UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON D.C. 20460

OFFICE OF THE ADMINISTRATOR
SCIENCE ADVISORY BOARD

July 18, 2008

EPA-CASAC-08-016

The Honorable Stephen L. Johnson
Administrator
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, D.C. 20460

Subject: Clean Air Scientific Advisory Committee (CASAC) Comments and Recommendations Concerning the Proposed Rule for the Revision of the National Ambient Air Quality Standards (NAAQS) for Lead

Dear Administrator Johnson:

The Clean Air Scientific Advisory Committee (CASAC), augmented by subject-matter-expert Panelists — collectively referred to as the CASAC Lead Review Panel (CASAC Panel) — met via a public teleconference on June 9, 2008. The purpose of this conference call meeting was to hold discussions and provide comments concerning the Environmental Protection Agency's (EPA) Proposed Rule for the Revision of the National Ambient Air Quality Standards (NAAQS) for Lead (40 CFR Parts 50, 51, 53 & 58), which the Agency released on May 1, 2008, and which was published in the *Federal Register* on May 20, 2008 (73 FR 29184–29291). The CASAC Panel held a subsequent public teleconference meeting on July 8, 2008 to discuss, and for the chartered CASAC to approve, the draft letter (dated June 30, 2008) containing our comments and recommendations. The CASAC Panel roster is enclosed.

While the CASAC is pleased that the Agency has recommended substantially lowering the allowable air concentration (*i.e.*, the level of the NAAQS) for lead in ambient air — which has not been revised since 1978 — the CASAC has several critical concerns vis-à-vis the Notice of Proposed Rulemaking (NPR), including:

- ongoing problems with respect to the implementation of EPA's revised NAAQS review process;
- the last-minute introduction of a new analytical framework — *i.e.*, the "Air-related IQ Loss Evidence-based Framework" — as the *basis* for setting the primary (human-health based) Lead NAAQS — a framework that was not previously presented for review by the CASAC or the public and also apparently excludes other analyses that had been produced to date by the Agency and subject to such external review;

- the Agency's consideration of values for certain critical parameters (*e.g.*, the air-to-blood ratio and the slope of the concentration-response function curve) in this analytical framework that are contrary to those recommended by the CASAC, and that would justify a significantly-higher level for the primary Lead NAAQS than the CASAC recommended — at the expense of the values for those selfsame parameters that the CASAC documented as being most relevant for the low levels of blood lead (Pb) found in U.S. children today;

- the misrepresentation of the CASAC's statement that "the primary lead standard should be set so as to protect 99.5 % of the population from exceeding an IQ loss of 1-2 points" to wrongfully suggest that CASAC declared that an *average* loss of one to two IQ points in the population was an acceptable public-health endpoint; and

- the Agency's proposal of a range for the level of the primary standard that includes an upper bound (*i.e.*, 0.3 $\mu g/m^3$) which is higher — and therefore less health-protective — than that recommended in the final EPA Staff Paper and by the CASAC in any of its previous letters to you on this subject.

The following paragraphs describe in detail these and other concerns that the CASAC identified in the Agency's proposed rule for the revision of Lead NAAQS and, where applicable, reiterate the scientific basis for the CASAC's previous recommendations.

Implementation of Agency's Revised NAAQS Review Process

Before commenting on the substance of the NPR, the members of the chartered (statutory) CASAC wish to note that they are extremely, and increasingly, concerned about the lack of a reliable, standard "roadmap" for the implementation of the new NAAQS review process, as starkly illustrated by the content of this NPR. With the introduction of any new process, of course, it is essential that such a "path forward" be clearly delineated and followed from the outset. However, CASAC members cannot overstate how dissatisfying it has been to observe the introduction of the Agency's revised process for reviewing the NAAQS — especially in the middle of the current review of the Lead NAAQS — without any discernible, well-organized plan.

As a significant example of the root cause of the CASAC's frustration, we noted in our January 23, 2008 letter on this subject (EPA-CASAC-08-008) that, in the memorandum from EPA Deputy Administrator Marcus Peacock dated December 7, 2006, the Agency stated the new process would include a true *policy assessment* that reflects the views of EPA management — to be published in the *Federal Register* as an advance notice of proposed rulemaking (ANPR) — that would "describe a range of options for standard setting, in terms of indicators, averaging times, [statistical] form, and ranges of levels for any alternative standards," along with the underlying scientific justification and supporting data and analyses for each of these." The Deputy Administrator's memo goes on to state that such a policy assessment would "help … 'bridge the gap' between the Agency's scientific assessment and the judgments required of the Administrator in determining whether it is appropriate to retain or revise the standards." Therefore, the CASAC was surprised to read in the NPR that, "in analyses *subsequent to* the Staff Paper and ANPR, the Agency has *primarily* considered the evidence in the context of an

alternative evidence-based framework'' (73 FR 29238, italics not in original) — that is, the aforementioned "air-related IQ loss framework." While it is entirely reasonable to expect that the policy assessment contemplated by the Deputy Administrator's December 2006 memo would *include* such an "evidence-based" analytical framework, the CASAC notes with dismay that *this alternative framework is not found in the Lead Staff Paper, the Lead Risk Assessment or the ANPR for the Lead NAAQS.*

Therefore, the CASAC is led to conclude that the ostensible scientific basis for standard-setting that had been previously presented for rigorous review by the CASAC and the public was substituted at the last minute for an "alternative" analytical framework that EPA plainly notes was their *primary consideration* as the basis for the proposed rule for the Lead NAAQS. At a minimum, the manner in which this process is being implemented suggests that the Agency is "winging it" in an *ad hoc*, rather than a systematic, manner. This is not what the public expects of their EPA.

Finally, the CASAC notes with disappointment that, to date, there has been no response from the Agency to our January 23, 2008 letter. In that letter, the CASAC complimented certain features of the new NAAQS process (*e.g.*, the "kick-off" science workshop and the integrated science assessment. However, the CASAC also requested a modification of other aspects of the revised process (such as the absence of a meaningful policy assessment discussed above) that appear to be ever-shifting and that tend to conceal the Agency's underlying scientific analyses from its own, statutorily-mandated scientific advisory body.

Introduction of New Air-Related IQ Loss Evidence-based Framework

By the Agency's own acknowledgment, as noted above, the analyses that led to the proposed range for the standard, especially the upper bound of 0.3 $\mu g/m^3$ (and possibly extending as high as 0.5 $\mu g/m^3$), are based primarily on consideration of the evidence found "in the context of an alternative evidence-based framework" resulting from analyses conducted subsequent to the release of the Final Lead Staff Paper (November 1, 2007) and the ANPR for the Lead NAAQS (December 17, 2007) — that is, the evidence in a single new meta-analysis, entitled the "Air-related IQ Loss Evidence-based Framework." The following comments are focused primarily on this new analytical framework:

1. **Timing:** In the professional judgment of the CASAC, *the issuance of the NPR is far too late a point in the regulatory process to introduce a set of new and apparently determinative risk calculations.* The CASAC notes that the Agency's stated intent is that this evidence-based framework "builds on a recommendation by the CASAC Pb Panel" (73 FR 29237). The CASAC infers that this recommendation stems from the information contained in Appendix D of the CASAC's letter of March 27, 2007 (EPA-CASAC-07-003) concerning its review of the 1st Draft Lead Staff Paper (December 2006) and the Draft Lead Exposure and Risk Assessments (December 2006). The CASAC included Appendix D in its letter in order to provide the Agency with several population-based risk assessment analyses for the primary Lead NAAQS. However, the CASAC questions why EPA's analyses reflected in this "Air-related IQ Loss Evidence-based Framework" were not explicitly presented to the CASAC much sooner, either as part of the Agency's 2nd Draft Lead Human Exposure and Health Risk Assessments (July 2007), the Final Lead Risk Assessment (November 2007), or the Final

Lead Staff Paper (November 2007) — or, at the very least, aired for open review by the CASAC and the public in the ANPR (December 2007). Instead, at this very late stage in the rulemaking process, we are presented with a set of heretofore unseen quantitative analyses — an unfortunate scenario that, by definition, precludes an in-depth, thoughtful deliberation by the CASAC. Our objections to these analyses are noted in detail below. Moreover, there is considerable concern that this might be an example of EPA's "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 set aside, with this single new meta-analysis used as the exclusive basis for the proposed NAAQS level. The range of proposed standards appears to be predominantly driven by alternative — and, in the CASAC's judgment, unwarranted — assumptions of the appropriate concentration-response (C-R) functions 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 Lead NAAQS. *Significantly, the CASAC notes that, aside from this new "air-related IQ loss evidence-based framework," no other analyses are presented that support a level as high as 0.3 (or 0.5) µg/m^3.*

3. **Air Pb-to-blood Pb ratios:** The analytical results are constrained to an assumed range of air-to-blood ratios of 1:3 to 1:7, which is described as being consistent "with the results and observations drawn from the exposure assessment, including related uncertainties" (73 FR 29197). But this is only true if one: (1) discards the many estimated ratios that fall above this range; (2) ignores the clear indications that the air Pb to blood Pb ratio *increases* as both air Pb and blood Pb *decrease*; and (3) assumes that the related "uncertainties" are directionally-biased and somehow justify the use of lower ratios that are more representative of the much *higher* air Pb and blood Pb levels found in the U.S. in the 1970s and 80s. By contrast, EPA's Final Lead 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" (p. 5-17) — that is, *not* 1:3 to 1:7.

Even from EPA's 1986 Air Quality Criteria Document (AQCD) for Lead, the analysis cited as Brunekreef *et al.* (*J. Air Pollut. Control Assoc.* 1983; 33: 872-876) indicated an air-to-blood ratio of 1:8.5. The Schwartz and Pitcher analyses (Schwartz, J., Pitcher, H., *J. Official Stat.* 1989; 5(4): 421-431) suggest a ratio of 1:9 or 1:10. Additionally, results from Hayes *et al.* (*Pediatrics* 1994; 93:195–200) suggested a range from about 1:6 (at high air Pb levels near 1 µg/m^3) to 1:16 (at ambient air Pb of about 0.25 µg/m^3 — which are within the range currently being considered for the Lead NAAQS). In EPA's Final Lead Risk 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" (73 FR 29197), although it later notes (73 FR 29215) 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 lead exposure pathways are considered.

The NPR states (73 FR 29197), "For the general urban case study, air-to-blood ratios ranged from 1:2 to 1:9…. [and] this pattern of model-derived ratios generally support the range of ratios obtained from the literature and also supports the observation that lower ambient air Pb levels are associated with [a] higher air-to-blood ratio." As several CASAC Panel members noted in their individual written comments attached to the CASAC's March 27, 2007 letter (EPA-CASAC-07-003), the best documented evidence for the blood-to-air ratio under current conditions is based on actual epidemiology data showing that declines in U.S. national blood Pb levels from the National Health and Nutrition Examination Survey (NHANES) surveys tracked declines in EPA- and state-monitored air Pb levels over the same time period and the air-to-blood ratio was 1:10. Given that there is agreement that the *lower* the current air Pb levels the *higher* the air-to-blood ratio, *the CASAC recommends that the Agency use an air-to-blood ratio closer to 1:9 or 1:10 as being most reflective of current conditions*.

4. **C-R Functions:** The critical concentration-response 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 of the NPR (73 FR 29203), the analysis identifies two groups of C-R functions — one with *steeper* slopes (ranging from -1.71 to -2.94 IQ points per µg/dl blood Pb) and one with *shallower* slopes (ranging from -0.4 to -1.79 IQ points per µg/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" (73 FR 29239). *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 Pb concentrations and exhibiting much higher blood Pb levels than is appropriate for current U.S. populations and the levels under consideration for a revised Lead NAAQS.*

For example, the median blood Pb level for children one to five (1-5) 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 blood Pb level was 3.5 µg/dl. However, all eight of the "shallow slope" C-R functions presented in Table 1 had geometric mean blood Pb levels (indicated as "BLL" in Table 1) greater than 3.3 µg/dl, and the four studies with slopes below the median value of -0.9 IQ points/µg/dl BLL had geometric mean blood levels ranging between 4.3 and 9.7 µg/dl. Within the shallow-slope group, the only studies with geometric mean BLLs less than 4 µg/dl (which were the only studies in that group based entirely on U.S. 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 Pb 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 blood Pb level population subsets of larger population studies), the NPR (73 FR 29209) 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" (73 FR 29209). Therefore, the NPR admits that the slope of the C-R functions steepens at lower concentration and also concedes that this is more reflective of the current blood Pb levels. However, the NPR then concludes that limiting the C-R analysis to this range of blood Pb levels would introduce "bias." This vague statement is not only completely unscientific (since any assertion of "bias" should be accompanied by a demonstration of why that is the case and include appropriate references), it is also *at best a specious argument, since we are indeed concerned with current blood Pb levels in the setting of a health-protective NAAQS, not with blood Pb levels of the past.*

Furthermore, the CASAC rejects the suggestion that the existence of "a larger set of studies" (73 FR 29238) indicating C-R functions with shallower slopes is scientifically-relevant for choosing the most appropriate C-R functions for risk analyses. Rather, the selection of C-R function should be based on determining which studies indicate slopes that best reflect the current, lower blood Pb levels for children in the U.S. — which, in this instance, are those studies from which *steeper* slopes are drawn.

In turn, the CASAC notes that three additional studies have recently been published that confirm the steep slope at the lowest blood lead concentrations (Surkan *et al.*, *NeuroToxicology* 2007; 28:1170–1177; Solon *et al.*, *J Pediatr* 2008; 152:237–43; and Jusko *et al.*, *Environ Health Perspect* 2008; 116:243–248, the last of which is a follow-up of the cohort first described in Canfield *et al.*, *New Engl J Med* 2003; 348:1517–26).

5. **Target IQ Decrements:** The air-related IQ loss framework proposes a target mean IQ decrement of roughly one to two (1-2) points in the population as a level of damage that the proposed standard is intended to protect against. This target level has been erroneously attributed as being the CASAC's recommendation. The use of this target level is inappropriate for several reasons. First, in the CASAC's letter dated March 27, 2007 (EPA-CASAC-07-003) from its review of the Agency's 1st Draft Lead Staff Paper and Draft Lead Exposure and Risk Assessments, the CASAC wrote that "*the CASAC Lead Review Panel considers that a population loss of 1-2 IQ points is highly significant from a public health perspective. Therefore, the primary lead standard should be set so as to protect 99.5% of the population from exceeding that IQ loss*" (italics in original).

The CASAC wishes to emphasize that this comment refers to 1-2 IQ points as being a "highly significant" loss to be *prevented — not* as a desired national damage level goal that a standard should be set to assure. The CASAC also notes that the recommendation is that IQ decrements as large as this should be prevented in all but a small percentile of the population — and certainly not accepted as a reasonable change in *mean* IQ scores across the entire population. *Indeed, if a loss of one 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 proposed 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 U.S. ambient air and blood lead concentrations.* However, by combining the *lowest* air-to-blood Pb ratios (1:3), the *shallowest* C-R slope (-0.9) and a *higher-than-acceptable* IQ decrement endpoint (>1 IQ point), *the NPR subsequently, even*

shockingly, goes on to suggest (73 FR 29244) that a standard as high as 0.5 µg/m^3 would somehow be adequate to protect public health — while failing to point-out that, at the higher air-to-blood ratios and steeper C-R slopes more representative of current U.S. exposures, this contemplated level of the standard would allow mean losses of five (5) IQ points or more.

Level of the Primary Lead Standard

As noted above, the proposed upper-bound level of 0.3 µg/m^3 for the revised Lead NAAQS lies above the upper bound of levels recommended by both EPA Staff and by the CASAC Panel. The NPR indicates (73 FR 29190) 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 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 µg/m^3 or less…" (73 FR 29241). (For the CASAC's previous advice to the Agency concerning this CASAC-recommended level of the Lead NAAQS, see our letters dated March 27, 2007 [EPA-CASAC-07-003, p. 6 & Appendix D]; September 27, 2007 [EPA-CASAC-07-007, p. 2]; and January 22, 2008 [EPA-CASAC-08-007, pp. 2, 5].) Accordingly, since the overwhelming majority of public comments, the recommendations in the EPA Staff Paper and underlying risk and exposure analyses, and the CASAC Panel's unanimous recommendations advocated a maximum level of 0.2 µg/m^3 or less, it is not clear either where this proposal for a *higher* (that is, less stringent) level of 0.3 µg/m^3 level for the primary Lead NAAQS originated (*i.e.*, on what scientific basis) or why it is necessary at this late stage in the rulemaking process to seek additional public comment on levels for the Lead NAAQS ranging as high as 0.5 µg/m^3.

Lead NAAQS Indicator

In several rounds of previous comments, the CASAC Panel recommended that a revised (and substantially-lowered) Lead NAAQS should be accompanied by a transition of the sampling indicator from total suspended particulates (TSP) to a low-volume ambient air monitor for lead in particulate matter (PM) less than 10 micrometers in diameter (PM_{10}) in ambient air. In the CASAC's advice dated January 22, 2008 (EPA-CASAC-08-007), the CASAC noted that the CASAC 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," adding that "a more accurate and precise Pb-PM_{10} indicator would provide a more stable determination of compliance with the new lower Lead NAAQS." With regard to concerns over a potential loss of ultra-coarse lead particles by PM_{10} samplers, the CASAC 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 Lead NAAQS." In a subsequent teleconference consultation by the CASAC Ambient Air Monitoring and Methods (AAMM) Subcommittee held on March 25, 2008, a majority of the subcommittee members also supported a transition from TSP to low-volume PM_{10} sampling for lead (see EPA-CASAC-08-010 dated April 14, 2008).

The CASAC needs to call attention to the fact that these recommendations were based, in part, on an *assumption* that the level of the primary Lead 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 lead 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-two difference is small compared to the factor of 10 to 100 of the recommended lowering 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 with the publication of this proposed rule for the revision of the Lead NAAQS the Agency now appears to disagree with previous staff recommendations — as well as those of the CASAC and the "overwhelming majority" of the public — 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 health protection afforded at the level of the standard that the CASAC proposed. *Significantly, a particulate (PM_{10}) Lead 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.* Therefore, if the level of the standard is set toward the upper end of the range the Agency is now considering, the CASAC is unanimous in its recommendation that the current TSP indicator should *not* be changed. As previously recommended, a transition to a PM_{10} indicator would be preferable, but only at a level conservatively below an upper bound of 0.2 $\mu g/m^3$ or lower.

Lead NAAQS Averaging Time and Form

The NPR proposes consideration of a monthly averaging time with a "second highest month in three years" form, but also seeks comment on retaining the current "calendar" quarter "not to be exceeded" form. The CASAC wishes to emphasize that there is no logic for averaging only by "calendar" quarter, as there is nothing unique about effects that may occur exclusively during the four calendar seasons. A "rolling" three-month (or 90-day) average would be more logical than a "calendar" quarter. The CASAC's previous recommendations — both in the current review cycle and during the prior review of the Lead NAAQS conducted in the 1980s — advocated reducing the averaging time of the Lead NAAQS from "calendar" quarter to monthly, with the rationale that adverse effects could result from exposures over as few as 30 days' duration. A monthly or "rolling" 30-day averaging time with a "not to be exceeded" form would be more protective against adverse short-term effects than a form (such as a "second-highest month in three years") that periodically allows a month of exposures to much higher concentrations.

Zero Level for the Lead NAAQS

The NPR has raised the question of the feasibility of a Lead NAAQS of "zero." While it would not be practical to set an enforceable primary Lead NAAQS of zero, it is both entirely

appropriate and indeed very important that we as a Nation have the goal of reducing exposure of our children to lead to as close to zero as feasible. The reasons for this are numerous, and include: (1) lead is an apparent non-threshold neurotoxicant that reduces cognitive abilities in children (that is, by directly affecting children's IQ loss) so that the smaller the amount of Pb in air and from other sources of lead, the smaller the blood Pb and associated IQ loss; (2) such neurotoxic effects of lead as IQ loss appear to be persistent and may be irreversible; and (3) the environmental reality for childhood lead exposures is that these exposures often occur concurrently with exposures to mixtures of other neurotoxicants, with these multiple exposures producing an additive neurotoxicity over that for lead alone. Nonetheless, consistent with the CASAC's previous advice in this current review cycle for the Lead NAAQS, the CASAC continues to believe that the level of the primary Lead standard unanimously recommended by the CASAC — *i.e.*, an upper bound for the primary Lead NAAQS of *no higher than 0.2 µg/m^3* — is necessary to provide an adequate margin of safety for the protection of human health, including susceptible subpopulations such as children, as explicitly required by the Clean Air Act for primary NAAQS.

The CASAC stands ready to assist you by advising the Agency concerning the scientific basis on which to base your scientific policy judgments, as EPA Administrator, in setting the NAAQS. It is our sincere desire and goal to work more closely and effectively with the Agency in the future. As always, the members of the CASAC wish EPA well in our vital — and, as previously stated, our mutual — efforts to protect both human health and the environment.

Sincerely,

/Signed/

Dr. Rogene F. Henderson, Chair
Clean Air Scientific Advisory Committee

Enclosure

NOTICE

This report has been written as part of the activities of the U.S. Environmental Protection Agency's (EPA) Clean Air Scientific Advisory Committee (CASAC), an independent Federal advisory committee administratively-located under the EPA Science Advisory Board (SAB) Staff Office that is chartered to provide extramural scientific information and advice to the Administrator and other officials of the EPA. The CASAC is structured to provide balanced, expert assessment of scientific matters related to issue and problems facing the Agency. This report has not been reviewed for approval by the Agency and, hence, the contents of this report do not necessarily represent the views and policies of the EPA, nor of other agencies in the Executive Branch of the Federal government, nor does mention of trade names or commercial products constitute a recommendation for use. CASAC reports are posted on the EPA Web site at: http://www.epa.gov/casac.

U.S. Environmental Protection Agency
Clean Air Scientific Advisory Committee (CASAC)
CASAC Lead Review Panel

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*Dr. Luoma did not participate in the June 9, 2008 or the July 8, 2008 public teleconferences or the CASAC's advisory activity to provide comments on the NPR.