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Revising the National Ambient Air Quality Standard for Lead

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Revising the National Ambient Air Quality Standard for Lead

Summary

The Administrator of the Environmental Protection Agency (EPA), under a court order to review the National Ambient Air Quality Standard (NAAQS) for lead, proposed to revise the standard on May 1, 2008, reducing it from 1.5 micrograms per cubic meter ($\mu g/m^3$) to within the range of 0.10 to 0.30 $\mu g/m^3$. The proposal's publication in the *Federal Register* will begin a 60-day public comment period. The agency must promulgate a final standard by September 15, 2008.

NAAQS are standards for outdoor (ambient) air that are intended to protect public health and welfare from harmful concentrations of pollution. If the Administrator ultimately strengthens the lead standard, he will be concluding that protecting public health and welfare requires lower concentrations of lead pollution in ambient air than the level previously held to be safe. Lead particles can be inhaled or ingested, and, once in the body, can cause lower IQ and effects on learning, memory, and behavior in children. In adults, lead exposure is linked to increased blood pressure, cardiovascular disease, and decreased kidney function.

Regulation of airborne lead is often described as one of the key successes of the Clean Air Act and of the Environmental Protection Agency. In 1970, when lead was widely used as a gasoline additive, emissions of lead nationwide totaled 224,100 tons. Lead was also present then in many consumer products, and thus was emitted to the air in industrial processes and from waste incinerators. The phasing out of lead from gasoline, paint, and other products, as well as stricter controls on industrial emissions, reduced lead emissions 98%, to 4,228 tons in 2000.

The reduction in lead emissions and ambient concentrations have led some to suggest that there is no longer a need for an ambient air quality standard for lead. Others, including the Clean Air Scientific Advisory Committee (CASAC), an independent panel of scientists who advise the EPA Administrator, conclude that the current NAAQS (established in 1978) is far too lenient, that lead in ambient air still poses a threat to public health, and that the NAAQS should be significantly strengthened. CASAC recommended that the standard be reduced from 1.5 $\mu g/m^3$ to no higher than 0.2. In proposing a more stringent NAAQS, the Administrator sided with the scientists, rejecting the argument that the standard is no longer needed; but his proposed range is, in part, not as stringent as they recommended. His decision appears to rest, in part, on a potentially controversial interpretation of the statutory requirement to "protect ... public health" with "an adequate margin of safety."

The May 2008 proposal follows a multi-year review of the science. Assuming a new standard is promulgated, nonattainment areas will first be identified (not expected to occur until September 2011), following which there will be a 5-10 year-long implementation process in which states and local governments will identify and implement measures to reduce lead in the air. EPA has also proposed expanding the monitoring network for lead. Only about 3% of U.S. counties have lead monitors.

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Introduction

On May 1, 2008, EPA Administrator Stephen Johnson proposed to strengthen the National Ambient Air Quality Standard (NAAQS) for lead. As soon as the proposal is published in the *Federal Register*, a 60-day public comment period will begin. Public hearings are scheduled for June 12 in St. Louis and Baltimore. A final decision on the standard is required by September 15, 2008.[1]

When the current standard for lead was promulgated in 1978, lead was a widespread air pollutant. Eighty to ninety percent of it was emitted by the nation's automobiles and trucks, a majority of which ran on leaded gasoline. Leaded gasoline was gradually phased out in the 1970s, 1980s, and early 1990s, and both emissions and concentrations of lead in the air plummeted. Emissions fell more than 96% from 1979 to 2000. Ambient concentrations fell by a similar percentage.[2] As of March 12, 2008, only two areas with a combined population of 4,664 people had air that remained in violation of the 1978 lead NAAQS.[3]

These developments have led some to suggest that there is no longer a need for an ambient air quality standard for lead. Others, including the independent scientific advisory panel that advises EPA's Administrator, conclude that the current NAAQS (established in 1978) is far too lenient, that lead in ambient air still poses a threat to public health, and that the NAAQS should be significantly strengthened as the result of the current review. In proposing a new standard, the Administrator generally agreed with his scientific advisers, proposing to lower the standard to somewhere in a range 80% to 93% below the 1978 standard. The proposed range is, in part, though, not as stringent as the scientists recommended; thus, the Administrator's final choice may prove to be controversial.

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[1] The schedule was set by the consent decree in Missouri Coalition for the Environment v. U.S. EPA, 2005 Westlaw 2234579 (E.D. Mo. Sept. 14, 2005).

[2] The data on lead emissions come from various years of EPA's *National Air Quality and Emission Trends Reports* (titles vary somewhat from year to year), which can generally be found at [http://www.epa.gov/air/airtrends/reports.html].

[3] The two areas are East Helena, Montana, and Herculaneum, Missouri, both of which have been the site of lead smelters. The East Helena smelter closed in 2001. The Herculaneum smelter continues to operate. For additional information, see U.S. EPA, Greenbook, at [http://www.epa.gov/oar/oaqps/greenbk/lindex.html].

This report provides background on NAAQS, the process used to establish them, the factors leading to the reduction in lead emissions, the proposed changes to the lead standard, as well as information regarding the potential effects of any revision.

The Role of NAAQS in Improving Air Quality

What Are NAAQS? NAAQS are standards that apply to ambient (outdoor) air pollutants that exhibit two characteristics: (1) they may reasonably be anticipated to endanger public health or welfare; and (2) their presence in the air results from numerous or diverse mobile or stationary sources.[4] The Clean Air Act provides for two types of NAAQS: primary standards, "the attainment and maintenance of which in the judgment of the [EPA] Administrator ... are requisite to protect the public health," with "an adequate margin of safety"; and secondary standards, necessary to protect public welfare, a broad term that includes damage to crops, vegetation, property, building materials, etc.[5]

NAAQS are at the core of the Clean Air Act, even though they do not directly regulate emissions. In essence, they are standards that define what EPA considers to be clean air.

Implementing a NAAQS. Once a NAAQS has been set, EPA uses monitoring data and other information submitted by the states to identify areas that exceed the standard and must, therefore, reduce pollutant concentrations to achieve it. After these "nonattainment" areas are identified (which EPA estimates will occur in September 2011 for any new lead standards), state and local governments would produce State Implementation Plans which outline the measures they will implement to reduce pollution levels and attain the standards. Lead nonattainment areas would have five years after their designation to actually attain the standard, with a possible extension of five more years.

As will be noted in more detail later, most areas of the country do not monitor lead emissions. Thus, in addition to strengthening the lead standard, the Administrator's proposal would expand the requirements for lead monitoring. Installing the additional monitors and compiling up to three years of data to determine compliance could mean that designation of nonattainment areas might take an additional 3-4 years, depending on the form of standard the agency adopts. Thus, implementing a new standard is likely to be a lengthy process.

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[4] Authority to establish NAAQS comes from both Sections 108 and 109 of the act (42 U.S.C. 7408 and 7409); this definition of criteria pollutants is found in Section 108. The authority and procedures for controlling the sources of criteria pollutants are found throughout Titles I, II, and IV of the act. Pollutants that are less widely emitted are generally classified as "hazardous air pollutants" and are regulated under a different section of the act (Section 112).

[5] The Clean Air Act's definition of welfare is found in Section 302(h) of the act (42 U.S.C. 7602(h)).

Other Pollution Control Measures. In addition to requiring states to submit implementation plans, EPA also acts to control many of the NAAQS pollutants wherever they are emitted, through national standards for products that might emit them (particularly fuels) and through emission standards for new stationary sources (e.g., lead smelters).

The NAAQS Review Process

Schedule for Review. The Clean Air Act requires the agency to review each NAAQS every five years. That schedule is rarely met, but it often triggers lawsuits that force the agency to undertake a review. In the case of lead, the last review of the NAAQS was completed in 1978.[6] The Missouri Coalition for the Environment and others filed suit over EPA's failure to complete a review in 2004, and a consent decree established the schedule EPA is following in reviewing the standard.[7] The schedule required EPA to propose any revision of the standard by May 1, 2008, and to promulgate a final decision by September 15, 2008.

How the Process Works. Reviewing an existing NAAQS is a long process.[8] As a first step, EPA scientists review the scientific literature published since the last NAAQS revision, and summarize it in a report known as a Criteria Document or Integrated Science Assessment. Generally, there are hundreds or thousands of scientific documents reviewed, covering such subjects as environmental concentrations, human exposure, toxicology, animal studies and animal-to-human extrapolation, epidemiology, effects on vegetation and ecosystems, and effects on man-made materials.[9] A second document that EPA prepares, the Staff Paper or Policy Assessment, summarizes the information compiled in the Criteria Document and provides the Administrator with options regarding the indicators, averaging times, statistical form, and numerical level (concentration) of the NAAQS.

To ensure that these reviews meet the highest scientific standards, the 1977 amendments to the Clean Air Act required the Administrator to appoint an independent Clean Air Scientific Advisory Committee (CASAC). CASAC has seven members, largely from academia and from private research institutions. In conducting NAAQS reviews, their expertise is supplemented by panels of the nation's leading experts on the health and environmental effects of the specific pollutant or pollutants under review. These panels can be quite large. The current lead review panel has 15 members, in addition to the 7 statutory members of CASAC. CASAC and the public make suggestions regarding the membership of the panels on specific pollutants, with the final selections made by EPA. The panels

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[6] 43 *Federal Register* 46246, October 5, 1978.

[7] See footnote 1.

[8] For a discussion of the process, and of changes to the process that EPA is now implementing, see CRS Report RL33807, *Air Quality Standards and Sound Science: What Role for CASAC?*, by James E. McCarthy.

[9] EPA indicates that more than 6,000 new studies on lead health effects, environmental effects, and lead in the air have been published since 1990.

review the agency's work during NAAQS-setting and NAAQS-revision, rather than conducting their own independent reviews.

Adding or Deleting NAAQS Pollutants. The pollutants to which NAAQS apply are generally referred to as "criteria" pollutants. Six pollutants are currently identified as criteria pollutants: ozone, particulates, carbon monoxide, sulfur dioxide, nitrogen oxides, and lead. The EPA Administrator can add to this list if he determines that additional pollutants meet the act's criteria (endangerment of public health or welfare, and numerous or diverse sources); he can delete them if he concludes that they no longer do so. Whether lead still meets these criteria is one of the issues EPA considered in its current review of the standard.

Lead Emission Reduction: Success, but Not Generally Due to NAAQS

The reduction of lead emissions is often described as one of the key successes of the Clean Air Act and of the Environmental Protection Agency. In 1970, emissions of lead totaled 224,100 tons. By 2000, emissions had been reduced 98%, to 4,228 tons.[10]

Little of that success is attributable to the setting of a NAAQS, however. The agency did not set a NAAQS for lead until 1978 (by which time lead emissions had already declined about 40%), and it established the NAAQS then only as a result of a lawsuit filed by the Natural Resources Defense Council and others.[11] After promulgating the NAAQS, the agency did not identify nonattainment areas until 1991. The great bulk of the lead reductions "occurred prior to 1990," according to EPA.[12] So, in general, the reduction of lead in ambient air did not come about as a result of the 1978 NAAQS, or in the manner prescribed by Title I of the Clean Air Act, wherein nonattainment areas are identified and the states or areas in which they are located submit to EPA State Implementation Plans that identify local and national measures that will be implemented to help such areas reach attainment.

Most of the reduction was a side-benefit of other Clean Air Act programs, especially the regulation of emissions from new automobiles, beginning in the mid-1970s. In order to meet more stringent requirements for emissions of hydrocarbons, nitrogen oxides, and carbon monoxide, which took effect in 1975, the auto industry installed catalytic converters on new cars. Gasoline with lead additives would have fouled the catalytic converters, rendering them useless; so, in anticipation of the

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[10] U.S. EPA, *National Air Quality and Emission Trends Reports*, cited previously.

[11] NRDC v. Train, 411 F. Supp. 864 (S.D.N.Y. 1976) aff'd., 545 F. 2d 320 (2d Cir. 1976). EPA was ordered to list lead as a criteria pollutant and to develop NAAQS. The agency listed lead March 31, 1976, and on October 5, 1978, established a NAAQS for lead.

[12] U.S. EPA, *Review of the National Ambient Air Quality Standard for Lead: Policy Assessment of Scientific and Technical Information, OAQPS Staff Paper*, November 2007, p. 2-5, at [http://www.epa.gov/ttnnaaqs/standards/pb/data/20071101_pb_staff.pdf].

converters' widespread adoption, EPA mandated the sale of unleaded fuel in the early 1970s, and eventually banned the use of lead in gasoline entirely.

Being a metal, lead remains in the environment, even though emissions have declined. Thus, although human exposure to lead has declined, it has not done so by as much as the decrease in emissions would suggest. Furthermore, research conducted since the 1970s suggests that lead has significant health impacts at levels well below those previously considered safe.

Current sources of emissions include utility and other boilers, leaded fuel still used in some general aviation airplanes, trace lead contaminants in diesel fuel and gasoline, lubricating oil, iron and steel foundries, primary and secondary lead smelters, hazardous waste incinerators, and about 30 smaller categories of sources.[13] In addition, there continues to be exposure from lead particles in soil or dust re-suspended in the atmosphere as a result of vehicular traffic, construction, agricultural operations, and the wind.[14]

EPA's Proposal

EPA proposes to deal with the remaining issue of lead in ambient air by both strengthening the lead NAAQS and by expanding the network of monitors that are used to measure attainment.

The Primary Standard. The primary (health-based) standard, promulgated in 1978, has been set at 1.5 micrograms per cubic meter ($\mu g/m^3$) averaged over three months. The current review has found evidence of health effects at the levels of exposure currently experienced by much of the U.S. population. The Staff Paper reported "significant associations between Pb [lead] exposures and a broad range of health effects," including, in children, neurological effects, notably intellectual attainment, attention, and school performance, with "long-term consequences over a lifetime."[15] The Staff Paper also reported effects on the immune system, with "increased risk for autoimmunity and asthma."[16] In adults, the Staff Paper found associations between lead exposure and "increased risk of adverse cardiovascular outcomes, including increased blood pressure and incidence of hypertension, as well as cardiovascular mortality."[17] Lead exposure also was associated with reduced kidney function, with adverse impacts enhanced in those with diabetes, hypertension, and chronic renal insufficiency.

As a result, both EPA staff and the CASAC recommended strengthening the NAAQS. According to the Staff Paper:

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[13] Ibid., Table 2-2, p. 2-7.

[14] Ibid., p. 2-10.

[15] Ibid., p. 3-22.

[16] Ibid.

[17] Ibid.

> Staff concludes that it is appropriate for the Administrator to consider an appreciable reduction in the level of the standard, reflecting our judgment that a standard appreciably lower than the current standard could provide an appropriate degree of public health protection and would likely result in important improvements in protecting the health of sensitive groups. We recommend that consideration be given to a range of standard levels from approximately 0.1-0.2 $\mu g/m^3$ (particularly in conjunction with a monthly averaging time) down to the lower levels included in the exposure and risk assessment, 0.02 to 0.05 $\mu g/m^3$.[18]

CASAC concurred, stating in a January 22, 2008 letter that it "... unanimously affirms EPA staff's recognition of the need to substantially lower the level of the primary NAAQS for Lead, to an upper bound of no higher than 0.2 $\mu g/m^3$ ...."[19]

The Administrator agreed that the primary NAAQS should be substantially lowered, but he chose a less stringent range of 0.10 to 0.30 $\mu g/m^3$. The proposal requests comments on alternative levels as high as 0.50 $\mu g/m^3$, and below 0.10.

The Administrator also proposed two options for revising the averaging time and form used to determine whether an area meets the standard. Instead of the current not-to-be-exceeded form, based on quarterly (3-month) averages of lead concentrations, the proposal would either revise the current averaging form to clarify that it applies across a three-year span (i.e., to demonstrate attainment, an area would need to show quarterly readings lower than the standard for 12 consecutive quarters); or the proposal would revise the measure to the second highest monthly average in a three-year span. According to agency staff, this latter form would better capture short-term increases in lead exposure, while allowing the average from one bad month (perhaps resulting from unusual meteorological conditions) to be disregarded. The agency notes that "control programs to reduce quarterly mean concentrations may not have the same protective effect as control programs aimed at reducing concentrations in every individual month."[20]

CASAC also recommended that consideration be given to changing from the calendar quarter to the monthly averaging time. In making that recommendation, CASAC emphasized support from studies suggesting that blood lead concentrations respond at shorter time scales than would be captured completely by quarterly values.[21]

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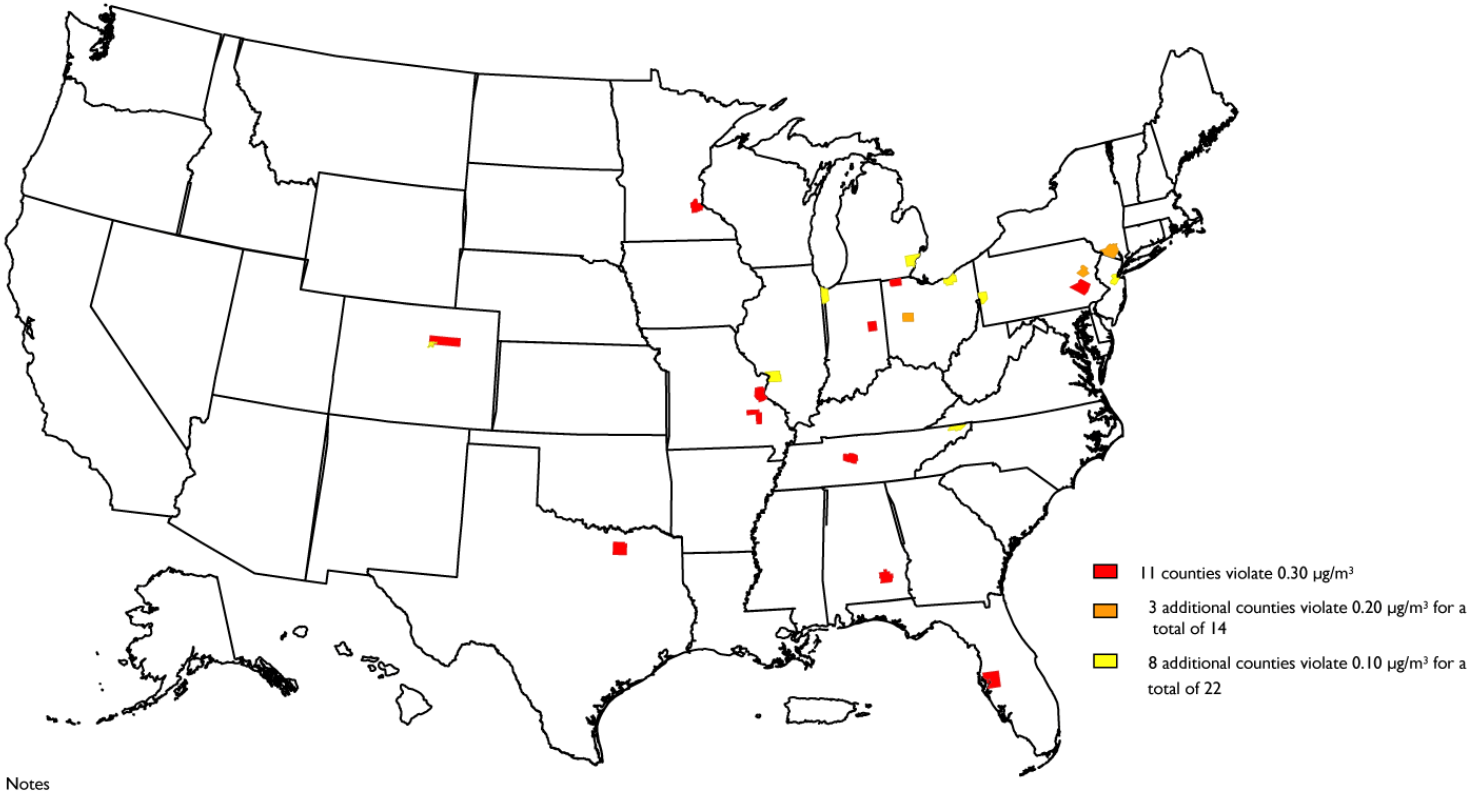
[18] Ibid., pp. 5-44 to 5-45.

[19] "Clean Air Scientific Advisory Committee's Review of the Advance Notice of Proposed Rulemaking (ANPR) for the NAAQS for Lead," Letter of Dr. Rogene Henderson, Chair, CASAC, to Hon. Stephen L. Johnson, Administrator, U.S. EPA, January 22, 2008, p. 5, at [http://yosemite.epa.gov/sab/sabproduct.nsf/427DE71C7D43AFDC852573D8006FB5BC/$File/EPA-CASAC-08-007-unsigned.pdf].

[20] U.S. EPA, National Ambient Air Quality Standards for Lead, Proposed Rule, pre-publication copy, p. 207 at [http://www.epa.gov/air/lead/pdfs/20080501_proposal_fr.pdf].

[21] Ibid.

Figure 1. Counties with Monitors Violating the Proposed Alternative Lead Standards Maximum Quarterly Mean (Based on 2004-2006 Air Quality Data)

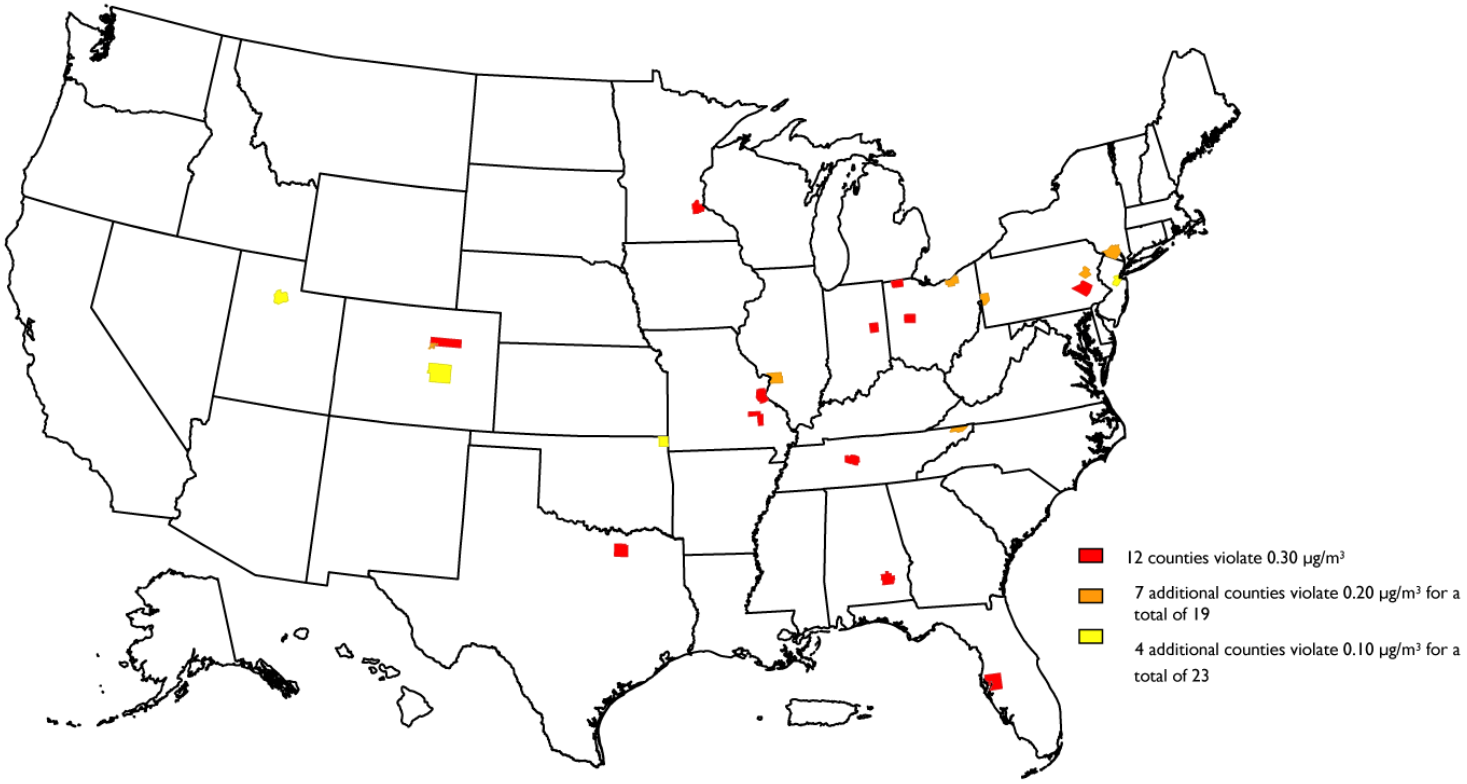


Notes

1. 22 of 104 monitored counties violate the lowest level in EPA's proposed range for this alternative lead standard measured as total suspended particles (TSP).
2. These estimates are based on the most recent air quality data available (2004 – 2006). EPA will not designate areas based on these data, but likely on data from 2008 – 2010.
3. The existing monitoring network for lead is not sufficient to determine whether many areas of the country would meet the proposed revised standards.
4. Monitored air quality data can be obtained from the AQS system at http://www.epa.gov/ttn/airs/airsaqs/

Source: U.S. EPA

Figure 2. Counties with Monitors Violating the Proposed Alternative Lead Standards Second Maximum Monthly Mean (Based on 2004-2006 Air Quality Data)



Notes

1. 23 of 104 monitored counties violate the lowest level in EPA's proposed range for this alternative lead standard measured as total suspended particles (TSP).
2. These estimates are based on the most recent air quality data available (2004 – 2006). EPA will not designate areas based on these data, but likely on data from 2008 – 2010.
3. The existing monitoring network for lead is not sufficient to determine whether many areas of the country would meet the proposed revised standards.
4. Monitored air quality data can be obtained from the AQS system at http://www.epa.gov/ttn/airs/airsaqs/

Source: U.S. EPA

As shown in **Figure 1** and **Figure 2**, the two methods of measuring attainment produce fairly similar, though not identical, results. At the weaker end of the proposed range (0.30 $\mu g/m^3$), 11 counties have monitors showing nonattainment using the quarterly form of the standard, versus 12 counties showing nonattainment using the monthly form. At the stronger end of the range (0.10 $\mu g/m^3$), 22 counties show nonattainment using quarterly averages, versus 23 counties using the monthly form. There is a more substantial difference in the middle of the proposed range, however: 14 counties versus 19 counties, depending on whether the standard is set as a quarterly or 2nd highest monthly average.

The Secondary Standard. As part of its current review, EPA also assessed the secondary (public welfare) NAAQS for lead, which is currently identical to the primary standard. The agency concluded that:

> A significant number of new studies have been conducted since 1978 that associate lead pollution with adverse effects on organisms and ecosystems. However, there is a lack of evidence linking various effects to specific levels of lead in the air.[22]

As a result, the Administrator proposed that the secondary standard be identical to the proposed primary standard.

Expanding the Lead Monitoring Network. Besides finding that the 1978 NAAQS is inadequate to protect public health and welfare, EPA's review concluded that "[t]he current monitoring network is inadequate to assess national compliance with the proposed revised lead standards."[23] Only 104 of the roughly 3,000 counties in the United States (about 3%) currently have lead monitors, leaving many areas of the country without any means of determining whether they are in violation of the lead NAAQS. In fact, according to EPA's Office of Air Quality Planning and Standards, at least 24 states have no monitors at all.[24] The locations of monitors and of major sources of lead emissions are shown in **Figure 3**.

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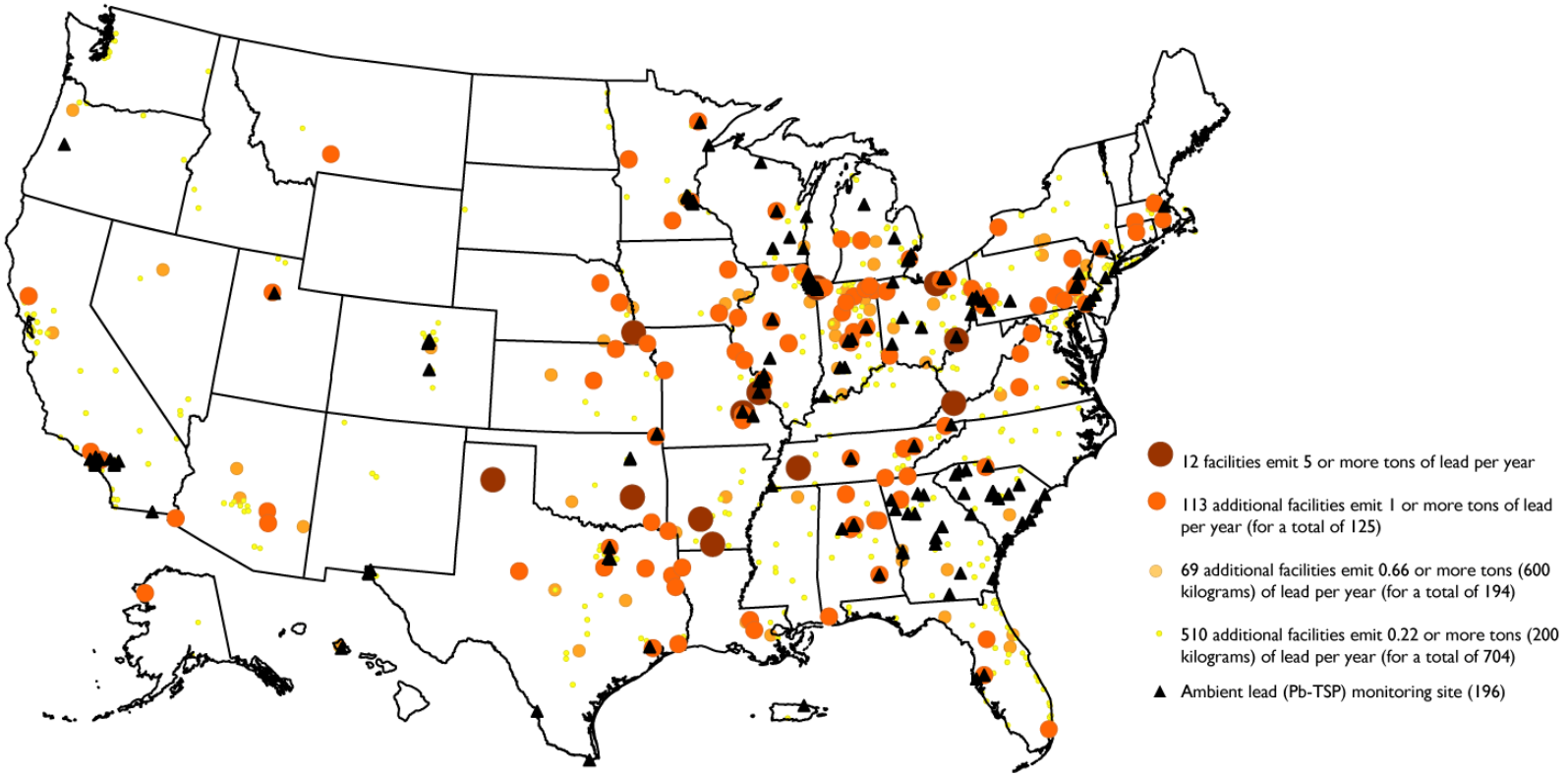
[22] U.S. EPA, "Fact Sheet: Proposed Revisions to the National Ambient Air Quality Standards for Lead," p. 3 at [http://www.epa.gov/air/lead/pdfs/20080501_factsheet.pdf].

[23] U.S. EPA, "May 2008 Proposal, National Ambient Air Quality Standards for Lead, General Overview," Text Slides, at [http://www.epa.gov/air/lead/pdfs/20080501_text1.pdf], p. 17.

[24] Several of the states without monitors have large sources of lead emissions. Arkansas, for example, has two of the 12 largest stationary sources of lead in the United States (those with lead emissions exceeding 5 tons per year), but, according to EPA, no ambient lead monitors. Similarly, large sources in Oklahoma, the Texas panhandle, and other locations appear to be located more than 100 miles from the nearest ambient monitor. Montana has one of only two nonattainment areas for the 1978 lead standard, but, according to EPA, it has no ambient lead monitors. Data on monitor locations was provided by EPA's Office of Air Quality Planning and Standards, May 6, 2008. See also "EPA to Seek Comment on Increasing Air Monitors as Part of Lead Rulemaking," *Daily Environment Report*, November 29, 2007, p. A-10.

Figure 3. Locations of Current Ambient Lead Monitors and Largest Stationary Sources of Lead Emissions



NOTES

1. Emissions estimates based on EPA's 2002 National Emissions Inventory (NEI) with modifications documented in Tom Pace's 05/01/08 memorandum and Marion Hoyer's 04/21/08 and 05/01/08 memoranda to the docket.
2. EPA is working to update the NEI to reflect more recent data in 2008.
3. The NEI includes more than 12,000 additional stationary sources that emit less than 0.22 tons per year of lead.
4. Ambient lead monitoring sites measure lead in total suspended particulate matter (Pb-TSP).
5. The 196 monitoring sites shown met 2004-2006 completeness criteria or were active as of 4/29/08.
6. The current monitoring network for lead is not sufficient to determine whether many areas of the country would meet the proposed revised standards.

Source: U.S. EPA

To address this shortfall, EPA proposed, in addition to a revised lead NAAQS, to require monitors near all sources of lead that exceed a threshold of between 200 and 600 kilograms (441 and 1,323 pounds) of emissions per year. The final threshold would be determined by the stringency of the Administrator's final choice of a NAAQS — a more stringent NAAQS would be tied to a monitoring requirement that includes areas with smaller sources.

EPA also proposes to require a small network of monitors to be placed in urban areas with populations greater than one million to gather information on the general population's exposure to lead in air.

Issues Raised by the NAAQS Review

The primary issue raised by EPA's proposal (as has been the case in EPA's recent reviews of the ozone[25] and particulate matter NAAQS[26]) is whether the Administrator's proposal is supported by the available science. The range chosen by the Administrator, while substantially stronger than the current (1978) standard, would allow him to set a final NAAQS 50% higher than the highest level recommended by both EPA's scientific staff and by the independent CASAC panel. In setting this range, the Administrator states that:

> ... in the case of Pb [lead] there are several aspects to the body of epidemiological evidence that add complexity to the selection of an appropriate level for the primary standard.... [T]he epidemiological evidence that associates Pb exposures with health effects generally focuses on blood Pb for the dose metric. In addition, exposure to Pb comes from various media, only some of which are air-related. This presents a more complex situation than does evidence of associations between occurrences of health effects and ambient air concentrations of an air pollutant, such as is the case for particulate matter and ozone. Further, for the health effects receiving greatest emphasis in this review (neurological effects, particularly neurocognitive and neurobehavioral effects, in children), no threshold levels can be discerned from the evidence. As was recognized at the time of the last review, estimating a threshold for toxic effects of Pb on the central nervous system entails a number of difficulties. The task is made still more complex by support in the evidence for a nonlinear rather than linear relationship of blood Pb with neurocognitive decrement, with greater risk of decrement-associated changes in blood Pb at the lower levels of blood Pb in the exposed population.[27]

Furthermore, the proposal maintains:

> ... the Administrator recognizes that there are currently no commonly accepted guidelines or criteria within the public health community that would provide a

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[25] For additional information on the ozone NAAQS, promulgated in March 2008, see CRS Report RL34057, *Ozone Air Quality Standards: EPA's March 2008 Revision*.

[26] For additional information on the PM NAAQS, see CRS Report RL33254, *Air Quality: EPA's 2006 Changes to the Particulate Matter (PM) Standard*.

[27] Proposed Lead NAAQS Rule, previously cited, pp. 211-212.

> clear basis for reaching a judgment as to the appropriate degree of public health protection that should be afforded to neurocognitive effects in sensitive populations, such as IQ loss in children.... In addition, the Administrator concludes that it is appropriate to consider various air-to-blood ratios, again recognizing the uncertainties in the relevant evidence.[28]

Given these uncertainties (particularly the range of air-to-blood ratios — i.e., the estimated correlation between airborne lead and blood lead levels — and the uncertainties in the concentration-response functions — i.e., the effect of changes in blood lead levels on IQ), the Administrator concludes that his decision would be supported by the science at any point in the proposed range of 0.10 to 0.30 $\mu g/m^3$.

Of particular interest is the Administrator's interpretation of the statutory language requiring him to set a standard that protects public health with an adequate margin of safety. The preamble to the proposed rule states that CASAC and the American Academy of Pediatrics both advised the agency that mean IQ loss within a range of 1 to 2 points "could be significant from a public health perspective." But the Administrator decided that a standard level should be selected to provide protection from air-related IQ loss *in excess of* this range (emphasis added).[29] In other words, the Administrator's interpretation of protecting public health with an adequate margin of safety was to choose a standard that would likely result in an IQ loss that his scientific advisers told him could be significant from a public health perspective.[30]

The degree to which these arguments prove controversial is likely to depend on where in the proposed range the Administrator sets the final standard. If his choice falls within the lower half (0.10 to 0.20 $\mu g/m^3$), there would be less ground for challenge. A standard in that portion of the range would be supported by EPA staff's conclusions based on their review of 6,000 scientific studies, and would be supported by the unanimous conclusions of the 23-member CASAC review panel, particularly if the standard were coupled with the monthly averaging requirement. If his choice falls in the upper half of the range (0.21 to 0.30 $\mu g/m^3$), it would lack this support and would almost certainly join other recent EPA decisions in being reviewed by the U.S. Court of Appeals for the D.C. Circuit.

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[28] Ibid., pp. 234-235.

[29] Ibid., p. 235.

[30] The exact words of the preamble are: "... the Administrator first notes that ideally air-related (as well as other) exposures to environmental Pb would be reduced to the point that no IQ impact in children would occur. The Administrator recognizes, however, that in the case of setting a NAAQS, he is required to make a judgment as to what degree of protection is requisite to protect public health with an adequate margin of safety. ... Considering the advice of CASAC and public comments on this issue, notably including the comments of the American Academy of Pediatrics, the Administrator proposes to conclude that an air-related population mean IQ loss within the range of 1 to 2 points could be significant from a public health perspective, and that a standard level should be selected to provide protection from air-related population mean IQ loss in excess of this range." Ibid.

Finalizing the Standard

Section 307(d) of the Clean Air Act sets out the procedures for proposal and promulgation of a NAAQS. It requires the establishment of a rulemaking docket[31]; it requires that the notice of proposed rulemaking in the *Federal Register* be accompanied by a statement of the proposal's basis and purpose, including a summary of the factual data on which the proposed rule is based, the methodology used in obtaining and analyzing the data, and the major legal interpretations and policy considerations underlying the proposed rule. The statement is required to set forth or summarize and provide a reference to any pertinent findings, recommendations, and comments by CASAC and the National Academy of Sciences, and, if the proposal differs in any important respect from any of these recommendations, provide an explanation of the reasons for such differences. The act also requires that any drafts of proposed and final rules submitted by the Administrator to the Office of Management and Budget (OMB) prior to proposal or promulgation, all documents accompanying those drafts, and all written comments thereon and EPA responses to such comments, be placed in the docket no later than the date of proposal. The proposal had not yet appeared in the *Federal Register* as of this writing, but a pre-publication copy is available on EPA's website,[32] and it is expected to be published within a short time.

Publication of the proposal in the *Federal Register* will set in motion a 60-day public comment period, with public hearings scheduled for June 12, 2008, in St. Louis and Baltimore. Comments can be submitted at [http://www.regulations.gov]. Upon completion of the public comment period, the agency reviews, evaluates, and summarizes the public comments and the Administrator makes a final choice regarding the standard. Under the consent decree in *Missouri Coalition for the Environment*, as recently modified, the Administrator is required to do so by September 15, 2008.

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[31] In this case, the docket number is EPA-HQ-OAR-2006-0735.

[32] U.S. EPA, National Ambient Air Quality Standards for Lead, Proposed Rule, pre-publication copy, p. 207 at [http://www.epa.gov/air/lead/pdfs/20080501_proposal_fr.pdf].