



Review of the National Ambient Air Quality Standards for Lead

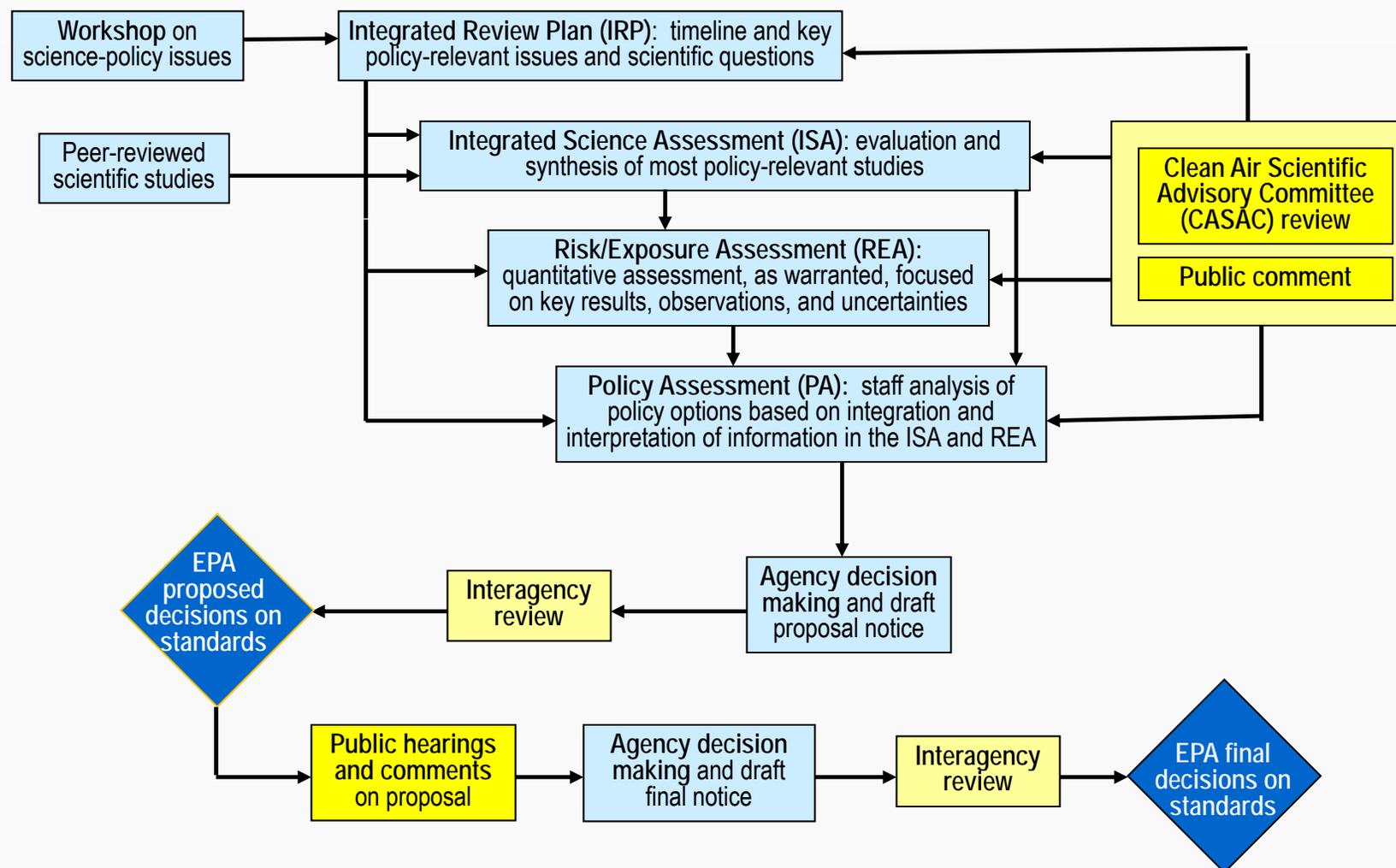
Draft Policy Assessment

Staff from the
Office of Air Quality Planning and Standards
U.S. Environmental Protection Agency

Feb 5-6, 2013
Meeting of Lead NAAQS Review Panel
Clean Air Scientific Advisory Committee



NAAQS Review Process





Schedule for the Current Review

Major Milestones		Projected Completion Date	Projected CASAC Review Date
Workshop to Discuss Key Policy-Relevant Issues		May 2010	
Integrated Review Plan	Draft	March 2011	May 5, 2011
	Final	Nov 2011	
Integrated Science Assessment	First Draft	May 2011	July 20-21, 2011
	Second Draft	Feb 2012	April 10-11, 2012
	Third Draft	Nov 2012	Feb 5-6, 2013
	Final	June 2013	
Risk/Exposure Assessment	Planning Document	June 2011	July 21, 2011
Policy Assessment (PA)	Draft PA	Jan 2013	Feb 5-6, 2013
	Final PA	July/Aug 2013	
Rulemaking	Proposed Rulemaking	Jan 2014	
	Final Rulemaking	Oct 2014	



Pb NAAQS Review Team

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Overview

- Policy Assessment (PA) - purpose and description
- Lead (Pb) NAAQS – history and multimedia aspects
- Considerations for primary Pb standard
- Considerations for secondary Pb standard
- Overview of CASAC Charge



Policy Assessment (PA) – Purpose and Description

- PA presents staff evaluation and conclusions on policy implications of key scientific and technical information
 - Draft PA presents preliminary staff conclusions
- PA helps “bridge the gap” between
 - Scientific and technical assessments presented in the ISA and REAs considered in the review and
 - Judgments required of the EPA Administrator’s determination as to whether it is appropriate to retain or revise the NAAQS
- Development of draft PA(s) is intended to facilitate
 - CASAC advice to EPA and recommendations to the Administrator as provided for in the Clean Air Act, and
 - Public input and comment

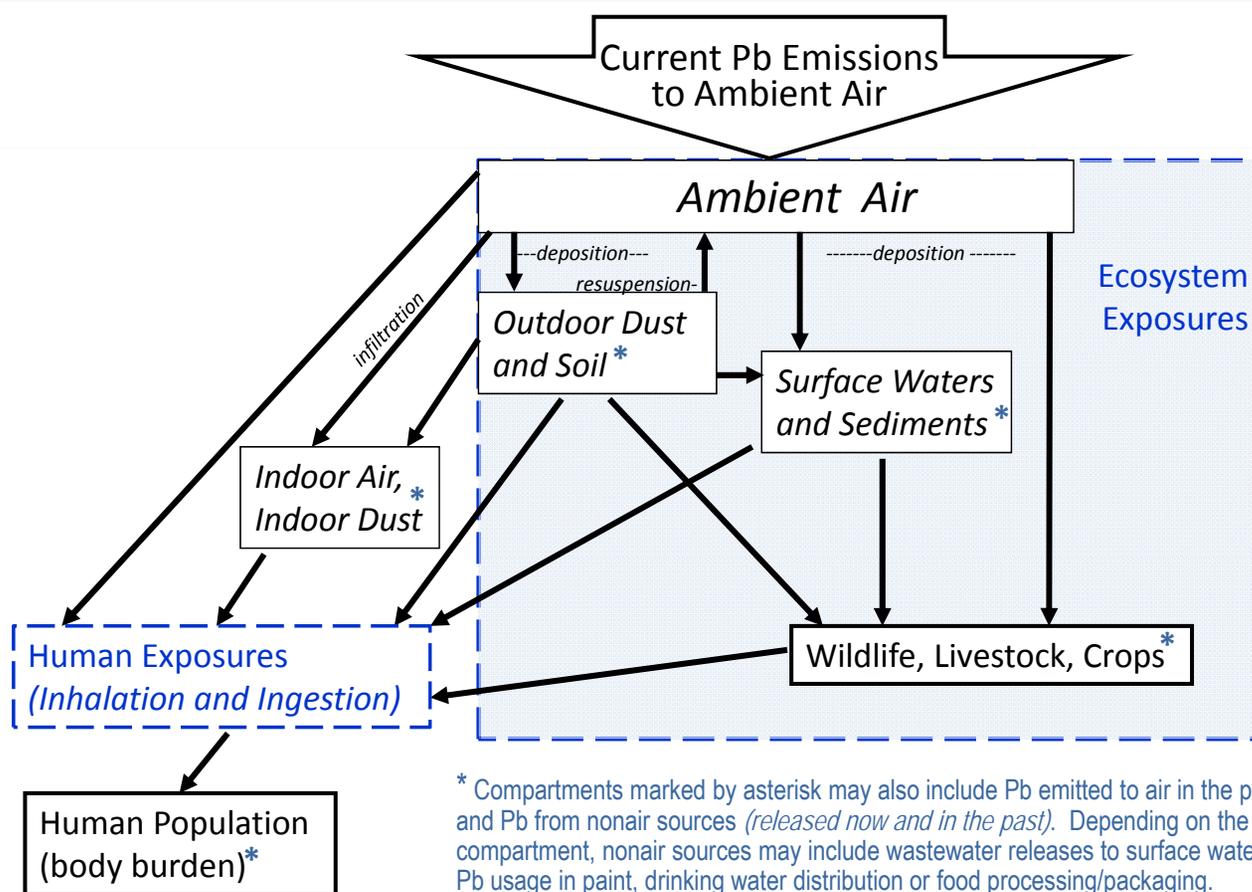


NAAQS for Lead (Pb)

- Pb NAAQS initially set in 1978
- Review of the 1978 NAAQS completed in October 2008
 - Large body of evidence accumulated over interval of nearly three decades called into question the adequacy of the primary and secondary standards
 - Primary Standard
 - Was not requisite to protect public health with an adequate margin of safety
 - Substantially revised, including lowering of level from $1.5 \mu\text{g}/\text{m}^3$ to $0.15 \mu\text{g}/\text{m}^3$
 - Secondary Standard
 - Needed substantial revision, however, relevant data lacking to provide basis for setting secondary standard that differs from the primary
 - Revised to be identical in all respects to primary standard



Multimedia Pathways of Pb Distribution in Environment and to Human Populations



* Compartments marked by asterisk may also include Pb emitted to air in the past and Pb from nonair sources (*released now and in the past*). Depending on the compartment, nonair sources may include wastewater releases to surface water or Pb usage in paint, drinking water distribution or food processing/packaging.



Policy Assessment for Primary Standard

- Does the currently available scientific evidence- and exposure/risk-based information, as reflected in the ISA and REA, support or call into question the adequacy of the protection afforded by the current Pb standard?



Policy Assessment for Primary Standard – Evidence-based Considerations

- Evidence available since last review continues to indicate:
 - Neurocognitive effects in young children is most sensitive endpoint
 - Blood Pb is most appropriate Pb exposure/dose indicator for health effects characterization
 - Air Pb contributes to Pb in blood; air-to-blood ratio estimates consistent with range from last review
 - Risk factors include early childhood ages (including prenatal life stage), nutritional status, proximity to sources (including residential factors), some racial/ethnic backgrounds
 - Epidemiological studies of blood Pb and studies estimating air-related blood Pb play key role in conclusions on health effects of ambient air Pb



Policy Assessment for Primary Standard

– Evidence-based Considerations (continued)

- Limited newly available evidence for inputs to evidence-based, air-related IQ loss framework generally consistent with previously available evidence
 - Framework, developed in last review, integrates two types of evidence to inform consideration of air-related Pb neurocognitive impacts on subset of children most exposed to air-related Pb
 - Evidence on relationships between ambient air Pb and air-related Pb in children's blood
 - Evidence on relationships between children's blood Pb and IQ loss
- Previously identified uncertainties remain:
 - Shape of dose-response curve for neurocognitive decrements (IQ) of air-related Pb in young children exposed to air Pb today
 - Air-to-blood ratios reflecting current transfers of air Pb to exposure media to children's blood Pb
 - Role of current air Pb exposures in contributing to other health effects in other populations



Policy Assessment for Primary Standard - Risk-based Considerations

- Risk estimates for air-related Pb drawn from 2007 REA
 - Generalized (local) Urban Case Study (interpolation of 2007 results)
 - Location-specific Urban Case Study
- Air-related Pb risk estimates roughly consistent with and generally supportive of estimates from evidence-based air-related IQ loss framework
 - Estimates are approximate, falling generally within rough lower and upper bounds
 - Limitations in ability to quantify air-related exposure and risk effect on upper bound contributes to overestimation, particularly at lower air Pb levels
- Uncertainties previously identified still remain
 - Uncertainty in air-related risk is greater in air quality scenarios for lower air Pb



Policy Assessment for Primary Standard - Preliminary Staff Conclusions

- Current body of evidence, in combination with exposure/risk information, supports primary standard as protective as current standard
- It is appropriate to consider retaining the current standard without revision, based on consideration of:
 - Health effects evidence, including particular emphasis on evidence-based air-related IQ loss framework
 - Key aspects on which standard is based are generally consistent with evidence in last review
 - Exposure/risk information (based on 2007 REA), as supporting information, with associated complexities and limitations
 - Reasonable judgments on
 - Consideration of uncertainties in evidence and exposure/risk, including increased uncertainty at lower air levels
 - Public health implications of estimated air-related blood Pb and risk levels under current standard
 - Appreciable uncertainty as to whether would be reductions in public health risk from alternate lower standards



Policy Assessment for Secondary Standard

- Does the currently available scientific evidence- and exposure/risk-based information, as reflected in the ISA and REA, support or call into question the adequacy of the protection afforded by the current secondary Pb standard?



Policy Assessment for Secondary Standard - Evidence-based Considerations

- Evidence available since last review continues to indicate:
 - Pb deposition to soils has decreased since the phase-out of leaded on-road gasoline
 - Bioavailable Pb is a better predictor of effect on organisms than the overall amount of Pb in the system
 - Pb has effects on growth, reproduction and survival, and these effects can be adverse to organisms and ecosystems
- There continues to be limited evidence that links current ambient air Pb emissions and deposition to environmental media (e.g., soil, sediment, water, and biota) with ecological effects
- The connection between air concentration and ecosystem exposure and associated potential for welfare effects continues to be poorly characterized, and is more so for conditions associated with the current standard (than had been the case for the prior standard)



Policy Assessment for Secondary Standard - Risk-based Considerations

- Case study results from 2006 REA vary in extent to which they reflect conditions associated with the current standard:
 - The Primary and Secondary Pb Smelter Case Studies are located in counties which exceed the current standard
 - It is unknown whether current air concentrations at the Near Roadway Case Study sites exceed the current Pb standard, although soil concentrations include deposition associated with higher past concentrations during usage of leaded gasoline
 - In Hubbard Brook Case Study, ambient air Pb concentrations likely do not directly impact stream Pb levels under air quality conditions associated with meeting the current standard
 - The extent to which past (vs current) air emissions of Pb have contributed to surface water or sediment Pb concentrations at the locations identified in the Nationwide Screen remains unclear
- When considered with regard to air-related ecosystem exposures likely to occur with air Pb levels that just meet the current standard, the risk information does not provide evidence that the current standard is inadequate



Policy Assessment for Secondary Standard - Preliminary Staff Conclusions

- Currently available evidence does not include evidence of significant effects at lower concentrations or evidence of higher level ecosystem effects beyond those reported in the last review
- There are significant difficulties in interpreting effects evidence from laboratory studies to the natural environment and linking those effects to ambient air Pb concentrations
- No new critical loads information is available that would inform our interpretation of the public welfare significance of the effects of Pb in various ecosystems
- Risk evidence does not call into question the adequacy of the current standard
- There is no new evidence to inform the consideration of a distinct secondary standard
- It is appropriate to consider retaining the current standard without revision



Policy Assessment

- Overview of Charge for CASAC Review

- Introductory and Background Material (chapter 1)
 - Characterization of context, background on past reviews and scope for current review
- Ambient Air Lead (chapter 2)
 - Characterization of most relevant information on emissions, air quality, Pb concentrations in other media and ambient Pb monitoring
- Primary Standard
 - Health Effects and Exposure/Risk Information (chapter 3)
 - Characterization of key aspects of health effects evidence, including differences from last review
 - Characterization of quantitative exposure/risk estimates, and associated limitations and uncertainties, in context of current review



Policy Assessment

- Overview of Charge for CASAC Review (continued)

- Review of the Primary Standard (chapter 4)
 - Considerations informing preliminary conclusions, including focus on air-related, evidence-based IQ loss framework
 - Panel views on adequacy of current standard
- Secondary Standard
 - Welfare Effects and Exposure/Risk Information (chapter 5)
 - Characterization of key aspects of welfare effects evidence, including differences from last review
 - Characterization of quantitative screening-level risk assessment, and associated limitations and uncertainties, in context of current review
 - Review of the Secondary Standard (chapter 6)
 - Considerations informing preliminary conclusions
 - Panel views on adequacy of current standard