

National Ambient Air Quality Standards (NAAQS) for Particulate Matter (PM)

Current Review – Focus on Primary PM_{2.5} Standards



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Overview

- Statutory requirements
- Current standards
 - Basis for 2006 primary PM_{2.5} standards
 - 2009 remand of primary PM_{2.5} annual standard
- Current review
 - Review process to date
 - Health effects and susceptible populations
 - Primary PM_{2.5} standards
 - Primary PM₁₀ standard
 - Secondary PM standards

Statutory Requirements

- **Primary (health-based) standards . . . in the “judgment of the Administrator” are “requisite” to protect public health with an “adequate margin of safety”**
 - “Requisite” – sufficient but not more than necessary
 - “Adequate margin of safety” – intended to address uncertainties associated with inconclusive evidence, and to provide a reasonable degree of protection against hazards that research has not yet identified
- **Secondary (welfare-based) standards . . . in the “judgment of the Administrator” are “requisite to protect the public welfare from any known or anticipated adverse effects”**
 - Welfare effects include . . . “effects on soils, water, crops, vegetation, man-made materials, animals, wildlife, weather, visibility and climate . . .”

Statutory Requirements (cont.)

- **NAAQS**, and the scientific information upon which they are based, are to be reviewed every five years
- An **independent scientific review committee**. . . shall complete a review of the science and standards . . . and “shall recommend to the Administrator any new . . . standards and revisions of existing . . . standards as may be appropriate”
 - This function performed by **Clean Air Scientific Advisory Committee (CASAC)**
- In setting NAAQS:
 - EPA is required to engage in “reasoned decision making” to translate scientific evidence into standards
 - In so doing, **EPA may not consider cost in setting standards** . . . Rather, cost is considered in developing control strategies to meet the standards

Current PM Standards: Primary and Secondary Standards are Identical

Indicator	Averaging Time	
	Annual	24-hour
PM _{2.5} (Fine Particles)	15 µg/m ³ Annual arithmetic mean, averaged over 3 years	35 µg/m ³ 98 th percentile, averaged over 3 years
PM ₁₀ (Coarse Particles)	-----	150 µg/m ³ not to be exceeded more than once per year on average over a three year period

Basis for Primary PM_{2.5} Standards

- 1997 - Administrator considered epidemiological evidence and data on air quality relationships to set a “**generally controlling**” **annual standard** in conjunction with a **24-hour standard to provide supplemental protection**
 - Strongest evidence from short-term exposure studies; long-term exposure studies more limited
- 2006 - Administrator used a different evidence-based approach
 - **Annual standard**: Administrator based level on **long-term** exposure studies only
 - Greatest weight placed on multi-city **mortality** studies - **Harvard Six Cities** and **ACS** studies
 - Judged key long-term exposure **morbidity** studies in children provided uncertain basis for establishing level (e.g., **S. California Children’s Health Study**)
 - Long-term mean PM_{2.5} concentrations from short-term exposure studies were not considered
 - **24-hour standard**: Administrator based level on **short-term** exposure studies only
 - Predominantly single-city studies available; limited multi-city studies

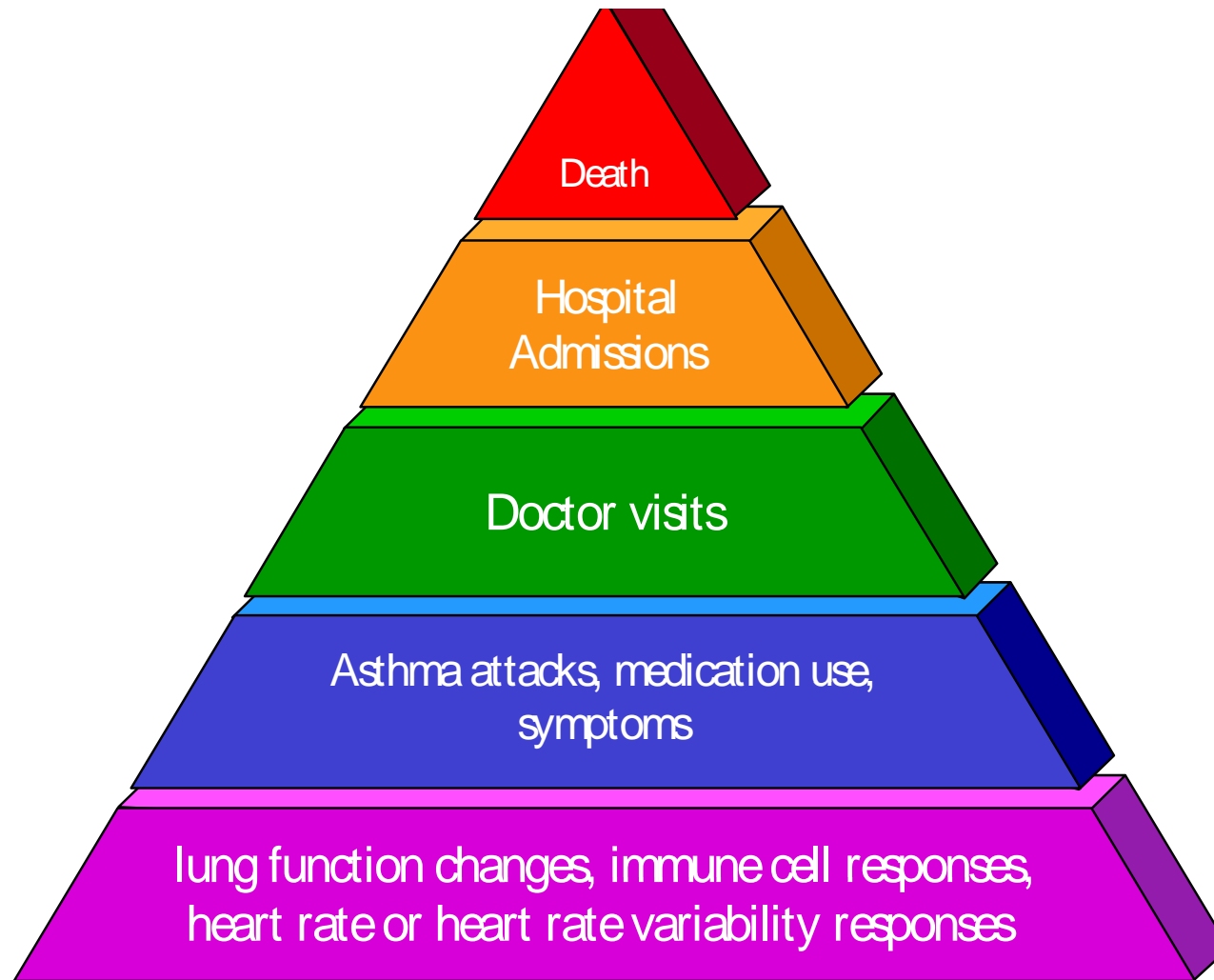
Remand of Primary Annual PM_{2.5} Standard

- US Court of Appeals, DC Circuit, issued decision on Feb 24, 2009
 - Court concluded, “EPA failed adequately to explain why, in view of risks posed by short-term exposures and the evidence of morbidity resulting from long-term exposures, its annual standard is sufficient to *protect public health with an adequate margin of safety*”
- Remanded annual standard for further consideration of:
 - Whether it provides an **adequate margin of safety** from risk of *short-term exposures*
 - Whether it provides an **adequate margin of safety** against *morbidity in children and other vulnerable subpopulations* from long-term exposures
- Primary 24-hour PM_{2.5} standard, as revised in 2006, was not challenged by litigants

Review Process to Date

- Initiated in 2007
- **Integrated Science Assessment:** December 2009
 - Synthesis and assessment of most policy-relevant science
- **Risk/Exposure Assessments:** June/July 2010
 - Focus on fine particles and did not assess risks associated with coarse particles
- **Policy Assessment**
 - Staff conclusions of broadest range of policy options supported by the available scientific evidence, quantitative assessments, and air quality analyses
 - Staff conclusions address adequacy of current standards and potential alternative standards appropriate to consider
 - Second draft released June 2010; Final still to be issued
- Drafts of each document have been reviewed by CASAC and the public
 - Final documents take into consideration CASAC and public comments

PM Health Impacts: "Pyramid of Effects"



Susceptible Populations

- Persons with pre-existing heart or lung disease, including asthma
- Different life stages
 - Children
 - Older adults
- Persons with lower socioeconomic status (SES)
 - New evidence available in this review provides stronger evidence for this population
- Emerging evidence
 - Genetic variability
 - Additional pre-existing diseases and conditions (e.g., diabetes, obesity)
 - Neonates, infants



PM_{2.5} Health Evidence: What is New?

- Currently available evidence is **stronger** in comparison to information available in last review because of its **breadth** and **substantiation of previously observed effects**
- **Compelling evidence supports a causal relationship between PM_{2.5} and premature mortality and cardiovascular effects (long- and short-term exposures)**
- Additional evidence for a **broad range of PM_{2.5}-related health effects** including:
 - **Likely causal relationship** for respiratory effects (long- and short-term exposures)
 - **Suggestive of a causal relationship** for developmental/reproductive effects, cancer (long-term exposures)
 - Effects have been observed **at ambient concentrations allowed by current standards**
 - **No evidence** to support existence of a **discernible threshold** below which effects would not occur
 - Important uncertainties remain including understanding **relative toxicity** of different components in fine particle mixture

Primary PM_{2.5} Standards - Staff and CASAC Conclusions Based on Second Draft Policy Assessment

- **Staff concludes and CASAC concurs that currently available evidence clearly calls into question adequacy of current standards**
- **Staff concludes it is appropriate to consider alternative standards for a generally controlling annual standard with a 24-hour standard providing supplemental protection**
 - Annual standard level within range of 13-11 $\mu\text{g}/\text{m}^3$
 - 24-hour standard level within range of 35-30 $\mu\text{g}/\text{m}^3$
 - CASAC concurs with ranges presented in second draft PA and concludes, “the levels under consideration are supported by the epidemiological and toxicological evidence, as well as by the risk and air quality information”
- **No decisions have been made at this time**

Primary PM₁₀ Standard

- D.C. Circuit Court upheld EPA's 2006 decision to retain the 24-hour PM₁₀ standard and to revoke the annual PM₁₀ standard
- **Staff concludes** scientific evidence could support either **retaining** or **revising** current standard (second draft Policy Assessment)
 - **Retaining the standard** would place **more weight on uncertainties and limitations** with regard to body of health effects evidence
 - **Revising the standard** would place **more weight on positive associations** between coarse particles and health effects observed in locations that would likely have met the current standard
 - To the extent it is judged appropriate to revise the current standard, it would be appropriate to consider revising both the **level (within range of 85-65 µg/m³)** and **form (98th percentile form)**
- **CASAC recommends revising** current 24-hour PM₁₀ standard to **increase public health protection** (based on second draft Policy Assessment)
 - Concludes available evidence, while limited, is sufficient to call into question the level of protection provided by current standard
 - Recommends **98th percentile form** in conjunction with a level within a range of **75-65 µg/m³**
- **No decisions have been made at this time**

Secondary PM Standards

- Need to address remand of 2006 decision to set $PM_{2.5}$ secondary standards identical to primary standards
 - In 2009, D.C. Circuit Court concluded 2006 decision was “unreasonable and contrary to law”
- Current review focuses on $PM_{2.5}$ -related visibility impairment in urban areas
 - Recognize that visibility in Class I areas is addressed by the Regional Haze Program
- **Staff concludes and CASAC concurs** current information clearly calls into question adequacy of current standards (second draft Policy Assessment)
- Considering options for structuring a secondary standard distinct from the primary $PM_{2.5}$ standards in terms of:
 - Alternative indicators, averaging times, and forms
 - Selecting alternative standard levels that reflect appropriate degree of public welfare protection
- No decisions have been made at this time

Next Steps

- **Finalize Policy Assessment**
- **Propose Rule**
 - 90-day public comment period
- **Issue Final Rule**
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