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History of Previous Pb NAAQS Review: Focus on Key Policy-Relevant Issues

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SCIENCE

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Overview

- Overarching questions in NAAQS review
  - In light of newly available information, is current primary standard requisite to protect public health with an adequate margin of safety?
  - . . . is current secondary standard requisite to protect public welfare from any known or anticipated adverse welfare effects?
  - If not, what revisions are appropriate in terms of indicator, averaging time, level and form?
- Overarching aspects of last review
  - Focus on Pb from air emissions (air-related Pb)
  - In addressing questions of adequacy and need for revision
    - Primary weight given to evidence in considering indicator, averaging time, form, and level for primary standard
    - Support drawn from quantitative risk/exposure assessment for level

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History of Pb Standards

- 1978: Initial standards set
  - 1.5 µg/m^3 Pb in total suspended particles (Pb-TSP), calendar quarter average, not to be exceeded
  - Primary standard based on:
    - Maximum "safe" blood Pb level below threshold for anemia symptoms in young children
    - Nonair source contributions to blood Pb
    - Estimated relationship of Pb in air and Pb in children's blood
  - Secondary standard set to equal primary
- 1980s-90 – Review with no revision
- 2008 revisions
  - 0.15 µg/m^3 Pb in TSP, rolling 3-month average, not to be exceeded
  - Primary standard level
    - Selected to protect against air-related IQ loss, particularly in more highly-exposed children (exposed at the level of the standard)
    - Relied on framework that integrates evidence for relationships between
      - Pb in air and Pb in children's blood, and, Pb in children's blood and IQ loss
  - Secondary standard revised to equal revised primary

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Primary standard: Evidence-based considerations in last review

Need to revise:

- Primary consideration given to science evidence
  - Many new health studies published since standard set in 1978
    - >6,000 published since 1990, on array of effects
  - Serious health effects shown to occur at much lower blood Pb levels than those recognized as harmful in late 70s
    - Strong evidence of adverse effects at blood Pb levels well below 10 micrograms per deciliter (µg/dL)
    - No threshold or "safe" level for Pb in blood has been identified
    - Effects on children's developing nervous system, which can cause impacts into adulthood:
      - IQ loss, poor academic achievement, permanent learning disabilities, increased risk of delinquent behavior
  - Information on relationship between Pb in air and Pb in children's blood indicates larger air-to-blood ratio than when standard set

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Primary standard: Evidence-based considerations in last review (continued)

Conclusions on Level:

- Primary consideration given to evidence viewed within air-related IQ loss framework
  - Epidemiological studies in children demonstrate associations of blood Pb levels with IQ loss and other neurocognitive effects (concentration-response relationships)
    - Remarkably consistent results across numerous studies with varying designs and study populations
    - Associations still observed in most recent studies with populations having lower blood Pb levels
    - Evidence indicates incremental impact of Pb on IQ (per µg/dL) is greater at lower blood Pb levels
  - Studies relating air Pb to children's blood Pb (air-to-blood ratios)
    - Evidence indicates higher ratios expected at lower current (or future) air and blood Pb levels
- Lacking evidence-based "bright line", choice reflects public health policy judgments in light of strengths/limitations of evidence and approach
  - In developing evidence-based framework, used median of four concentration-response functions from epidemiological analyses with blood Pb levels closest to today's children, and a range of air-to-blood ratios
  - In considering levels for the standard in conjunction with framework for children exposed at level of standard, Administrator focused on air-related IQ loss less than 2 points

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Primary standard: Evidence-based considerations in last review (continued)

Conclusions on Averaging Time and Form:

- Primary consideration given to scientific evidence, recognizing inherently greater complexity related to Pb's multimedia/multipathway aspects
  - Lack of specificity as to duration of sustained air concentration associated with a particular blood Pb concentration
  - Rapid response of children's blood Pb levels to changes in Pb exposure
    - Analysis of children exposed to gasoline Pb found 1-month lag of blood Pb level response to leaded gasoline sales
  - Strong association of IQ with blood Pb measurement at time of IQ test (concurrent)
    - Concurrent blood Pb level strongly related to exposure events within past few months
  - Relatively rapid response of indoor dust Pb loading to ambient airborne Pb (weeks to few months)
    - Supported by dust Pb modeling analyses in quantitative risk assessment
  - Differing factors affecting response times for different exposure pathways
- Consideration given to limitations in protection provided by use of block calendar quarter, and associated calculation methods

Primary standard: Evidence-based considerations in last review (continued)

Conclusions on Indicator:

- Recognition that Pb in all particle sizes contributes to Pb in blood and associated health effects
  - Limited data to characterize relationships between Pb-TSP and Pb-PM_{10}, particularly at source-oriented sites
  - Uncertainty as to effectiveness of a Pb-PM_{10} indicator in controlling larger (ultra-coarse) Pb particles, which may have greater presence in areas of highest concentrations (near sources)
- Identified role for use of Pb-PM_{10} monitoring data under certain limited circumstances and under certain conditions
  - Limited data on relationships between Pb-TSP and Pb-PM_{10} are inadequate to support broad use of scaling factors for Pb-PM_{10} data with Pb-TSP standard

Primary standard: Evidence-based considerations in this review

- Availability of new evidence to inform understanding of
  - Relationships between children's blood Pb and neurological effects at lowest blood Pb levels and related uncertainties
    - New studies conducted at blood levels closer to those of current population of young children
  - Mechanisms influencing dose-response relationships
  - Other health effects and blood Pb levels at which they may occur
    - Other susceptible populations
  - Air-to-blood relationships for current blood Pb levels and air quality conditions
  - Relationships between Pb-TSP and Pb-PM_{10}, particularly at source-oriented sites

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Primary standard: Risk/exposure-based considerations in last review

Need to revise:

- Administrator judged risk/exposure assessments to provide support to evidence-based conclusion on need for primary standard revision
  - Children's exposure to air Pb and associated IQ loss estimated in five case studies, representing two types of population exposures
    - Populations in localized areas with air Pb concentrations at or somewhat near standard
    - Location-specific urban populations with broader range of air-related exposures associated with meeting standard in the broader area
  - Considered quantitative risk estimates of IQ loss in children exposed under air quality conditions simulated to just meet 1978 standard
  - Administrator observed that IQ loss estimates associated with air-related Pb for conditions just meeting 1978 standard indicated risk of a magnitude "significant from a public health perspective"
    - Median IQ loss estimates above 2 points in all case studies

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Primary standard: Risk/exposure-based considerations in last review (continued)

Conclusions on Level:

- Administrator found exposure/risk assessments to provide useful perspective on risk from air-related Pb
  - Assessments indicate substantial reduction in air-related risk for range of alternative standards considered
    - Range of estimates varied between types of case studies consistent with differences in population exposure
  - Less weight placed on risk estimates, recognizing associated important uncertainties and limitations
  - Nonetheless, Administrator found risk estimates to be “roughly consistent with and generally supportive of” the air-related IQ loss estimates obtained from the evidence-based framework

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Primary standard: Risk/exposure-based considerations in this review

- Exposure assessment: Extent to which are advancements in data, methods, tools since last review that would reduce uncertainties in:
  - Modeling of ambient air-related Pb in indoor dust
  - Predicting air-related blood Pb levels in children
  - Refined analysis for disproportionately impacted populations (e.g., dietary deficient)
  - Predicting air-related blood Pb levels in adult study populations, in light of complexities associated with physiological sequestering/release of Pb from past exposures
- Risk assessment: Extent to which new evidence supports changes in scope, inputs or characterization of uncertainties
  - Health endpoints
  - Concentration-response functions, particularly at lower blood Pb levels
  - Susceptible population

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Secondary standard: Considerations in last review

- Need to revise: Consideration given to body of available evidence and screening-level risk assessment
  - Screening-level risk assessment suggests occurrences of environmental Pb concentrations under 1978 standard that could have adverse environmental effect in terrestrial and sediment dwelling organisms
  - Environmental Pb levels associated with atmospheric Pb concentrations and deposition combined with large reservoir of historical deposited Pb in all media

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Secondary standard: Considerations in last review (continued)

- Conclusions on indicator:
  - While recognize environmental mobility and ecological toxicity are affected by chemical characteristics and media of occurrence, information judged insufficent to identify indicator other than total Pb
    - Noted persistence of Pb and exposure of ecological receptors by multiple pathways
- Conclusions on level:
  - Evidence of airborne Pb influence on ecological systems
  - Lack of data to indicate appropriate level of Pb in environmental media associated with adverse effects
  - CASAC comments that significant change in air concentrations likely to significantly benefit exposures/impacts on terrestrial and aquatic systems in various regions
  - Administrator concurred with CASAC that secondary standard level should be set “at least as low as the level of the primary standard” and that data are lacking “to provide clear, quantitative basis for setting secondary standard that differs from primary standard” with regard to level or (indicator, averaging time, and form)

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Secondary standard: Considerations in this review

- Availability of new evidence to inform:
  - Characterization of levels of Pb in environmental media associated with adverse effects
  - Understanding of quantitative and dynamic relationships between Pb in air and Pb in various media and exposures of ecological receptors
  - Approaches to the assessment of air-related Pb effects on aquatic and terrestrial ecosystems