



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
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OFFICE OF THE ADMINISTRATOR
SCIENCE ADVISORY BOARD

July xx, 2008

EPA-CASAC-08-xxx

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

Subject: Clean Air Scientific Advisory Committee (CASAC) 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 (Lead 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 EPA’s 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 Lead Panel roster is attached as Appendix A.

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 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 frame-

1 work that are contrary to those recommended by the CASAC, and that would justify a
2 significantly-higher level for the primary lead (Pb) NAAQS than the Clean Air Scientific
3 Advisory Committee recommended — at the expense of the values for those selfsame pa-
4 rameters that the CASAC documented as being most relevant for the low levels of blood
5 lead (Pb-B) found in U.S. children today;

- 6 • the misrepresentation of the CASAC’s statement that “the primary lead standard should
7 be set so as to protect 99.5 % of the population from exceeding an IQ loss of 1-2 points”
8 to wrongfully suggest that CASAC declared that an *average* loss of one to two IQ points
9 in the population was an acceptable public-health endpoint; and
- 10 • the Agency’s proposal of a range for the level of the standard that includes an upper
11 bound (*i.e.*, 0.3 µg/m³) which is higher — and therefore less health-protective — than
12 that recommended in the final EPA Staff Paper and by the CASAC in any of its previous
13 letters to you on this subject.

14
15 The following paragraphs describe in detail these and other concerns that the Clean Air
16 Scientific Advisory Committee identified in the Agency’s proposed rule for the revision of Lead
17 NAAQS and, where applicable, reiterate the scientific basis for the previous recommendations
18 from the CASAC.

19 20 **Implementation of Agency’s Revised NAAQS Review Process**

21 Before commenting on the substance of the NPR, the members of the chartered (statu-
22 tory) CASAC wish to note that they are extremely, and increasingly, concerned about the lack of
23 a reliable, standard “roadmap” for the implementation of the new NAAQS review process, as
24 starkly illustrated by the content of this NPR. With the introduction of any new process, of
25 course, it is essential that such a “path forward” be clearly delineated and followed from the out-
26 set. However, CASAC members cannot overstate how dissatisfying it has been to observe the
27 introduction of the Agency’s revised process for reviewing the NAAQS — especially in the
28 middle of the current review of the Pb NAAQS — without any discernible, well-organized plan.
29

30 As a significant example of the root cause of the CASAC’s frustration, we noted in our
31 January 23, 2008 letter on this subject (EPA-CASAC-08-008) that, in the memorandum from
32 EPA Deputy Administrator Marcus Peacock dated December 7, 2006, the Agency stated the new
33 process would include a true *policy assessment* that reflects the views of EPA management — to
34 be published in the *Federal Register* as an advance notice of proposed rulemaking (ANPR) —
35 that would “describe a range of options for standard setting, in terms of indicators, averaging
36 times, [statistical] form, and ranges of levels for any alternative standards,” along with the under-
37 lying scientific justification and supporting data and analyses for each of these.” The Deputy
38 Administrator’s memo goes on to state that such a policy assessment would “help ... ‘bridge the
39 gap’ between the Agency’s scientific assessment and the judgments required of the Administra-
40 tor in determining whether it is appropriate to retain or revise the standards.” Therefore, the
41 CASAC was surprised to read in the NPR that, “in analyses *subsequent* to the Staff Paper and
42 ANPR, the Agency has *primarily* considered the evidence in the context of an *alternative* evi-
43 dence-based framework” (73 FR 29238, emphasis added) — that is, the aforementioned “air-
44 related IQ loss framework.” While it is entirely reasonable to expect that the policy assessment

1 contemplated by the Deputy Administrator’s December 2006 memo would *include* such an “evi-
2 dence-based” analytical framework, the CASAC notes with dismay that *this alternative frame-*
3 *work is not found in the Lead Staff Paper, the Lead Risk Assessment or the ANPR for the Lead*
4 *NAAQS.*

5
6 Therefore, the CASAC is led to conclude that the ostensible scientific basis for standard-
7 setting that had been previously presented for rigorous review by the CASAC and the public was
8 substituted at the last minute for an “alternative” analytical framework that EPA plainly notes
9 was their *primary consideration* as the basis for the proposed rule for the Lead NAAQS. At a
10 minimum, the manner in which this process is being implemented suggests that the Agency is
11 “winging it” in an *ad hoc*, rather than a systematic, manner. This is not what the public expects
12 of their Environmental Protection Agency.

13
14 Finally, the CASAC notes with disappointment that, to date, there has been no response
15 from the Agency to our January 23, 2008 letter in which the CASAC requested a modification of
16 what appears to be an ever-shifting NAAQS review process that tends to conceal the Agency’s
17 underlying scientific analyses from its own, statutorily-mandated scientific advisory body.

18 19 **Introduction of New Air-Related IQ Loss Evidence-based Framework**

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

- 28 **1. Timing:** In the professional judgment of the Clean Air Scientific Advisory Committee, *the*
29 *Notice of Proposed Rulemaking is far too late a point in the regulatory process to introduce*
30 *a set of new and controlling risk calculations.* These analyses could have much more pro-
31 ductively been included as part of the lead risk/exposure assessment, further integrated with
32 other analyses in a draft or the Final Lead Staff Paper, or at the very least aired for open re-
33 view by the CASAC and the public in the ANPR. The CASAC notes that the Agency’s
34 stated intent is that this evidence-based framework “builds on a recommendation by the
35 CASAC Pb Panel” (73 FR 29237) — apparently from the CASAC’s letter of March 27, 2007
36 [EPA-CASAC-07-003], specifically Appendix D and, in particular, Table 2 therein (p. D-5).
37 However, this last-minute introduction of a set of heretofore unseen quantitative analyses
38 precludes an in-depth, thoughtful deliberation by the CASAC. Our objections to these analy-
39 ses are noted in detail below. Moreover, there is considerable concern that this might be an
40 example of EPA’s “standard operating procedures” under the new NAAQS review process.
- 41 **2. Exclusivity:** All other previous analyses, risk/exposure assessments, staff, CASAC and pub-
42 lic recommendations appear to have been set aside, with this single new meta-analysis used
43 as the exclusive basis for the proposed NAAQS level. The range of proposed standards ap-
44 pears to be predominantly driven by alternative — and, in the CASAC’s judgment, unwar-

1 ranted — assumptions of the appropriate concentration-response (C-R) functions to relate IQ
2 score point reductions to blood Pb concentrations, combined with a policy judgment that a
3 mean population loss of up to two IQ points is the desired health outcome of a revised Lead
4 NAAQS. *Significantly, the CASAC notes that, aside from this new “air-related IQ loss evi-*
5 *dence-based framework,” no other analyses are presented that support a level as high as 0.3*
6 *(or 0.5) $\mu\text{g}/\text{m}^3$.*

- 7 **3. Air Pb-to-blood Pb ratios:** The analysis results are constrained to an assumed range of air-
8 to-blood ratios of 1:3 to 1:7, which is described as being consistent “with the results and ob-
9 servations drawn from the exposure assessment, including related uncertainties” (73 FR
10 29197). This is only true if one: discards the many estimated ratios that fall above this range;
11 ignores the clear indications that the air Pb to blood Pb ratio *increases* as both air Pb and
12 blood Pb *decrease*; and assumes that the related “uncertainties” are directionally-biased and
13 somehow justify the use of lower ratios that are more representative of the much *higher* air
14 Pb and blood Pb levels found in the U.S. in the 1970s and 80s. By contrast, EPA’s current
15 (2007) Lead Staff Paper noted that, while “there is uncertainty and variability in the absolute
16 value of an air-to-blood relationship, the current evidence indicates a notably greater ratio...
17 *e.g., on the order of 1:3 to 1:10” (that is, not 1:3 to 1:7).*

18 Even from EPA’s 1986 Air Quality Criteria Document (AQCD) for Lead, the analy-
19 sis cited as Brunekreef *et al.* (1983) indicated an air-to-blood ratio of 1:8.5. The more recent
20 Schwartz and Pitcher analyses suggest a ratio of 1:9 or 1:10. Additionally, results from
21 Hayes (1994) suggested a range from about 1:6 (at high air Pb levels near $1 \mu\text{g}/\text{m}^3$) to 1:16
22 (at ambient air Pb of about $0.25 \mu\text{g}/\text{m}^3$ — which are within the range currently being consid-
23 ered for the Lead NAAQS). In EPA’s Final Lead Risk Assessment, estimated ratios ranged
24 from 1:2 to 1:9 across the range of alternative standards considered for the urban case study
25 and from 1:10 to 1:19 across the range of alternative standards considered for the primary
26 smelter. The NPR discredits these risk assessment calculations by noting (without attribution
27 of authorship) that “some have suggested, however, that the regression modeling ... could
28 produce air-to-blood Pb ratios that are biased high” (p. 29197) although it later notes (p.
29 29215) that the ratios used in the risk assessment “reflect a subset of air-related pathways re-
30 lated to inhalation and ingestion of indoor dust [and that] inclusion of the remaining path-
31 ways would be expected to yield higher ratios.” The lower end of the proposed range (1:3)
32 reflects the much higher air and blood levels encountered decades ago, while the upper end
33 of the range (1:7) fails to account for the higher ratios expected at lower current and future
34 air and blood Pb levels, especially when multiple air-related Pb exposure pathways are con-
35 sidered.

36 As noted on p. 29197 of the NPR, “For the general urban case study, air-to-blood ra-
37 tios ranged from 1:2 to 1:9.... [and] this pattern of model-derived ratios generally support the
38 range of ratios obtained from the literature and also supports the observation that lower am-
39 bient air Pb levels are associated with [a] higher air-to-blood ratio.” As several Lead Panel
40 members noted in their individual written comments attached to the CASAC’s March 27,
41 2007 letter (EPA-CASAC-07-003), the best documented evidence for the blood-to-air ratio
42 under current conditions is based on actual epidemiology data showing that declines in U.S.
43 national blood lead levels from the National Health and Nutrition Examination Survey
44 (NHANES) surveys tracked declines in EPA- and state-monitored air Pb levels over the same
45 time period and the air-to-blood ratio was 1:10. Given that there is agreement that the *lower*

1 the current air lead levels the *higher* the air-to-blood ratio, *the CASAC recommends that the*
2 *Agency use an air-to-blood ratio closer to 1:9 or 1:10 as being most reflective of current*
3 *conditions.*

- 4 **4. C-R Functions:** The critical concentration-response functions used in this meta-analysis
5 represent the estimated slope of the relationship between IQ point decrements and blood Pb
6 concentration. As summarized in Table 1 of the NPR (73 FR 29203), the analysis identifies
7 two groups of C-R functions — one with *steeper* slopes (ranging from -1.71 to - 2.94 IQ
8 points per µg/dl blood Pb) and one with *shallower* slopes (ranging from -0.4 to -1.79 IQ
9 points per µg/dl blood Pb). The median value of the shallow-sloped group (-0.90) is subse-
10 quently used (as the “2nd group of C-R functions”) in the summary Table 7 “Estimates of Air-
11 Related Population Mean IQ Loss for Children Exposed at the Level of the Standard” (p.
12 29239). *Like the lowest air-to-blood Pb ratio (1:3), the shallow-slope C-R function (-0.9) is*
13 *based on analyses of populations exposed to much higher air lead concentrations and exhib-*
14 *iting much higher blood lead levels than is appropriate for current U.S. populations and the*
15 *levels under consideration for a revised Lead NAAQS.*

16 For example, the median blood lead level (BLL) for children 1 to 5 years of age from
17 the NHANES survey dropped from 3.5 µg/dl in 1988–91 to 1.9 µg/dl in 2003–04 (at which
18 time the 90th percentile BLL was 3.5 µg/dl. However, all eight of the “shallow slope” C-R
19 functions presented in Table 1 had geometric mean BLLs greater than 3.3 µg/dl, and the 4
20 studies with slopes below the median value of -0.9 IQ points/µg/dl BLL had mean blood lev-
21 els ranging between 4.3 and 9.7 µg/dl. Within the shallow-slope group, the only studies with
22 mean BLL levels less than 4 µg/dl (which were the only studies in that group based entirely
23 on U.S. population groups) had slopes of -1.6 and -1.8 respectively. *It is only the combina-*
24 *tion of the lowest C-R slopes and lowest air Pb to blood Pb ratios — both representative of*
25 *much higher exposure conditions of 30 years ago — that provides any basis for considering*
26 *a standard as high as 0.3 µg/m³.*

27 In questioning the validity of the higher slope C-R functions (typically based on
28 lower Pb blood level population subsets of larger population studies), the NPR (p. 29209)
29 first notes that “these analyses are quite suitable for the purpose of investigating whether the
30 slope at lower concentration levels is greater compared to higher concentration levels” — but
31 then cautions that the “use of such coefficients as the primary C-R function in a risk analysis
32 such as this may be inappropriate.” The NPR further notes that while a subset of children
33 with maximal blood Pb levels below 7.5 µg/dl “may better represent current blood Pb levels,
34 not fitting a single model using all available data may lead to bias” (p. 29209). Therefore,
35 the authors of the NPR admit that the slope of the C-R functions steepens at lower concentra-
36 tion and also concede that this is more reflective of the current blood Pb levels. However,
37 the Notice of Proposed Rulemaking then concludes that limiting the C-R analysis to this
38 range of blood Pb levels would introduce “bias.” This vague statement is not only com-
39 pletely unscientific (since any assertion of “bias” should be accompanied by a demonstration
40 of why that is the case and include appropriate references), it is also *at best a specious argu-*
41 *ment, since we are indeed concerned with current blood lead levels in the setting of a health-*
42 *protective NAAQS, not with blood lead levels of the past.*

1 Furthermore, the CASAC rejects the suggestion that the existence of “a larger set of
2 studies” (73 FR 29238) indicating C-R functions with shallower slopes is scientifically-
3 relevant for choosing the most appropriate C-R functions for risk analyses. Rather, the se-
4 lection of C-R function should be based on determining which studies indicate slopes that
5 best reflect the current, lower blood lead levels for children in the U.S. — which, in this in-
6 stance, are those studies from which *steeper* slopes are drawn.

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

- 12 **5. Target IQ Decrements:** The air-related IQ loss framework proposes a target mean IQ de-
13 crement of roughly one to two (1-2) points in the population as a level of damage that the pro-
14 posed standard is intended to protect against. This target level has been erroneously attributed
15 to the CASAC’s recommendations. The use of this target level is inappropriate for several
16 reasons. First, in the CASAC’s letter dated March 27, 2007 (EPA-CASAC-07-003) from its
17 review of the Agency’s 1st Draft Lead Staff Paper and Draft Lead Exposure and Risk As-
18 sessments, the CASAC wrote that “*the CASAC Lead Review Panel considers that a popula-*
19 *tion loss of 1-2 IQ points is highly significant from a public health perspective. Therefore,*
20 *the primary lead standard should be set so as to protect 99.5% of the population from ex-*
21 *ceeding that IQ loss*” (italics in original).

22 The CASAC wishes to emphasize that that this comment refers to 1-2 IQ points as
23 being a “highly significant” loss to be *prevented* — *not* as a desired national damage level
24 goal that a standard should be set to assure. The CASAC also notes that the recommendation
25 is that IQ decrements as large as this should be prevented in all but a small percentile of the
26 population — and certainly not accepted as a reasonable change in *mean* IQ scores across the
27 entire population. *Indeed, if a loss of one IQ point (rather than losses of up to 3.9 points) in*
28 *mean IQ levels were considered a significant loss to be prevented, this analysis would point*
29 *to a range of proposed standards between 0.05 and 0.2 µg/m³, with the lower end of that*
30 *range being more consistent with the higher C-R slopes and higher air-to-blood ratios repre-*
31 *sentative of current U.S. ambient air and blood lead concentrations. However, by combin-*
32 *ing the lowest air-to-blood Pb ratios (1:3), the shallowest C-R slope (-0.9) and a higher-than-*
33 *acceptable IQ decrement endpoint (>1 IQ point), the NPR subsequently, even shockingly,*
34 *goes on to suggest (73 FR 29244) that a standard as high as 0.5 µg/m³ would somehow be*
35 *adequate to protect public health — while failing to point-out that, at the higher air-to-blood*
36 *ratios and steeper C-R slopes more representative of current U.S. exposures, this contem-*
37 *plated level of the standard would allow mean losses of 5 IQ points or more.*
38

39 Level of the Primary Lead Standard

40 In a manner consistent with the Agency’s recent proposed and final rules for the revision
41 of the NAAQS for airborne particulate matter (PM) and ozone, the proposed upper-bound level
42 of 0.3 µg/m³ for the revised Pb NAAQS lies above the upper bound of levels recommended by
43 both EPA Staff and by the CASAC Lead Review Panel. The NPR indicates (73 FR 29190) that
44 three general sets of recommendations were taken into account in developing this proposal: “(1)

1 staff assessments ...upon which staff recommendations for revisions to the primary Pb standard
2 are based, (2) CASAC advice and recommendations...and (3) public comments...”; and further
3 states that “among the many public comments the Agency has received in this review regarding
4 the level of the standard, the overwhelming majority recommended appreciable reductions in the
5 level, *e.g.*, setting it at 0.2 $\mu\text{g}/\text{m}^3$ or less...” (p. 29241). (For the CASAC’s previous advice to
6 the Agency concerning this CASAC-recommended level of the Lead NAAQS, see our letters
7 dated March 27, 2007 [EPA-CASAC-07-003, p. 6 & Appendix D]; September 27, 2007 [EPA-
8 CASAC-07-007, p. 2]; and January 22, 2008 [EPA-CASAC-08-007, pp. 2, 5].) Accordingly,
9 since the overwhelming majority of public comments, the recommendations in the EPA Staff
10 Paper and underlying risk and exposure analyses, and the Lead Panel’s unanimous recommenda-
11 tions *all* advocated a maximum level of 0.2 $\mu\text{g}/\text{m}^3$ or less, it is not clear either where this pro-
12 posal for a *higher* (that is, less stringent) level of 0.3 $\mu\text{g}/\text{m}^3$ level for the primary Pb standard
13 originated (*i.e.*, on what scientific basis) or why it is necessary at this late stage in the rulemaking
14 process to seek additional public comment on a level for the Lead NAAQS as high as 0.5 $\mu\text{g}/\text{m}^3$.
15

16 **Pb NAAQS Indicator**

17 In several rounds of previous comments, the CASAC Lead Review Panel recommended
18 that a revised (and substantially-lowered) Lead NAAQS should be accompanied by a transition
19 of the sampling indicator from total suspended particulates (TSP) to a low-volume ambient air
20 monitor for lead in particulate matter less than 10 micrometers in diameter (PM_{10}) in ambient air.
21 In the CASAC’s advice dated January 22, 2008 (EPA-CASAC-08-007), the CASAC noted that
22 the Lead Panel “unanimously supported the selection of an [PM_{10}] indicator that can be more
23 robustly measured and thus would be more representative of actual population exposures,” add-
24 ing that “a more accurate and precise Pb- PM_{10} indicator would provide a more stable determina-
25 tion of compliance with the new lower Lead NAAQS.” With regard to concerns over a potential
26 loss of ultra-coarse lead particles by PM_{10} samplers, the Lead Panel further noted that “it would
27 be well within EPA’s range of discretionary options to accept a slight loss of ultra-coarse lead at
28 some monitoring sites by selecting an appropriately conservative level for the revised Pb
29 NAAQS.” In a subsequent teleconference consultation by the CASAC Ambient air Monitoring
30 and Methods (AAMM) Subcommittee held on March 25, 2008, a majority of the subcommittee
31 members also supported a transition from TSP to low-volume PM_{10} sampling for lead.
32

33 The CASAC needs to call attention to the fact that these recommendations were based, in
34 part, on an *assumption* that the level of the primary Pb NAAQS would be “substantially” low-
35 ered to the EPA Staff-recommended range (with an TSP indicator) of between 0.1 to 0.2 $\mu\text{g}/\text{m}^3$
36 as an upper bound and 0.02 to 0.05 $\mu\text{g}/\text{m}^3$ as a lower bound (with the added consideration that
37 the selection be made somewhat “conservatively” within this range to accommodate the potential
38 loss of ultra-coarse Pb with a PM_{10} Pb indicator). For example, at most population-orientated
39 monitoring sites, levels of PM_{10} Pb are essentially the same as TSP Pb, but at source-oriented
40 monitoring sites with high coarse mode particulate lead emissions, TSP Pb was roughly twice as
41 high as PM_{10} Pb. This factor-of-two difference is small compared to the factor of 10 to 100 of
42 the recommended lowering in the level of the standard, and could be readily accommodated by
43 considering a slightly more conservative upper bound of 0.1 $\mu\text{g}/\text{m}^3$ rather than 0.2 $\mu\text{g}/\text{m}^3$.
44

45 However, since with the publication of this proposed rule for the revision of the Lead
46 NAAQS the Agency now appears to disagree with previous staff recommendations — as well as

1 those of the CASAC and the “overwhelming majority” of the public — and is considering an up-
2 per bound of $0.3 \mu\text{g}/\text{m}^3$ and possibly as high as $0.5 \mu\text{g}/\text{m}^3$, a transition from TSP to PM_{10} at these
3 much less protective upper levels of the proposed range could represent a critical weakening of
4 the health protection afforded at the level of the standard that the CASAC proposed. *Signifi-*
5 *cantly, a particulate (PM_{10}) lead standard at $0.5 \mu\text{g}/\text{m}^3$ could potentially allow TSP Pb levels as*
6 *high as $1 \mu\text{g}/\text{m}^3$ at sites near large sources with coarse-mode particulate lead emissions.* There-
7 fore, if the level of the standard is set toward the upper end of the range the Agency is now con-
8 sidering, the CASAC is unanimous in its recommendation that the current TSP indicator should
9 *not* be changed. As previously recommended, a transition to a PM_{10} indicator would be prefer-
10 able, but only at a level conservatively below an upper bound of $0.2 \mu\text{g}/\text{m}^3$ or lower.
11

12 **Pb NAAQS Averaging Time and Form**

13 The NPR proposes consideration of a monthly averaging time with a “second highest
14 month in three years” form, but also seeks comment on retaining the current “calendar” quarter
15 “not to be exceeded” form. The CASAC wishes to emphasize that there is no logic for averaging
16 only by “calendar” quarter, as there is nothing unique about effects that may occur exclusively
17 during the four calendar seasons. A “rolling” three-month (or 90-day) average would be more
18 logical than a “calendar” quarter. The CASAC’s previous recommendations — both in the cur-
19 rent review cycle and during the prior review of the Lead NAAQS conducted in the 1980s —
20 advocated reducing the averaging time of the Pb NAAQS from “calendar” quarter to monthly,
21 with the rationale that adverse effects could result from exposures over as few as 30 days’ dura-
22 tion. A monthly or “rolling” 30-day averaging time with a “not to be exceeded” form would be
23 more protective against adverse short-term effects than a form (such as a “second-highest month
24 in three years”) that periodically allows a month of exposures to much higher concentrations.
25

26 **Zero Level for the Lead NAAQS**

27 The Administrator has raised the question of the feasibility of a Lead NAAQS of “zero.”
28 While it would not be practical to set an enforceable primary Pb NAAQS of zero, it is both en-
29 tirely appropriate and indeed very important that we as a Nation have the goal of reducing expo-
30 sure of our children to lead to as close to zero as feasible. The reasons for this are numerous, and
31 include: (1) lead is an apparent non-threshold neurotoxicant that reduces cognitive abilities in
32 children (that is, by directly affecting children’s IQ loss) so that the smaller the amount of Pb in
33 air and from other sources of lead, the smaller the Pb-B and associated IQ loss; (2) such neuro-
34 toxic effects of Pb as IQ loss appear to be persistent and may be irreversible; and (3) the envi-
35 ronmental reality for childhood lead exposures is that these exposures often occur concurrently
36 with exposures to mixtures of other neurotoxicants, with these multiple exposures producing an
37 additive neurotoxicity over that for lead alone. Nonetheless, consistent with the CASAC’s pre-
38 vious advice in this current review cycle for the Pb NAAQS, the CASAC continues to believe
39 that the level of the primary lead standard unanimously recommended by the CASAC — *i.e.*, an
40 upper bound for the primary Pb NAAQS of *no higher than $0.2 \mu\text{g}/\text{m}^3$* — is necessary to provide
41 an adequate margin of safety for the protection of human health, including susceptible subpopu-
42 lations such as children, as explicitly required by the Clean Air Act for primary NAAQS.
43

44 The Clean Air Scientific Advisory Committee stands ready to assist you by advising the
45 Agency concerning the scientific basis on which to base your scientific policy judgments, as

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1 EPA Administrator, in setting NAAQS. It is our sincere desire and goal to work more closely
2 and effectively with the Agency in the future. As always, the members of the CASAC wish EPA
3 well in our vital — and, as previously stated, our mutual — efforts to protect both human health
4 and the environment.

5

6 Sincerely,

7

8 */Signed/*

9

10 Dr. Rogene Henderson, Chair
11 Clean Air Scientific Advisory Committee

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14 Attachment: Appendix A

NOTICE

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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>.

Appendix A – Roster of the CASAC Lead Review Panel

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

CASAC MEMBERS

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*Dr. Luoma did not participate in this CASAC Lead Review Panel advisory activity.