with a broad range of adverse effects, including loss of cognitive function (e.g., significant IQ deficit), as well as cardiovascular disease, kidney disease, attention deficit disorder, behavioral problems, and immune system disorders. Scientific studies also clearly demonstrate that lead causes adverse health effects in young children at blood lead levels that are much lower than levels previously considered harmful. Further, there is no evidence of a threshold level at which no adverse health effects are associated with lead exposure. The scientific literature overwhelmingly supports the need to revise the primary lead NAAQS in order to protect public health with an adequate margin of safety.

Level and Form of the Lead NAAQS

In the NPR, EPA proposes a lead NAAQS within the range of 0.10 µg/m^3 to 0.30 µg/m^3, based on the concentration of lead in TSP (73 FR 29190). Based on the relevant scientific studies, the upper range of EPA's proposed lead NAAQS may not be health protective. The NESCAUM states urge EPA to set the revised lead NAAQS at a level no greater than 0.15 µg/m^3, based on the concentration of lead in TSP (see below for more details on the indicator). The EPA staff and CASAC have indicated that the upper bound of the primary lead NAAQS must be no higher than 0.20 µg/m^3, with a monthly averaging time. However, health studies clearly document significant IQ loss and present the possibility of substantial health effects at levels above 0.15 µg/m^3 (see Table 2 of the CASAC letter[2] and Appendix A). While the adverse health effects associated with levels below 0.15 µg/m^3 remain uncertain, there is no known threshold in the relationship between blood lead and IQ loss. Understanding the health effects of lead at lower levels remains an important area for further research. Due to the uncertainties associated with

[2] Letter to Stephen Johnson, EPA Administrator, from Rogene Henderson, CASAC Chair, EPA-CASAC-07-003, p. F-64 (March 27, 2007).

lead exposure at lower levels, a NAAQS in the lower range of possible values is justified in the interest of protecting public health, with an adequate margin of safety.

NESCAUM is concerned as to why EPA did not follow CASAC's unanimous recommendation for establishing the lead NAAQS at a level that is, at a minimum, no higher than 0.20 $\mu g/m^3$ (monthly average). Based on the preponderance of information supporting the need for a lead NAAQS at a level of at least 0.20 $\mu g/m^3$, NESCAUM is also concerned that EPA is requesting comment on levels for the lead NAAQS as high as to 0.50 $\mu g/m^3$ (73 FR 29184). The EPA staff and the CASAC (EPA's scientific advisors) unanimously agree that any level above 0.20 $\mu g/m^3$ is not health protective. Furthermore, a NAAQS set at such a level is not supported by any of the relevant scientific studies.

We note, along with CASAC, that the most recent epidemiologic studies demonstrate a statistically significant relationship between blood lead and IQ loss at levels well below 5 µg/dL. We recognize that lead is a multi-media pollutant. However, the risk analysis scenarios presented by EPA for current conditions, using the Agency's hybrid dust model, show that the "recent" air exposure pathway contributes anywhere from 28 to 57 percent of the total amount of ingested lead. Additionally, recent air exposures still contribute 27 percent under an alternative primary NAAQS of 0.20 $\mu g/m^3$ (maximum monthly average), and only fall to 13 percent under an alternative primary lead standard of 0.050 $\mu g/m^3$ (maximum monthly average). Since there is no known threshold in the relationship between blood lead and IQ loss, the level of the current primary lead standard clearly provides no margin of safety from ambient air lead exposures, and the midpoint of the range recommended by EPA (0.20 $\mu g/m^3$) still leaves our nation's children exposed to unacceptably high levels of lead.

NESCAUM agrees with EPA's recommended option #2 in the NPR to shorten the averaging time from quarterly to monthly for determining compliance with the NAAQS, using the second highest monthly average over a three-year period (73 FR 29236). This provides an averaging time that is closer to the critical exposure periods for children, as blood lead concentrations respond at shorter time scales than are captured by quarterly values.

<u>Lead Indicator</u>

Choosing the appropriate lead indicator requires a balance of complex issues. Different sources can emit different lead particle sizes, which in turn may warrant supplemental measurements using high-volume TSP or other non-NAAQS indicator techniques.

NESCAUM supports a primary lead NAAQS of no greater than 0.15 $\mu g/m^3$ with a TSP indicator. Values above 0.15 $\mu g/m^3$ are not justified. NESCAUM recognizes that the existing high-volume TSP monitors have significant limitations. We recommend, however, that EPA retain TSP as the indicator (unless the NAAQS is set at a level below 0.15 $\mu g/m^3$) and that within the next five years it should develop an updated TSP monitor to adequately characterize all particle sizes of lead in ambient air. An updated TSP monitor should include reduced variability of measurements (e.g., wind speed, wind direction), ability for sequential sampling, and better options for analytical techniques.

If the EPA were to select PM-10 as the indicator, then NESCAUM would recommend that EPA set the lead NAAQS at a level of 0.05 $\mu g/m^3$. NESCAUM agrees that PM-10 may be an appropriate surrogate in light of some of the limitations with the high-volume TSP monitors. In this situation, PM-10 may be appropriate in the short term (dependent on the level of the standard), but because PM-10 monitors may miss up to 50 percent of larger particles near lead sources, adjustments would need to be made through a future rulemaking to develop a better method that can adequately measure all particle sizes in ambient air. NESCAUM only supports use of PM-10 as the indicator under limited circumstances, e.g., if EPA were to set the lead NAAQS at the level of 0.050 $\mu g/m^3$. Another option for EPA to consider is a hybrid approach, whereby that EPA allows PM-10 to be the NAAQS indicator as long as the PM-10 data are less than 50 percent of the NAAQS level. If the PM-10 data exceed that threshold, then EPA would require that a TSP high-volume sampler be used at that site. This implies that two Federal Reference Methods – a low-volume PM-10 FRM and the existing high volume TSP FRM – be allowed for use for Pb compliance monitoring.

EPA requests comment on providing default scaling factors for use of PM-10 data in conjunction with a TSP indicator (73 FR 29232). NESCAUM strongly recommends against any use of scaling factors. The ratio of PM-10 to TSP high-volume lead is highly variable, and depends on the nature of the source of the lead. Any scaling factor would need to be site-specific, and would thus be impractical to implement. Since many sources are known to produce only small particles, these sources could be measured with PM-10. If these PM-10 monitors were above 50% of the NAAQS, then the indicator should be required to be switched to TSP, thus eliminating the need for a scaling factor.

In the NPR, EPA proposes allowing a reduction in sampling frequency if the most recent three-year design value is less than 70 percent of the NAAQS (73 FR 29265). NESCAUM recommends that if a monitor is less than 50 percent of the NAAQS, it should be eligible for a reduction of the sampling frequency from one-in-three days to one-in-six. This could be based on one year of data or a review of past data, if available. This reduction should only be allowed with the caveat that if any one monthly average is above 50 percent of the standard, then TSP must be used at that location until 12 months pass with no monthly average above 50 percent of the standard.

Lead Monitor Design

NESCAUM urges EPA to reassess and redesign the monitors used to implement the new lead NAAQS. The existing monitoring network was designed for the current standard, and no longer meets current needs. More research is needed to understand lead in the environment and to better assess and characterize sources and exposure scenarios. Different types of monitoring approaches are needed to match the various lead source types and conditions. EPA should take a source-based approach to developing the next lead monitoring network.

Ideally, for purposes of public health protection in the current NAAQS review cycle, PM in the size range including particles of over 10 micrometers (µm) (i.e., up to 40 or 50 µm aerodynamic diameter) is considered a better indicator for lead in air than PM-10. We realize, however, that it is not possible to develop a low-volume sampler that can effectively sample particles within this size range up to the 24 kilometer per hour windspeeds required by the FRM test method. At best, a low volume TSP sampler with a 15-20 µm aerodynamic diameter cutpoint might meet the FRM testing requirements. NESCAUM urges EPA to start developing this type of low volume sampler as soon as possible. There is ample information in the scientific literature, dating back to the late 1970's and as recent as 2005, on various inlet designs for larger particles. The new methodology should have a well-defined cut-point, no sensitivity to wind direction, and, to the extent possible, minimal influence of wind speed on the cut-point. The sample inlet should be able to be used with existing PM-10 low-volume FRM and Federal Equivalency Method (FEM) samplers to allow for automated (i.e., sequential) sampling. We suggest that the health effects research community be involved in determining what the characteristics of the inlet size fraction will be in any new low-volume TSP sampler.

A suggested approach would be to use the existing PM FRM sampler louvered inlet without any further size fractionation. The collection efficiency of this inlet has been characterized[3,4] and is commercially available from BGI, Incorporated.[5] This methodology would still have some dependence on wind speed and need a water trap, but would be an improvement over the existing high-volume TSP sampler that EPA proposes for the lead indicator sampling method.

EPA should review and evaluate research done to date that attempts to improve upon low-volume TSP sampler design. Examples include the inlet design concepts used in the Wide Range Aerosol Collector (WRAC),[6] and the PM-15 low-volume inlet developed by Wedding.[7,8]

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[3] Tolocka, M.P., Peters, T.M., Vanderpool, R.W., Chen, F.-L., Wiener, R.W. *On the Modification of the Low Flow-Rate PM10 Dichotomous Sampler Inlet*. Journal of Aerosol Science and Technology, Vol. 34, No. 5, May 2001, pp. 407-415. Free access at: http://www.informaworld.com/index/X8LUNWAPUGFGE007.pdf

[4] Kenny, L., Beaumont, G., Gudmundsson, A., Thorpe, A., Koch, W. *Aspiration and Sampling Efficiencies of the TSP and Louvered Particulate Matter Inlets*. J. Environ. Monit., 2005, 7, pp. 481-487. Free access at: http://www.rsc.org/delivery/_ArticleLinking/DisplayArticleForFree.cfm?doi=b419001g&JournalCode=EM and http://www.rsc.org/suppdata/EM/b4/b419001g/b419001g.pdf

[5] BGI, Incorporated is located in Waltham, MA. See part # PQTSP (http://bgiusa.com/aam/pq200.htm).

[6] Burton, R.M., Lundgren, D.A. *WRAC: a size selective sampler for large particles.* Journal of Aerosol Science and Technology, Vol. 6, No. 3, 1987, pp. 289-301. Free access at: http://www.informaworld.com/smpp/ftinterface~content=a778329299~fulltext=713240930

Given the current lead NAAQS implementation timeline, NESCAUM realizes that any new sampler development other than a simple modification of the PM-10 low-volume inlet would not be ready in time for September 2008 implementation. However, if sampler development commences soon, a more appropriate, practical, and fully characterized lead indicator sampling method could be ready for the next lead NAAQS review.

We further urge EPA to revise and update the wind tunnel testing protocols used for characterizing particle sampler inlets (53 CFR, subpart D). The existing protocol is more than two decades old, and must allow more modern methodology to be used in the testing process.

Lead Reduction Strategy

NESCAUM encourages EPA to develop and implement a national lead reduction strategy that addresses all sources of environmental lead, including but not limited to consumer products, metals recycling, steel production, lead acid battery disposal, aviation gasoline, tire weights, fishing lures, paint, and diesel lube oil. Such an approach would greatly assist states in their State Implementation Plan (SIP) development efforts for lead nonattainment areas, and speed the process for minimizing lead exposure nationwide. We also urge EPA to review the secondary lead smelter National Emission Standard for Hazardous Air Pollutants (NESHAP) to identify further reductions in lead that may be obtained through the residual risk program.

NESCAUM also encourages EPA to continue to support research to assist with the understanding of ambient air lead exposures. These areas in need of further research include: (1) air concentrations of lead near roadways; (2) air concentrations of lead near general aviation facilities; and (3) what causes the difference between the high-lead and low-lead cities in the Speciation Trends Network (STN) cities.

Lead Implementation

Based on statements in the ANPR and the consent decree under which the lead NAAQS review timeline was set, we expected to see, at a minimum, a draft implementation rule for the lead NAAQS along with the NAAQS proposal. In the NPR, however, EPA offers to the states a previous implementation rule and guidance documents that are over 10 years old. We urge EPA to develop an overall implementation approach, guidance, and an implementation rule that

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[7] Wedding, J. *Ambient Aerosol Sampling. History, Present Thinking, and a Proposed Inlet for Inhalable Particles.* Environ. Sci. Technol., Vol. 16, No. 3, 1982, pp. 154-161. Free access at: http://pubs.acs.org/cgi-bin/abstract.cgi/esthag/1982/16/i03/f-pdf/f_es00097a007.pdf

[8] Wedding et al., *Large Particle Collection Characteristics of Ambient Aerosol Samplers.* Environ. Sci Technol. Vol 11, No. 4, 1977, pp. 387-390. Free access at: http://pubs.acs.org/cgi-bin/abstract.cgi/esthag/1977/11/i04/f-pdf/f_es60127a005.pdf

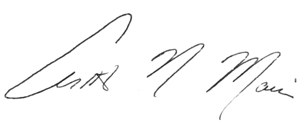
addresses the current challenges that are presented through current lead emissions and routes of exposure. The rules and guidance documents should reflect current technologies and reflect thoughtful choices on how to implement the lead NAAQS in order to protect public health. Such documents must be issued in very short order, in a timeframe sufficient for states to implement the lead NAAQS.

NAAQS Review Process

NESCAUM remains concerned about EPA's new NAAQS review process. In the NPR, EPA indicates that "[t]he substantial number of comments we received on the Pb NAAQS ANPR helped inform the narrower range of options we are proposing and taking comment on today." (73 FR 29189). EPA also indicates in the NPR that "the Agency has not developed formal responses to comments received on the ANPR…" (73 FR 29190) due to time constraints, and that "if commenters believe that comments on the ANPR are fully applicable to the proposal and wish to ensure that those comments are fully addressed by EPA as part of the final rulemaking, the earlier comments should be resubmitted during the comment period on this proposal."(73 FR 29190). In response, we are attaching our January 15, 2008 comments to EPA on the ANPR for reconsideration (see Appendix B). Our comments, particularly on the science, the health effects, and NAAQS review process, are timely and germane, and we would like to see EPA respond to them.

If you or your staff has any questions regarding the issues raised in this letter, please contact Leah Weiss of NESCAUM at 617-259-2094.

Sincerely,



Arthur N. Marin
Executive Director

Attachments:
Appendix A: Analyses for the Recommendation of a Revised Lead NAAQS
Appendix B: January 15, 2008 Letter from NESCAUM to U.S. EPA Docket ID No. EPA-HQ-OAR-2006-0735

Cc: NESCAUM Directors
Lydia Wegman, EPA/OAQPS
Deirdre Murphy, EPA/OAQPS
Mark Schmidt, EPA/OAQPS
Kevin Cavender, EPA/OAQPS
Larry Wallace, EPA/OAQPS
Tim Hanley, EPA/OAQPS
Lew Weinstock, EPA/OAQPS
Richard Wayland, EPA/OAQPS

APPENDIX A

These analyses provide the scientific rationale for the recommendation of a revised Pb NAAQS level of ≤0.15 ug/m^3 (2nd max monthly form). We agree with the Clean Air Scientific Advisory Committee (CASAC) determination that the revised Pb NAAQS should be substantially lowered. However, our comprehensive review of the available documents indicates that the CASAC suggested Pb NAAQS level of ≤0.2 ug/m^3 may be too high. The scientific evidence suggests that "significant" health effects (an IQ loss at the population level exceeding 1-2 IQ points as determined by CASAC) may occur below the level of 0.2 ug/m^3. As such, we are recommending a level of ≤0.15 ug/m^3 (2nd max monthly form).

In the March 27, 2007 CASAC letter to the Environmental Protection Agency (EPA) Administrator, the CASAC summarized three approaches to derive values for a revised Pb NAAQS. Approach A followed the process used during the 1978 Pb NAAQS review and in the World Health Organization (WHO) 2000 guidance documents. Essentially, a not-to-be-exceeded value of 5 ug/dl of blood Pb (the dose metric) was used as a starting point and reduced to a level of 2.5 ug/dl in order to be protective of 99.5 % of the population. The CDC screening level of 10 ug/dl blood Pb was deemed to be too high, as newer studies have shown that adverse health effects occur down to 5 ug/dl blood Pb. From the 2.5 ug/dl blood Pb, contributions from the non-air portion of exposure were subtracted out. This accounted for 1.4 ug/dl of the blood-Pb to arrive at a level of 1.1 ug/dl blood-Pb which then was divided by several potential slope factors representing the considered range of air-Pb to blood-Pb ratios. The air-to-blood ratio slope factor will be represented as follows: A:B # with the number indicating the increase in ug/dl blood Pb concentration per each incremental rise of 1 ug/m^3 air-Pb concentration. We determined that an A:B ratio in the range of 5 (used by the WHO) to 7 would be the most appropriate. An A:B 5 ratio would be the midpoint of the range suggested by the EPA and an A:B 7 ratio would be the midpoint between the WHO ratio and the A:B ratio derived by Schwartz and Pitcher from the correlation between the reduction in gasoline Pb and blood Pb or the upper end of the range suggested by the EPA. Both of these are within the A:B ratio range considered by the CASAC. Using the A:B ratio slope factor of 7 (the upper end of our recommended range) produces a corresponding NAAQS value of 0.157 ug/m^3.

Approach B calculates the level of the Pb NAAQS necessary to keep 99.5 % of children below a blood Pb of 5 ug/dl taking into account Pb contributions from all exposures, solely using the A:B ratio derived by Schwartz and Pitcher (1:9.1). We feel that both the lower end and this upper end of the range of considered A:B ratios (1:3 and 1:9-10, respectively) contain enough uncertainty associated with them to limit our range considered to 1:5 to 1:7. Even with the use of the upper end of the full A:B range (A:B 9.1), the CASAC derived NAAQS level from this approach was 0.11 ug/m^3. The use of the A:B ratio slope factor at the upper end of our considered range (A:B 7) indicates that a NAAQS of ≤0.15 ug/m^3 (2nd max monthly form) would be protective of public health.

Approach C relates airborne Pb to the adverse health effect of developmental neurotoxicity in children, with IQ decrement as the risk metric (determined to be the most sensitive endpoint). This approach again uses various options for potential A:B ratio slope factors resulting in a range in the suggested level for the revised NAAQS. We have already discussed our thoughts as to the most appropriate range for the A:B ratio slope in the previous paragraphs, so now we address the concentration/dose-response curve slope factor. The concentration/dose-response curve slope factor will be represented as follows: C-R # with the number indicating the downward shift in IQ points at a population level per each incremental increase of 1 ug/dl in blood Pb. While we agree that the Lanphear et al. 2005 study is among the stronger studies of IQ loss associated with low blood Pb levels, it is not the only study researching this relationship. Therefore, consideration of a range of C-R slope factors is more appropriate then to only use the highest overall C-R slope factor of -2.94 IQ points calculated from this dataset (using only the 103 children with blood Pb levels below the cutpoint of 7.5 ug/dl). Additionally, even within this one study, there have been a variety of different ways of analyzing the data which has provided different slope factor values. For example, a different analysis of this same dataset is listed in Table 1 of the NPR indicating a C-R -2.29 slope (at a blood Pb level of 2 ug/dl). Please also refer to the discussion in the EPA staff paper for more information on the concerns with using the C-R slope factor of -2.94 in the derivation of risk assessment values (pp 4-4 to 4-9). Given the CASAC's use of only the upper end of all the potential C-R slope factors, we are unsure how they even could have themselves recommended their upper limit for the range of potential levels to be 0.2 ug/m^3. Reviewing Table 1 of their March 27, 2007 letter, it indicates that using even the lowest potential A:B 5 ratio slope factor results in an IQ loss of 3.0 points, which is above what they considered to be a significant amount of IQ loss.

We followed the method used in the CASAC's A:B ratio slope factor determination by considering a range of values. An analysis of the tables in both the Criteria Document (CD) and the Notice of Proposed Rulemaking (NPR) representing the C-R slope factors for IQ loss follows. Table 8-7 of the CD indicates that even when a cutpoint of 10 ug/dl was used to determine the C-R slope at low blood Pb levels, the slope ranged from -0.4 IQ points to a high end of -1.8 IQ points. Table 1 of the NPR contains some of the same C-R slope factors but their range is from -0.4 IQ points to the -2.94 IQ points. We decided to use the available information to calculate our own C-R slope factor range to prevent a significant loss of IQ points as determined by the CASAC. A C-R slope factor of -1.31 IQ points was derived by averaging the C-R slope factors found in the variety of studies listed in Table 1 of the NPR and Table 8-7 of the CD. Only the C-R slope factors resulting from blood Pb levels < 10 ug/dl were used to represent the lower average blood Pb levels of today. If a study had its < 10 ug/dl subset analyzed more than once, the slope factor values were averaged together prior to being entered into the full list of slope factor values to then provide the final overall average. If, however, a study had at least one slope value in both the shallower and steeper slope categories, then both were entered into the final list. The Lanphaer 2005 study was unique in that it had more than one of these slope factor values in both the steeper slope and the shallower slope categories. Therefore, the two shallower slope values were averaged together and the two steeper slope values were averaged together before both averages were then entered into the full list of slope values to calculate the across-the-studies average. This process prevented any given study from contributing too large of an influence to the overall average calculated across studies. This derived value represented the lower end of our range. The upper end of our range was determined to be at a C-R slope factor of -1.8 IQ points from the Canfield et al. Rochester study, because this is the steepest individual C-R slope factor among all the studies analyzed in the Lanphaer et al. 2005 study and the highest C-R slope factor listed in Table 8-7 of the CD. While the two different ways of analyzing the Lanphaer et al. 2005 dataset discussed previously, resulting in C-R slope factors above our considered range, are included in Table 1 of the Notice of Proposed Rulemaking (NPR), our review indicates that the C-R slope factor of -1.8 IQ points is more appropriate as the upper end of the range considered. As discussed above, the Canfield et al. Rochester study is included in the Lanphaer et al. 2005 meta-analyses and has the steepest individual C-R curve of all the studies included. Also, as presented earlier, we have concerns with the use of the highest C-R slope factor of -2.94 IQ points calculated from the Lanphaer et al. 2005 study.

Therefore, we started with an airborne concentration level of 0.15 ug/m^3 and first applied the upper end of our considered range of A:B ratio slope factors of A:B 7 to derive a value of 1.05 ug/dl blood Pb. Then we applied the upper end of our considered range of C-R curve slope factors of C-R -1.8 to derive a total IQ loss of 1.89 IQ points. CASACs text referring to the significance of population IQ loss in this range reads as follows: "the primary lead standard should be set so as to protect 99.5% of the population from exceeding that IQ loss" (1-2 IQ points) (page 6 of CASAC's March 27, 2007 letter). Thus, using the highest ends of our considered A:B ratio and C-R curve slope factors still prevents a significant level of IQ loss at a population level as determined by CASAC (more than 2 IQ points). Using the high ends of the two slope factor ranges helps build in a margin of safety.

In conclusion, the analyses above following the framework provided by CASAC's three approaches in their March 27, 2007 letter indicate the recommended value of ≤0.15 ug/m^3 (2nd max monthly form) would be protective of public health with a margin of safety built in by using the highest ends of our considered slope factor ranges for both the A:B ratio and the C-R curve. In addition, CASAC stated in their March 27, 2007 letter that "These approaches consider existing information and the following assumptions: the population to be protected (99.5% of the population of children)".

Finally, Table 5-10 of the "Lead: Human Exposure and Health Risk Assessments for Selected Case Studies" (Risk Assessment) provides us additional justification for the recommended NAAQS level of ≤0.15 ug/m^3 (2nd max monthly form). This table summarizes the risk estimates for the 95th percentiles of exposure risk distributions and, using the Recent Air and LLL categories, indicates IQ losses of 1.3 IQ points and 2.2 IQ points for the Current Conditions category of the Chicago Location-specific and General urban Case Study and Air Quality Scenario, respectively. Both of these Current conditions are at an airborne concentration level of 0.14 ug/m^3 (max quarterly form). Because the max quarterly form and the 2nd max monthly form are similar in their resultant concentration values, our recommended ceiling level of 0.15 ug/m^3 (2nd max monthly form) for the Pb NAAQS would provide a similar level of public health protection as the 0.14 ug/m^3 (max quarterly form) NAAQS level. It has been determined by us and others that the LLL C-R function and the "Recent Air" Pb are the most appropriate to use. The recent air "refers to contributions from inhalation of ambient air Pb or ingestion of indoor dust Pb predicted to be associated with outdoor ambient air Pb levels, with outdoor ambient air also potentially including resuspended, previously deposited Pb". As indicated by Table 5-10 of the Risk Assessment, this NAAQS level is near the upper end of the levels required to prevent CASAC determined significant IQ losses at a population level (1.3 IQ points to 2.2 IQ points with an average of 1.75 IQ points).

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January 15, 2008

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Attention: Docket ID No. EPA-HQ-OAR-2006-0735

Re: *Advance Notice of Proposed Rulemaking – National Ambient Air Quality Standards for Lead*

Dear Administrator Johnson:

The Northeast States for Coordinated Air Use Management (NESCAUM) offer the following comments on the U.S. Environmental Protection Agency's (EPA's) Advance Notice of Proposed Rulemaking (ANPR), published on December 17, 2007 in the Federal Register, entitled *National Ambient Air Quality Standards for Lead* (72 FR 71488-71544). NESCAUM is the regional association of air pollution control agencies representing Connecticut, Maine, Massachusetts, New Hampshire, New Jersey, New York, Rhode Island, and Vermont.

Level and Form of the Lead NAAQS

NESCAUM agrees with the Clean Air Scientific Advisory Committee (CASAC) and the EPA Staff Paper that the current lead NAAQS does not protect public health with an adequate margin of safety. The lead NAAQS has not been revised since 1978 and the scientific evidence clearly documents adverse health effects occurring at concentrations substantially lower than the current standard. Furthermore, studies have found that adverse health effects occur in young children at much lower blood lead levels than recognized when the current standard was established. A threshold level at which no adverse health effects are observed has not been identified for lead. Despite significant decreases in ambient air lead concentrations and corresponding decreases in human blood-lead concentrations, lead exposure remains a public health concern. According to the CASAC, "data accumulated over the past three decades make it apparent that adverse health effects on both humans and other species appear at blood lead concentrations and environmental exposures well below those previously thought to pose important risks."[1] CASAC further states that "while airborne lead concentrations have been decreased throughout much of the United States, airborne lead remains a primary vehicle for movement of lead between different

[1] Letter to Stephen Johnson, EPA Administrator, from Rogene Henderson, CASAC Chair, EPA-CASAC-07-003, pp. 3-4 (March 27, 2007).

environmental compartments. While control of airborne lead is not sufficient by itself to control exposure to lead, it is an essential component of a successful control strategy."[2]

In the ANPR, the EPA requests comment on whether it is "appropriate" to revoke the NAAQS for lead or to remove lead from the list of criteria pollutants (72 FR 71542). The science indicates that lead needs not only to be retained as a criteria pollutant, but the NAAQS must also be substantially lowered from the current level in order to become protective of public health. NESCAUM urges that the EPA substantially lower the lead NAAQS, based on the scientific evidence outlined in the EPA Staff Paper and Risk Assessment and as supported unanimously by CASAC.

With respect to the form of the standard, shortening the averaging time from quarterly to monthly for determining compliance with the NAAQS is appropriate. This provides an averaging time that is closer to the critical exposure periods for children, as blood lead concentrations respond at shorter time scales than are captured by quarterly values.

Role of CDC's "Advisory" Level
The ANPR requests comment on the use of the Centers for Disease Control's (CDC's) "advisory level," i.e., the elevated blood lead level (BLL), of 10 µg/dL as the foundation for deriving the primary lead NAAQS (72 FR 71529). NESCAUM does not support the use of the current CDC BLL as a basis for the lead NAAQS. Using the CDC's BLL would not be in keeping with the law as it was not set according to the Clean Air Act legal requirement the EPA must follow of protecting public health with an adequate margin of safety. The CDC does not consider its BLL to be a safe blood lead level or even one without evidence of adverse effects. The CDC acknowledges that this is a remedial screening level that is used to identify children with elevated blood lead levels in order to target follow-up activities to reduce their lead exposures.

In addition, the EPA, CASAC, and CDC have determined that at BLLs below 10 µg/dL, there is an inverse relationship between BLL and cognitive function in children. A CDC expert panel reviewing the epidemiology literature on blood lead and childhood cognitive function determined that this conclusion was supported by the overall weight of evidence.[3] It also concluded that the evidence indicates a steeper slope in the dose-response relationship between BLL and IQ as the BLL decreases below 10µg/dL. The CDC panel also concluded that the observed associations between BLL and cognitive decrements below 10 µg/dL are caused, at least in part, by lead toxicity, although the strength and shape of the causal relationship is uncertain due to data limitations.

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[2] Letter to Stephen Johnson, EPA Administrator, from Rogene Henderson, CASAC Chair, EPA-CASAC-07-003, p. 4 (March 27, 2007).
[3] Centers for Disease Control and Prevention. 2005. Preventing lead poisoning in young children. Appendix: A review of evidence of adverse health effects associated with blood lead levels < 10 µg/dL in children. Atlanta: CDC. Available online at http://www.cdc.gov/nceh/lead/publications/pub_Reas.htm (accessed Jan. 15, 2008).

On its web site, the CDC explains that even though there are recent studies reporting adverse health effects at lower blood lead levels, it retained the 10µg/dL BLL due to difficulty in treatment and testing at lower levels, not because of no known health effects. Therefore, the BLL is based on practicality of treatment, not on observed health effects, at or below the 10 µg/dL level. While the CDC didn't lower its BLL, it stated that the recent studies "support making primary prevention of childhood lead poisoning a high priority for health, housing, and environmental agencies at the state, local, and federal levels."[4] This is a clear call by the CDC for measures that go beyond the purpose of its BLL and encompass the health protection requirements of a NAAQS set according the Clean Air Act.

The EPA has previously recognized that adverse health effects related to lead exposures have been documented at concentrations below 10 µg/dL. The EPA's Criteria Document states that the currently available health data "includes assessment of new evidence substantiating risks of deleterious effects on certain health endpoints being induced by distinctly lower than previously demonstrated lead exposures indexed by blood-lead levels extending well below 10 µg/dL in children and/or adults." Moreover, the dose-response relationship between blood lead concentrations and IQ in children supports the health benefits that will result from lowering ambient lead concentrations.

Because of the different purposes and legal requirements described above, the EPA's inclusion of CDC's BLL as a potential basis for the primary lead NAAQS in the ANPR is inappropriate. Adopting such an approach would be contrary to the law, scientifically unjustified, and not protective of public health.

NAAQS Review Process

NESCAUM is disappointed in the quality of this ANPR, and is very concerned about future NAAQS review processes if subsequent ANPRs follow this approach. While the EPA Staff Paper is clearly written, thoroughly documented, and provides the cornerstone of review in the NAAQS process, the ANPR lacks the same scientific rigor and is unable to stand alone as a document for policy recommendations. Basic scientific information is missing from the ANPR that is crucial in order to provide public comment. For example, the ANPR does not present specific scientific bases for supporting various potential revised NAAQS levels. On the other hand, it provides an extremely broad range of policy options, including those that are not supported by the science and/or have no attribution. As such, the ANPR has the flavor of a survey of policy options, rather than as a more informative science-based document that tells the public how the EPA intends to use the science for NAAQS rulemaking. It also fails to serve as a useful vehicle for soliciting relevant new information to inform that rulemaking.

[4] Centers for Disease Control and Prevention, http://www.cdc.gov/nceh/lead/faq/changebll.htm (accessed Jan. 14, 2008).

The weakness of this lead ANPR underscores the importance of the science-based EPA Staff Paper. Without access to the EPA Staff Paper, it would have been difficult for NESCAUM to develop its comments. Because there is a clear and compelling need for it, NESCAUM strongly supports retaining the EPA Staff Paper for subsequent NAAQS review processes. If the EPA proceeds in future NAAQS reviews with ANPRs as scientifically weak as this one, and further omits a science-based Staff Paper, subsequent NAAQS reviews will lack credibility.

Monitoring and Network Design

As noted in the CASAC's September 27, 2007 letter to the EPA, the existing lead TSP high volume Federal Reference Method (FRM) is an outdated sampling method with a poorly defined and highly variable size cut. A review of the monitoring requirements for lead is well overdue. NESCAUM recognizes that developing a new FRM within the existing NAAQS revision schedule is not possible. Any new monitoring method should be critically evaluated in order to provide a monitoring network that ensures the protection of public health. At minimum, the EPA should conduct research on the relationship between PM-10 and TSP and/or on the feasibility of a new TSP method. NESCAUM further encourages the EPA to consider an alternative Federal Equivalent Method sampling technology if the EPA chooses not to change or propose a revised lead FRM.

When the EPA proposes its monitoring method, it should include both the analytical methods appropriate to the sampling media, such as Inductively Coupled Plasma Mass Spectroscopy (ICPMS) or X-ray Fluorescence (XRF), as well as the sampling instrumentation.

If the EPA chooses to retain the high volume TSP method, it must specifically consider sampler height, as this parameter is especially important for lead monitoring. The spatial scale of lead sampling is in part determined by the height of the sampler inlet above ground. The EPA's current vertical siting requirements need to be tightened, with a higher minimum and lower maximum height above ground.

NESCAUM plans to provide further comment on the EPA's proposed monitoring method when it is published in the forthcoming proposed rulemaking.

Mobile Source Exposures

The EPA acknowledges there are very limited data addressing vulnerable subpopulations in areas of potentially increased lead exposure. This lack of information is in part due to the limited size and spatial coverage of the present lead monitoring network and a poor correlation between monitoring locations and proximity of the largest lead sources. In this regard, NESCAUM notes that the EPA's exposure and risk assessment identifies combustion of leaded aviation gasoline as the single largest category of lead emissions in the United States. Further, the EPA Staff Paper acknowledges that there are no lead monitoring network sites within a mile of any of the general aviation facilities where leaded aviation gasoline is in use.

In a parallel action (EPA-HQ-OAR-2007-0294), the EPA is soliciting comments on a petition submitted by Friends of the Earth that requests the EPA to regulate the lead content of aviation gasoline. The topics for which the EPA solicits comments include information on lead concentrations in the environment around airports and levels of human exposure; the same issues for which the EPA generally acknowledges in this ANPR that there is a serious lack of information available.

In tandem with addressing the form and level of a new NAAQS for lead, NESCAUM requests that the EPA ensure that the monitoring network will be designed to provide data to facilitate a more reliable characterization of human exposure and risk from the use of aviation gasoline and from other significant lead emission sources.

Planning Impacts

The EPA is under a court order to complete "[a]ll tasks necessary for implementation…on or before September 1, 2008."[5] Any revision to the lead NAAQS will trigger numerous activities for the states. In addition to designing and implementing a new monitoring network and gathering data sufficient for making designations, states will need to develop a State Implementation Plan-quality inventory to assist in determining any control measures that may be needed. The EPA must begin planning for such activities now, particularly with respect to inventories and an implementation rule. NESCAUM expects that the EPA, in its Notice of Proposed Rulemaking, will provide appropriate draft documents with respect to anticipated planning and implementation requirements.

If you or your staff has any questions regarding the issues raised in this letter, please contact Leah Weiss of NESCAUM at 617-259-2094.

Sincerely,

Executive Director

Cc: NESCAUM Directors
Lydia Wegman, EPA, OAQPS
Deirdre Murphy, EPA, OAQPS

[5] *Missouri Coalition for the Env't v. U.S. EPA*, Memorandum and Order, Case No. 4:04CV00660 ERW (E.D. Mo. Sept. 14, 2005).