

# **CASAC and the NAAQS**

## **“What’s going on”**

**Jonathan M. Samet, M.D., M.S.**

**Chairman, CASAC and**

Professor and Flora L. Thornton Chair,  
Department of Preventive Medicine

USC Keck School of Medicine

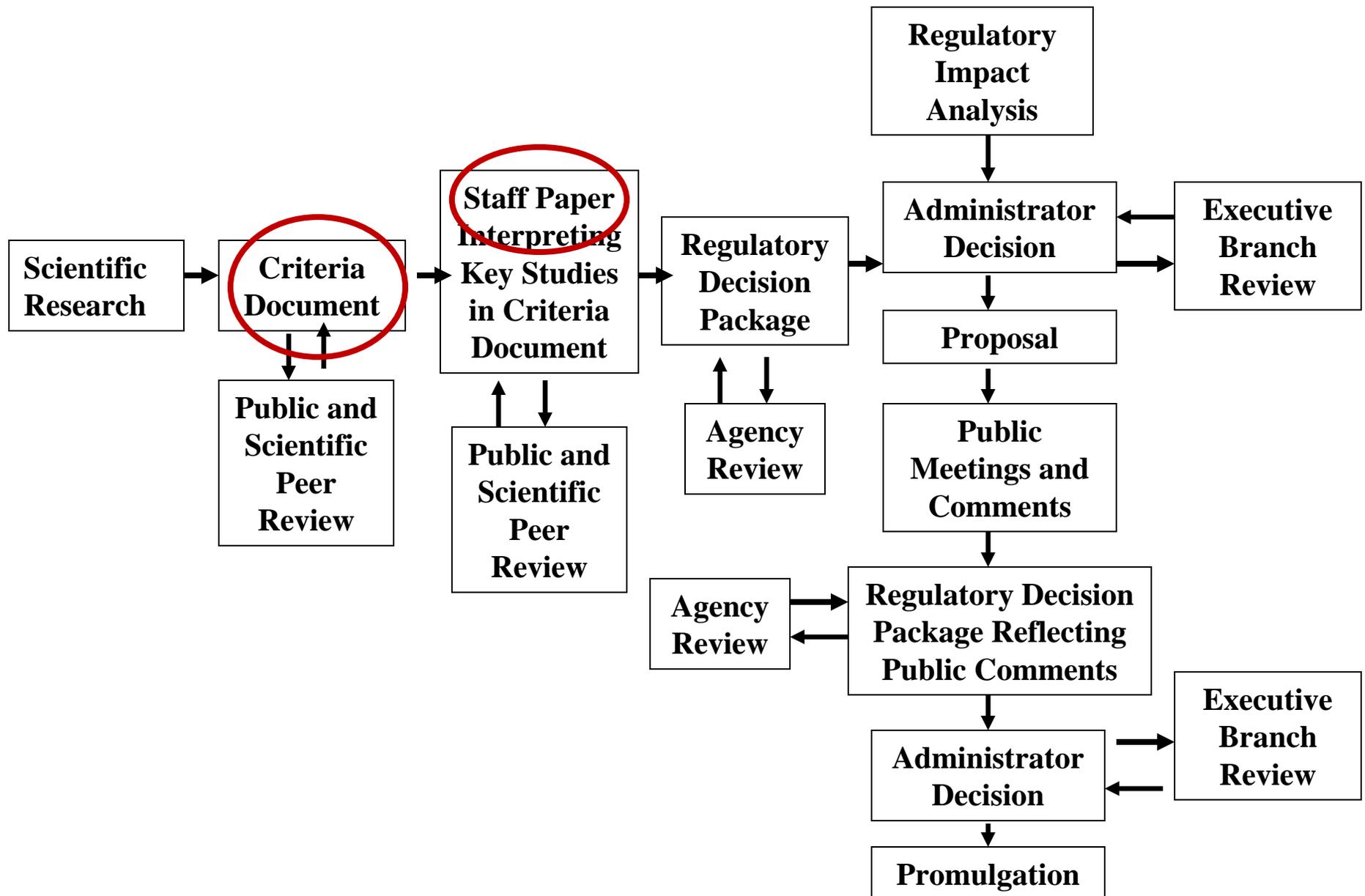
Director, USC Institute for Global Health



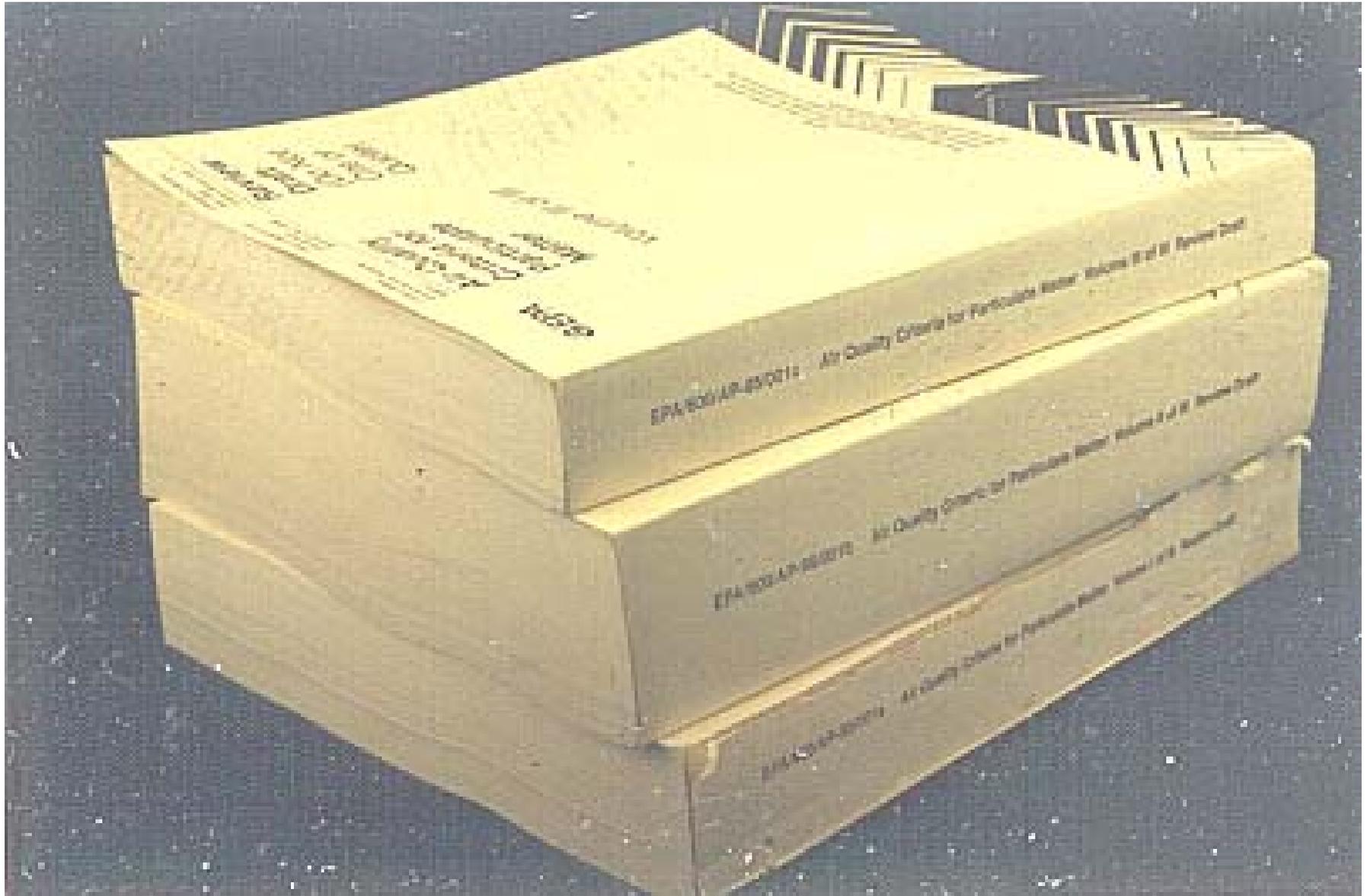
## The Mandate: Clean Air Act

Section 109 (42 U.S.C. 7409) directs the Administrator to propose and promulgate “primary” and “secondary” NAAQS for pollutants identified under section 108. Section 109(b)(1) defines a primary standard as one *“the attainment and maintenance of which in the judgment of the Administrator, based on such criteria and allowing an adequate margin of safety, is requisite to protect the public health.”*

# “**OLD**” NAAQS Standard Setting Process



# The Telephone Book: The Criteria Document



**Review of the National Ambient Air  
Quality Standards for Particulate Matter:**

**Policy Assessment of Scientific and  
Technical Information**

**OAQPS Staff Paper**



Office of Air Quality Planning and Standards  
U.S. Environmental Protection Agency  
Research Triangle Park, NC 27711

External Review Draft  
April 1990

**The Staff Paper**

- “Science bottom lines”
- Policy options



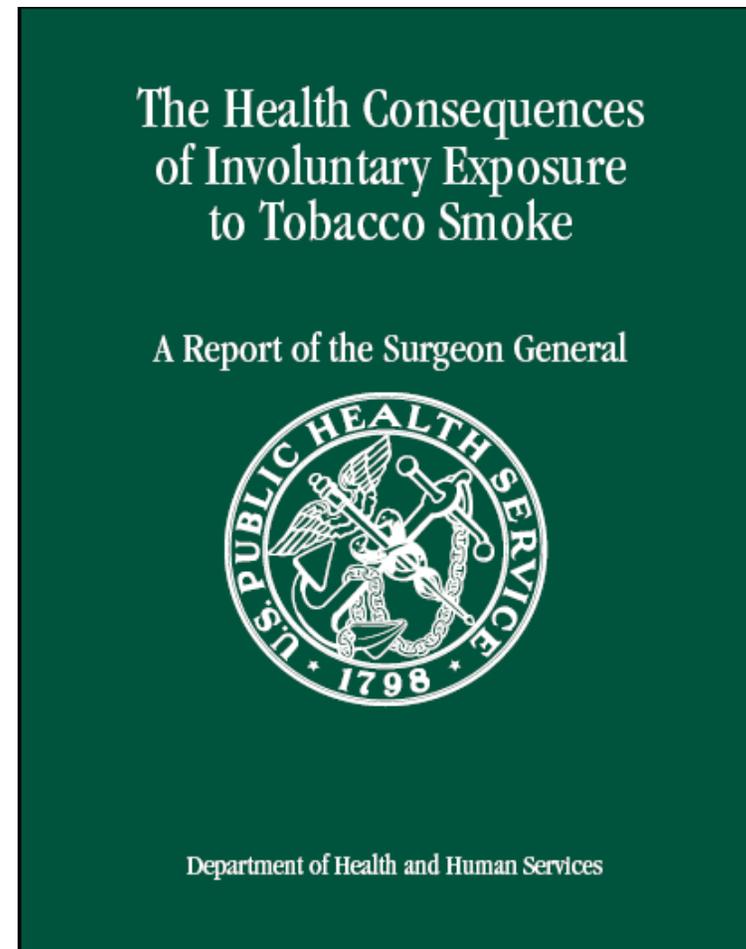
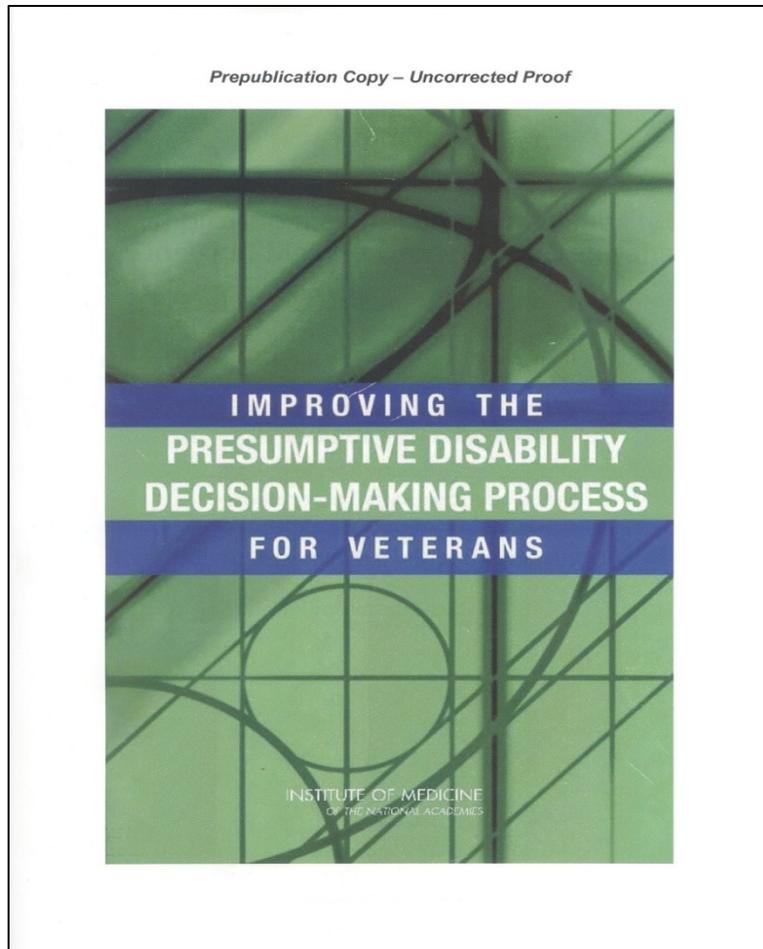
# Limitations of the Process

- Encyclopedic criteria document with little synthesis.
- Lack of defined process for evidence review and synthesis.
- Insufficient transparency in linkage between the Criteria Document and the Staff Paper.
- Inadequate tracking of responses to review.

# Evidence Review Methods are Well Established

- Systematic reviews
- Quantitative synthesis methods, aka meta-analysis
- Schemas for causal inference
- Classification systems for strength of evidence

# Examples





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

MAY 21 2009

THE ADMINISTRATOR

Jonathan Samet, M.D.  
Chair, Clean Air Scientific Advisory Committee  
U.S. Environmental Protection Agency  
1200 Pennsylvania Avenue, N.W.  
Mail Code 1400F  
Washington, D.C. 20460-0001

Dear Dr. Samet:

The National Ambient Air Quality Standards play a central role in enabling the U.S. Environmental Protection Agency to fulfill its mission to protect the nation's public health and the environment. It is critical that these standards are grounded in science.

With this in mind, I have examined the process that the Agency uses to review and update the NAAQS to ensure it takes into account the latest peer-reviewed science and the Clean Air Scientific Advisory Committee's expert advice on the science and the standards. Based on that review, I have set out a process that I believe will ensure the timeliness, scientific integrity, and transparency of the NAAQS review process. I believe this new NAAQS review process incorporates important improvements and recognizes CASAC's important role in advising the



## Technology Transfer Network National Ambient Air Quality Standards (NAAQS)

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NAAQS Home

Carbon Monoxide Standards

Carbon Monoxide Implementation

Lead Standards

Lead Implementation

Nitrogen Dioxide Primary Standards

Nitrogen Dioxide Secondary Standards

Nitrogen Dioxide Implementation

Ozone Standards

Ozone Implementation

Particulate Matter Standards

PM<sub>10</sub> Implementation

PM<sub>2.5</sub> Implementation

Sulfur Dioxide Primary Standards

Sulfur Dioxide Secondary Standards

Sulfur Dioxide Implementation

### NAAQS Review Process

You will need Adobe Acrobat Reader, available as a free download, to view some of the files on this page. See [EPA's PDF](#) page to learn more about PDF, and for a link to the free Acrobat Reader.

Sections 108 and 109 of the Clean Air Act (CAA) govern the establishment and revision of the National Ambient Air Quality Standards (NAAQS) to provide protection for the nation's public health and the environment. The process by which the EPA reviews NAAQS has evolved over time. In making changes to NAAQS review process over time, EPA has considered recommendations from the Clean Air Scientific Advisory Committee (CASAC) and other stakeholder groups that have substantial experience with the NAAQS process as changes have been made to the review process.

Below are relevant Agency documents regarding more recent changes to the NAAQS review process. Written communication between the Agency and CASAC regarding EPA's revised NAAQS process can be found at the following link: [Correspondence with the Clean Air Scientific Advisory Committee](#)

#### 2009

Recognizing the importance of scientific integrity and transparency, Administrator Lisa P. Jackson reexamined the NAAQS review process and modifications to the process made in the last administration. On May 21, 2009, Administrator Jackson called for key changes to the NAAQS review process including reinstating a policy assessment document that contains staff analyses of the scientific bases for alternative policy options for consideration by senior Agency management prior to rulemaking. This document, known as a "Staff Paper", will serve to "bridge the gap" between the scientific information and the judgments required of the Administrator in determining whether it is appropriate to retain or revise the standards. In conjunction with this change, EPA will no longer issue a policy assessment in the form of an Advance Notice of Proposed Rulemaking (ANPR).

- [Memo from EPA Administrator Jackson addressing revisit of NAAQS review process, May 21, 2009 \(PDF\)](#) (5pp, 280k)
- [Letter to the Clean Air Scientific Advisory Committee conveying May 21, 2009 memo from Administrator Jackson \(PDF\)](#) (2pp, 80k)

#### 2005-2008

In December 2005, the EPA Deputy Administrator requested that the Office of Air and Radiation (OAR) and the Office of Research and Development (ORD) conduct a "top-to-bottom review" of the process the Agency uses in setting and reviewing NAAQS. Advice and recommendations were requested from current and former members of the CASAC and other stakeholder groups that had substantial experience with the NAAQS review process. On April 3, 2006, the working group issued a report outlining their conclusions and recommendations.

##### April 3, 2006, EPA working group report on the NAAQS review process

- [Cover memo \(PDF\)](#) (2pp, 29k)
- [Executive Summary \(PDF\)](#) (4pp, 22k)
- [Report \(PDF\)](#) (41pp, 435k)
- [Attachments \(PDF\)](#) (76pp, 1.0 MB)

##### June 2006 Public Workshop

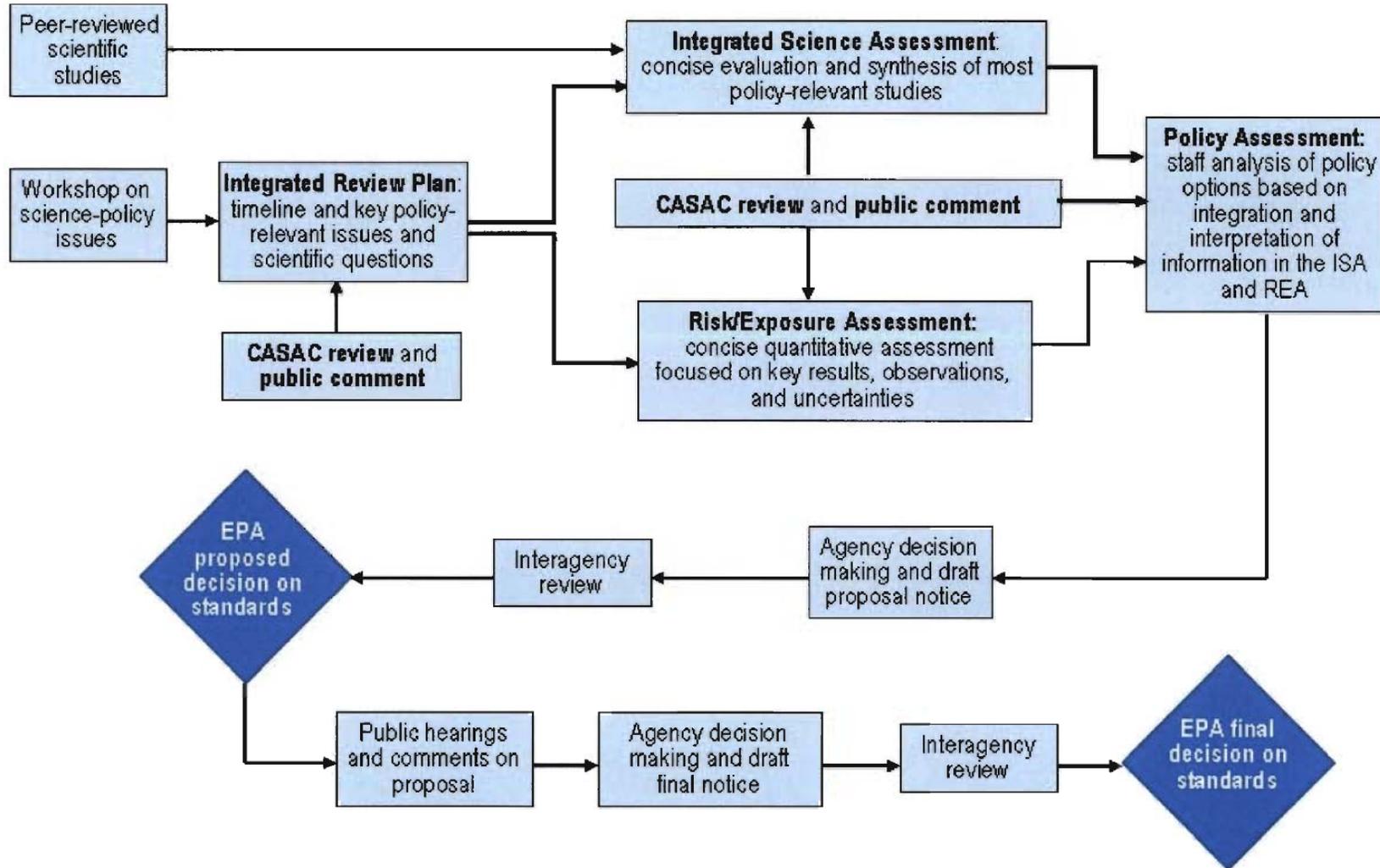
EPA held a public workshop on June 27, 2006 to discuss the process the Agency uses to review the NAAQS. The workshop provided the public the opportunity to present their views on the review process and to discuss the process with EPA officials. This workshop did not cover issues related to the ongoing review of any specific air quality standard.

- [List of speakers registered as of June 26, 2006 \(PDF\)](#) (2pp, 31k)
- [June 27 workshop: Overview presentation by Lydia Wegman, Office of Air Quality Planning & Standards, and Kevin Teichman, Office of Research & Development \(PDF\)](#) (9pp, 165k)
- [June 7, 2006: Federal Register Notice of Public Workshop to discuss the NAAQS Process](#)

##### Public Comments

# New NAAQS review process

April 2009



# Planning

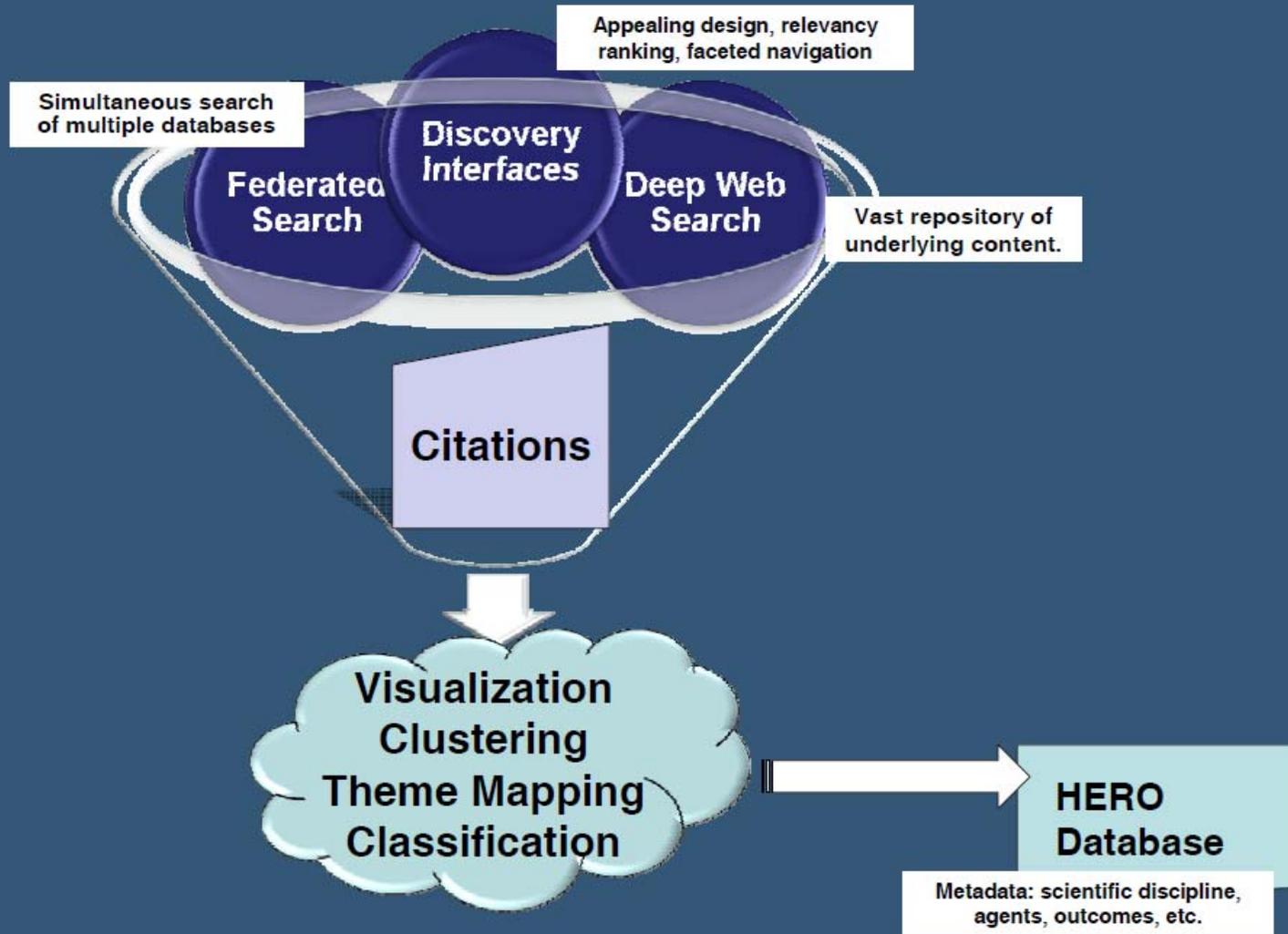
## Major Elements of the Process for Reviewing National Ambient Air Quality Standards

- *Planning:* The review process begins with the preparation of an integrated review plan that includes the science-policy questions that will frame the review, an outline of the process and schedule that the review will follow, and more complete descriptions of the purpose, contents, and approach for developing each of the key documents in the review. The Agency will hold a “kick-off” workshop early in the planning phase to get input from Clean Air Scientific Advisory Committee, U.S. Environmental Protection Agency-contracted outside scientists, and the public regarding policy-relevant questions from the prior review and any new policy-relevant science issues that have emerged since the last review. This workshop, together with early guidance from Agency management, should help inform the preparation of a draft IRP to be released for consultation with CASAC and public comment prior to issuance of a final IRP.

# Integrated Science Assessment

- *Integrated Science Assessment:* The science assessment document will provide a concise evaluation and integration of the policy-relevant science, including key science judgments that are an important aspect of the risk and exposure assessments. First and second drafts of the ISA will be released for CASAC review and public comment. In addition, special outreach will be made to experts in other Federal agencies whose missions include assessment of health and environmental scientific information to solicit their input and comment on the science assessment. More specifically, experts in the National Institutes of Health (e.g., the National Institute for Environmental Health Sciences), the Centers for Disease Control and Prevention, the Agency for Toxic Substances and Disease Registry, the National Institute for Occupational Safety and Health, and the National Park Service, as well as in other Federal health and environmental agencies, are to be included in this outreach, as appropriate. Also, the ongoing development and implementation of an electronic database, Health and Environmental Research Online, that facilitates a more continuous process to identify, characterize, and prioritize new scientific studies should be an integral part of the EPA's Office of Research and Development's ongoing scientific assessment activities.

# Literature Search & Screening





## Health & Environmental Research Online

*A comprehensive system to identify, compile, characterize, analyze, synthesize and prioritize scientific studies.*

- Facilitates complete, sustainable and effective assessment development
- Houses citations and study data from scientific literature
- Includes studies in EPA's priority areas
- Efficient and intelligent information extraction and synthesis
- Assures the highest scientific integrity in data quality.
- Employs advanced searching and screening techniques using advanced algorithms
- Utilizes rapid and comprehensive information retrieval
- Provides transparency to stakeholders and the public

## Details

<b>HERO ID</b>	156743
<b>Author(s)</b>	Mauad T; Rivero DH; de Oliveira RC; Lichtenfels AJ; Guimaraes ET; de Andre PA; Kasahara DI; Bueno HM; Saldiva PH
<b>Year</b>	2008
<b>Title</b>	Chronic exposure to ambient levels of urban particles affects mouse lung development
<b>Reference Type</b>	Journal Article
<b>Journal</b>	American Journal of Respiratory and Critical Care Medicine
<b>Volume</b>	178
<b>Page(s)</b>	721-728
<b>Abstract</b>	<p>RATIONALE: Chronic exposure to air pollution has been associated with adverse effects on children's lung growth. OBJECTIVES: We analyzed the effects of chronic exposure to urban levels of particulate matter (PM) on selected phases of mouse lung development. METHODS: The exposure occurred in two open-top chambers (filtered and nonfiltered) placed 20 m from a street with heavy traffic in São Paulo, 24 hours/day for 8 months. There was a significant reduction of the levels of PM(2.5) inside the filtered chamber (filtered = 2.9 +/- 3.0 microg/m(3), nonfiltered = 16.8 +/- 8.3 microg/m(3); P = 0.001). At this exposure site, vehicular sources are the major components of PM(2.5) (PM</p>
<b>Cited In</b>	PM 2009

# Data Extraction & Analysis

## Ambient Air Pollution and Respiratory Emergency Department Visits

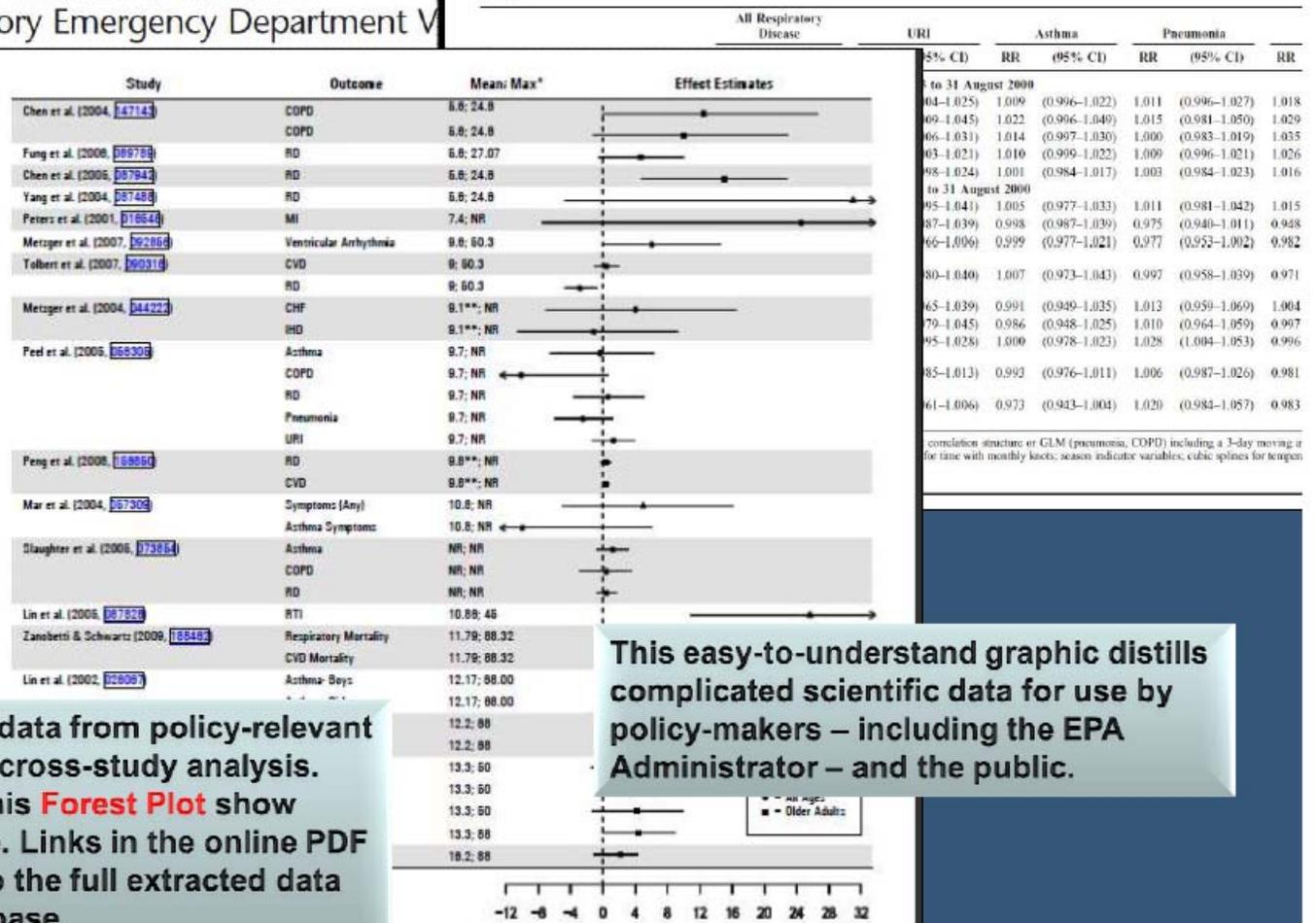
Jennifer L. Peel,<sup>1†</sup> Paige E. T. Knox,<sup>1†</sup> Todd J. Jan

**Background:** A number of emergency corroborated findings from mortality and regarding an association of ambient air outcomes. More refined assessment has been and available air quality data.

**Methods:** Measurements of 5 pollutants (ozone, nitrogen dioxide [NO<sub>2</sub>], carbon monoxide [CO], sulfur dioxide [SO<sub>2</sub>], and particulate matter) were available for the entire 1993 to 31 August 2000; detailed meteorological data were available for 25 months. We used emergency department visits from 31 hospitals for asthma, chronic obstructive pulmonary disease, pneumonia, and influenza.

**Results:** In single-pollutant models examining associations of pollutants (lags 0, 1, and 2): stand-alone ozone, NO<sub>2</sub>, CO, and PM<sub>10</sub> were associated with URI visits; a 2 μg/m<sup>3</sup> increase of PM<sub>10</sub> associated with a 3% increase in pneumonia visits; and a 3% increase in CO was associated with a 3% increase in pneumonia visits. Associations persisted beyond 3 days for

TABLE 3. Results of a priori Models\* for the Association of Daily Ambient Air Quality Measurements With Emergency Department Visits for Respiratory Disease



Scientists extract data from policy-relevant studies to use for cross-study analysis. Figures such as this **Forest Plot** show results at a glance. Links in the online PDF bring the reader to the full extracted data in the HERO Database.

This easy-to-understand graphic distills complicated scientific data for use by policy-makers – including the EPA Administrator – and the public.

Figure 2-9. Effect estimates from epidemiologic studies of PM<sub>10-2.5</sub> ordered by mean 24-h avg concentration as reported by the investigator.

# Classification of Strength of Evidence

- Causal relationship
- Likely to be a causal relationship
- Suggestive of a causal relationship
- Inadequate to infer a causal relationship
- Suggestive of no relationship

# Risk/Exposure Assessment

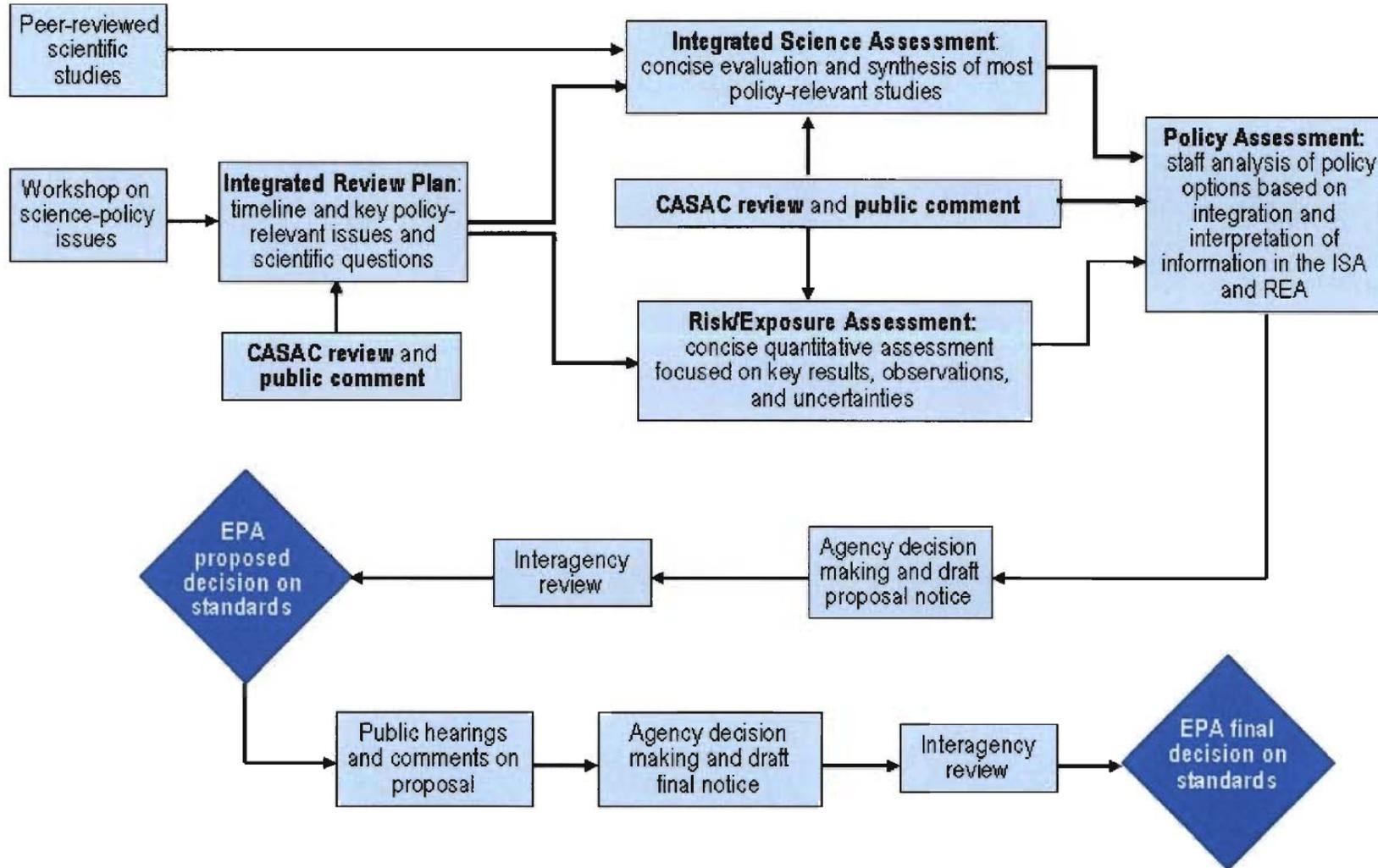
- *Risk/Exposure Assessment:* Risk and exposure assessments, focused on human health or welfare-related impacts, will provide a concise presentation of methods, key results, observations, and related uncertainties. A planning document that discusses the scope and methods planned for use in conducting the assessment will be prepared in concert with the first draft ISA; the first draft REA should be linked to the second draft ISA; and the second draft REA should be linked to the development of the final ISA. As with the ISA, in addition to CASAC review and public comment, special outreach will be made as appropriate to experts in other Federal agencies as noted above whose missions include assessment of health and environmental risk to solicit their input and comment on the risk/exposure assessment.

# Policy Assessment

- *Policy Assessment:* The preparation of a policy assessment document that provides a transparent staff analysis of the scientific basis for alternative policy options for consideration by senior Agency management prior to rulemaking, will be reinstated, and the use of an ANPR is discontinued. This policy assessment document should integrate and interpret information from the ISA and the REA to frame policy options for consideration by the Administrator. As it did in the past, this document is intended to help “bridge the gap” between the Agency’s scientific assessments, presented in the ISA and REA, and the judgments required of the Administrator in determining whether it is appropriate to retain or revise the standards. This document will be released in draft form for CASAC review and public comment. This document is intended to facilitate CASAC’s advice to the Agency and recommendations to the Administrator on any new standards or revisions to existing standards as may be appropriate, as provided for in the Clean Air Act.
- *Rulemaking:* As required by the Clean Air Act, the Agency will issue a proposed rule for public comment. Taking public comments into consideration, a final rule will be issued to complete the rulemaking.

# New NAAQS review process

April 2009





## Current Schedule

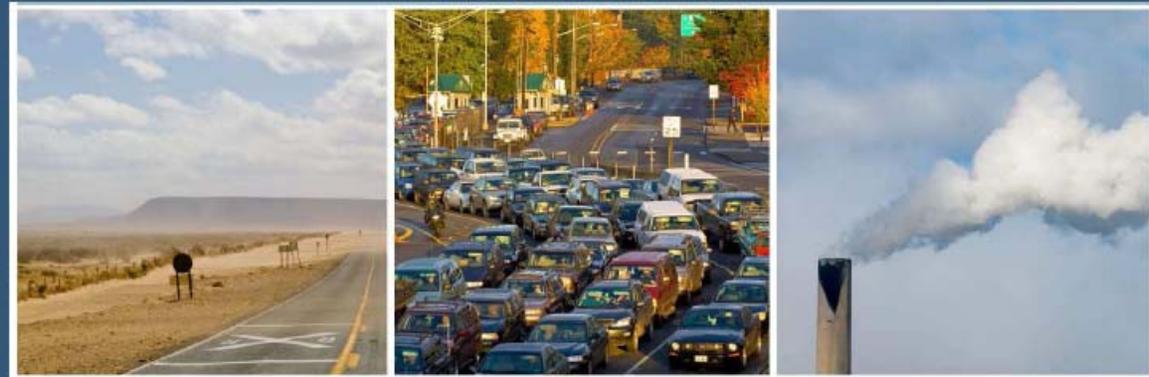
Final Integrated Science Assessment (ISA)	December 2009
2 <sup>nd</sup> Draft Urban-Focused Visibility Assessment (UFVA)	January 2010
2 <sup>nd</sup> Draft Risk Assessment (RA)	February 2010
1 <sup>st</sup> Draft Policy Assessment (PA)	March 2010
CASAC and public review of 2 <sup>nd</sup> draft RA and UFVA	March 10 -11, 2010
CASAC and public review of 1 <sup>st</sup> draft PA	April 8-9, 2010
Final RA and Final UFVA	April 2010
2 <sup>nd</sup> draft PA	May 2010
CASAC and public review of 2 <sup>nd</sup> draft PA	June 2010
Final PA	July 2010
Proposed Rule	November 2010
Final Rule	July 2011

For additional information, see [http://www.epa.gov/ttn/naaqs/standards/pm/s\\_pm\\_index.html](http://www.epa.gov/ttn/naaqs/standards/pm/s_pm_index.html)



# *Integrated Science Assessment for Particulate Matter (2<sup>nd</sup> External Review Draft)*

*Briefing for Clean Air Scientific Advisory  
Committee*





# NCEA-RTP PM ISA TEAM

*John Vandenberg – Division Director*  
*Debra Walsh – Deputy Division Director*  
*Mary Ross – Branch Chief*

*Lindsay Wichers Stanek – PM ISA Project Manager*

Jeff Arnold  
Christal Bowman  
James Brown  
Barbara Buckley  
Allen Davis  
Jean-Jacques Dubois  
Steven Dutton  
Tara Greaver  
Erin Hines  
Doug Johns  
Ellen Kirrane

Dennis Kotchmar  
Thomas Long  
Thomas Luben  
Qingyu Meng  
Kris Novak  
Joseph Pinto  
Jennifer Richmond-Bryant  
Jason Sacks  
David Svendsgaard  
Lisa Vinikoor  
William Wilson

# Overview

2<sup>nd</sup> draft ISA revisions in response to CASAC and public comments on 1<sup>st</sup> draft PM ISA:

- Focus on PM<sub>2.5</sub>, PM<sub>10-2.5</sub>, ultrafine PM
  - PM<sub>10</sub> studies as supportive for PM<sub>2.5</sub> or PM<sub>10-2.5</sub> causality determinations
- All causality determinations included in Chapter 2
  - Some determinations were revised
- Welfare determinations included in Chapter 2
- Restructuring of Susceptibility Chapter
- Other revisions to text and figures, addition of new sections
  
- Health and Environmental Research Online (HERO) system
  - PM citation hotlinks

# PM ISA Organization

- Chapter 1: Introduction
- Chapter 2: Integrative Health and Welfare Effects Overview
- Chapter 3: Source to Exposure
- Chapter 4: Dosimetry
- Chapter 5: Mode of Action
- Chapter 6: Integrated Health Effects of Short-term PM Exposure
- Chapter 7: Integrated Health Effects of Long-term PM Exposure
- Chapter 8: Susceptible Subpopulations
- Chapter 9: Welfare Effects

Annexes (more detailed summaries of evidence)

- A: Atmospheric science and exposure
- B: Dosimetry
- C: Human clinical
- D: Toxicology
- E: Epidemiology
- F: Source apportionment health studies

# PM ISA Revisions

## *Chapters 1 and 2*

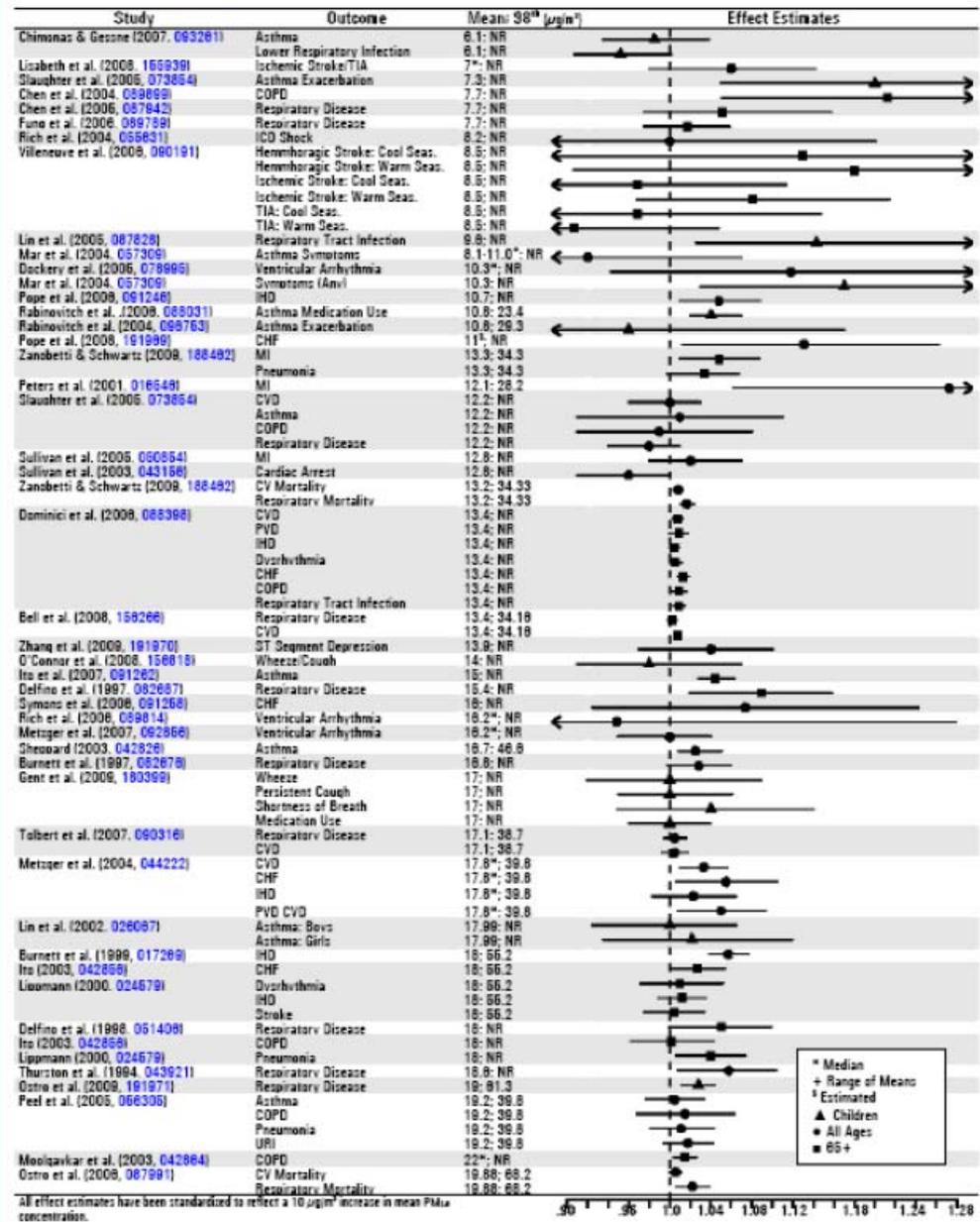
- Chapter 1 (Introduction)
  - Further detail added on history of previous PM NAAQS review
  - Expanded section on study selection criteria
  - Revised to include more specific considerations for causality determinations on PM
- Chapter 2 (Integrative Overview)
  - Reorganized to focus on effects of PM<sub>2.5</sub>, PM<sub>10-2.5</sub>, and ultrafine particles
  - Included all health causality conclusions
  - Added integration sections by PM size fraction
  - Added figures that incorporate effect estimates and the concentrations at which they are observed
  - Added new section on policy-relevant considerations
  - Included welfare effects

# Causality Determinations for Exposures to PM<sub>2.5</sub>

Health Category	Short-term Exposure	Long-term Exposure
Cardiovascular Effects	Causal	<b>Causal</b>
Respiratory Effects	Likely to be Causal	Likely to be Causal
Central Nervous System	Inadequate	-----
Mortality	Likely to be Causal	Likely to be Causal
Reproductive and Developmental	-----	Suggestive
Cancer, Mutagenicity, Genotoxicity	-----	<b>Suggestive</b>

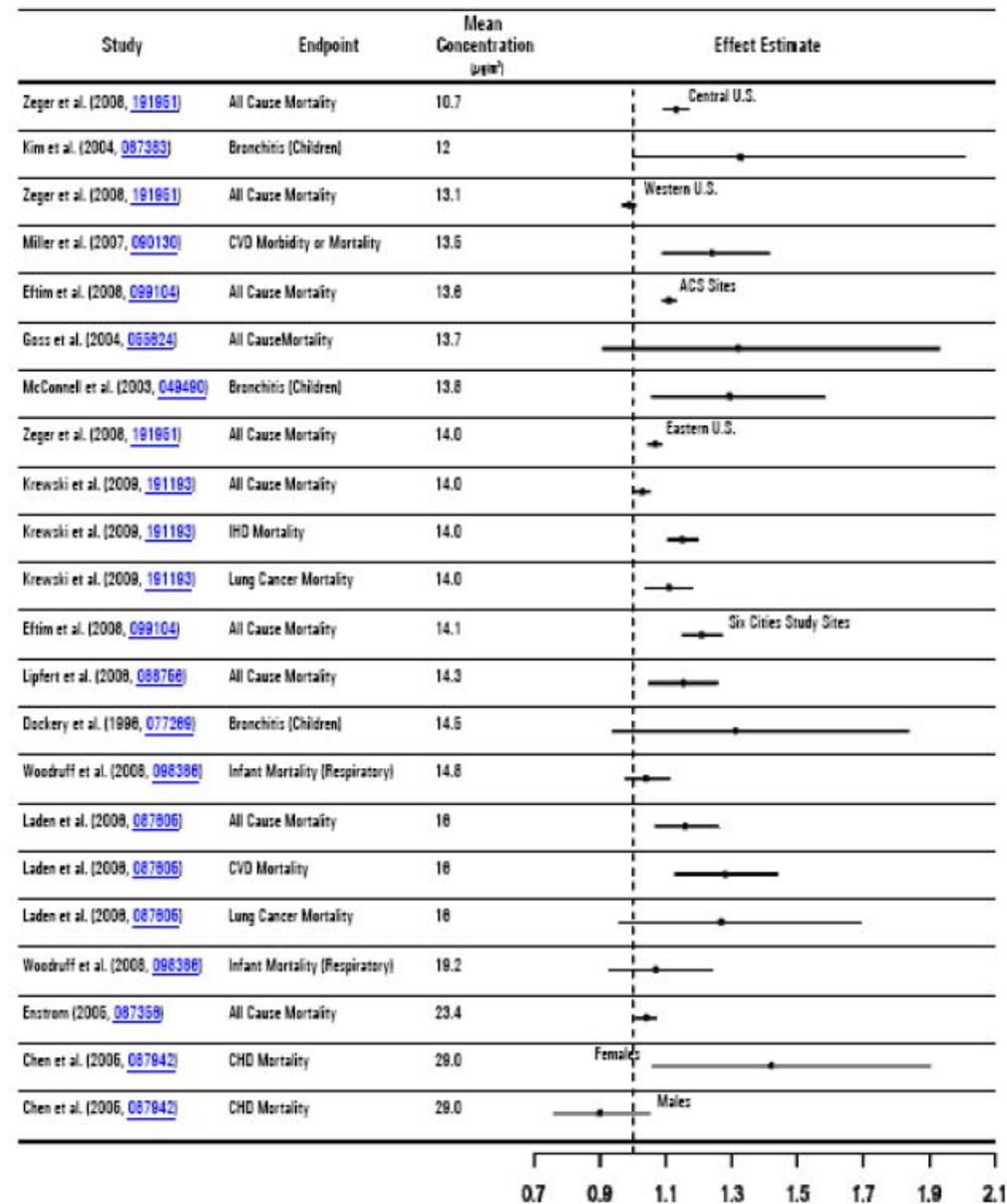
# Epidemiologic Effect Estimates for Short-Term Exposures to PM<sub>2.5</sub>

- Mean concentrations ranged from 6.1 to 22  $\mu\text{g}/\text{m}^3$
- Effects more precise and consistently positive with mean PM<sub>2.5</sub> concentrations  $\geq 13 \mu\text{g}/\text{m}^3$



# Epidemiologic Effect Estimates for Long-Term Exposures to PM<sub>2.5</sub>

- Mean concentrations ranged from 10.7 to 29.0  $\mu\text{g}/\text{m}^3$
- Effects more precise and consistently positive with mean PM<sub>2.5</sub> concentrations  $\geq 13.5 \mu\text{g}/\text{m}^3$

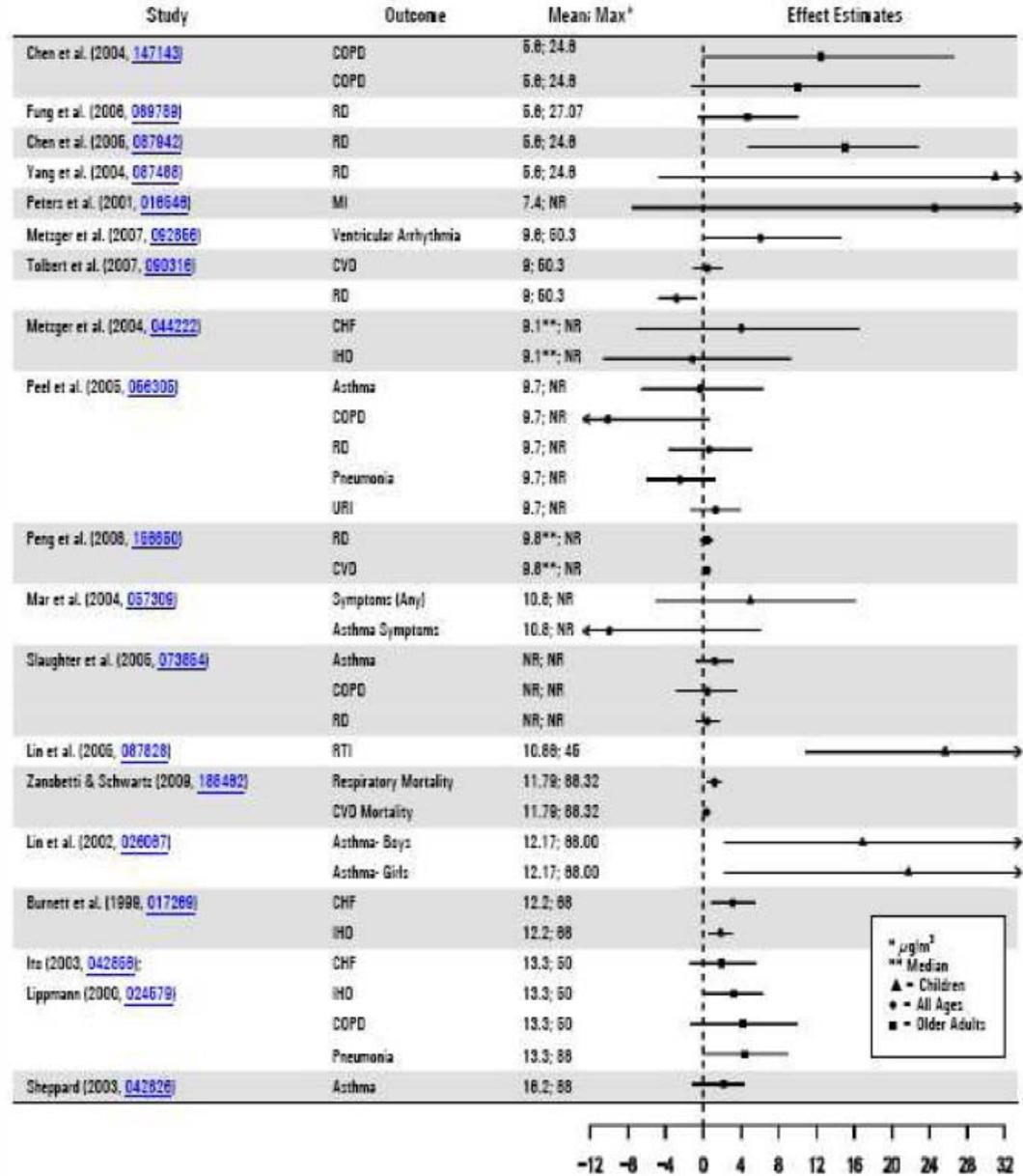


# Causality Determinations for Exposures to PM<sub>10-2.5</sub>

Health Category	Short-term Exposure	Long-term Exposure
Cardiovascular Effects	<b>Suggestive</b>	Inadequate
Respiratory Effects	Suggestive	Inadequate
Central Nervous System	Inadequate	-----
Mortality	Suggestive	Inadequate
Reproductive and Developmental	-----	Inadequate
Cancer, Mutagenicity, Genotoxicity	-----	Inadequate

# Epidemiologic Effect Estimates for Short-Term Exposures to PM<sub>10-2.5</sub>

- Mean concentrations ranged from 5.6 to 13  $\mu\text{g}/\text{m}^3$
- Of the maximum concentrations obtained, the range is 25-88  $\mu\text{g}/\text{m}^3$



# Causality Determinations for Exposures to Ultrafine PM

Health Category	Short-term Exposure	Long-term Exposure
Cardiovascular Effects	<b>Suggestive</b>	Inadequate
Respiratory Effects	<b>Suggestive</b>	Inadequate
Central Nervous System	Inadequate	-----
Mortality	Inadequate	Inadequate
Reproductive and Developmental	-----	Inadequate
Cancer, Mutagenicity, Genotoxicity	-----	Inadequate

# Causality Determinations for Welfare Effects of PM

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Welfare Effect	Causality Determination
Effects on Visibility	Causal
Effects on Climate	Causal
Ecological Effects	<b>Likely to be Causal</b>
Effects on Materials	Causal

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# PM ISA Revisions

## *Chapter 3 (Source to Human Exposure)*

- Included additional summaries of 2004 PM AQCD findings
- Reorganized size-specific sections: PM<sub>2.5</sub>, PM<sub>10-2.5</sub>, PM<sub>10</sub>, ultrafine
- Added new elements to the discussions on PM morphology, deposition, diesel emissions, PM<sub>10-2.5</sub> measurement techniques and satellite measurements
- Enhanced discussion on monitoring networks and spatial scales
- Expanded discussion on ultrafine particle composition and spatial variability including near-road environments
- Added analysis of PM constituent trends and hourly variability
- Expanded modeling discussion and consolidated it into a new section
- Reorganized exposure section by spatial scale and provided additional discussion of PM<sub>10-2.5</sub>, ultrafine PM, and multipollutant issues

# PM ISA Revisions

## *Chapters 4 (Dosimetry) and 5 (MOA)*

- Chapter 4 (Dosimetry)
  - Added section on modulation of deposition by physical activity
  - Updated section on tracheobronchial clearance
  - Added new discussion on effects of asthma, acute inflammation, and epithelial permeability to section on factors that modulate clearance
  - Added paragraph on leachable metals to clearance kinetics section
  
- Chapter 5 (Mode of Action)
  - Added paragraphs on ultrafine PM
  - Expanded discussions of:
    - neutrophilic inflammation
    - epithelial permeability
    - factors that affect resolution of inflammation/progression or exacerbation of disease
    - neural reflexes
    - translocation of PM or soluble PM components
    - additional gaps in knowledge
  - Added sections on epigenetics, lung development, atherosclerosis, and acute/chronic responses

## PM ISA Revisions *Chapters 6 and 7 (Health Chapters)*

- Refocused use of PM<sub>10</sub> studies as supportive for PM<sub>2.5</sub> or PM<sub>10-2.5</sub> causality determinations
- Changed causality determinations for a few health categories
- Used morbidity and cause-specific mortality evidence for causality determinations for cardiovascular and respiratory effects
- Considered controlled human exposure and toxicological studies of fresh diesel and gasoline exhaust as part of ultrafine PM evidence, as well as PM<sub>2.5</sub> evidence
- Included lung cancer mortality studies and toxicological studies conducted using intratracheal instillation and dermal routes of exposure to better characterize PM cancer effects
- Added new sections on epidemiologic studies of allergic responses and host defense

# PM ISA Revisions

## *Chapter 8 (Susceptible Subpopulations)*

- Revised definition for susceptibility:
  - populations that have a greater likelihood of experiencing health effects related to PM exposure
- Reorganized discussion for each susceptibility factor to:
  - Clearly identify whether the evidence is from studies of short- or long-term exposure
  - Focus the evidence on studies that examined health effects of PM<sub>2.5</sub> and PM<sub>10-2.5</sub>, while using PM<sub>10</sub> studies as supporting evidence where applicable



# Susceptible Subpopulations

Factor	Exposure	PM Size Fraction Evaluated
Children (< 18) <sup>15</sup>	Short-term	PM <sub>2.5</sub> , PM <sub>10-2.5</sub> , PM <sub>10</sub>
Older Adults (≥ 65)	Short-term	PM <sub>2.5</sub> , PM <sub>10-2.5</sub> , PM <sub>10</sub>
	Long-term	PM <sub>2.5</sub>
Pregnancy and Developmental Effects	Long-term	PM <sub>2.5</sub>
Gender	Short-term	PM <sub>2.5</sub> , PM <sub>10</sub>
	Long-term	PM <sub>2.5</sub> , PM <sub>10-2.5</sub> , PM <sub>10</sub>
Race/Ethnicity	Short-term	PM <sub>2.5</sub> , PM <sub>10</sub>
Genetic polymorphisms	Short-term	PM <sub>2.5</sub>
	Long-term	PM <sub>10</sub>
Cardiovascular Diseases	Short-term	PM <sub>2.5</sub> , PM <sub>10</sub>
	Long-term	PM <sub>2.5</sub>
Respiratory Illnesses	Short-term	PM <sub>2.5</sub> , PM <sub>10</sub>
	Long-term	PM <sub>10</sub>
Respiratory Contributions to Cardiovascular Effects	Short-term	PM <sub>2.5</sub> , PM <sub>10</sub>
Diabetes	Short-term	PM <sub>10</sub>
Obesity	Short-term	PM <sub>2.5</sub>
Health Status (e.g., Nutrition)	Short-term	PM <sub>2.5</sub>
Socioeconomic Status (SES)	Short-term	PM <sub>2.5</sub> , PM <sub>10-2.5</sub> , PM <sub>10</sub>
Educational Attainment	Short-term	PM <sub>2.5</sub> , PM <sub>10</sub>
	Long-term	PM <sub>2.5</sub>
Residential Location	Short-term	PM <sub>10</sub>

# PM ISA Revisions

## *Chapter 9 (Welfare Effects)*

### 9.2 Effects on Visibility

- Added new section on *Direct Optical Measurements*
- Added new section on *Value of Good Visual Air Quality*
- Several figures revised for clarity and consistency

### 9.3 Effects on Climate

- Expanded section on aerosol effects on climate with more details from the latest NOAA, NASA, and EPA and IPCC reports
- Described specific effects from specific size- and component-fractions in more detail
- Edited text for precision and flow
- Added more detail to climate section summary and carried through to summaries in Chapters 9 and 2

### 9.4 Ecological Effects

- Reorganized to focus on types of effects (i.e., direct vs. indirect) and effects of individual PM components (i.e., metals and organics)
- Added studies and revised causal determination



# Risk Assessment to Support the Review of the PM NAAQS – Second External Review Draft

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## Clean Air Scientific Advisory Committee Review Meeting



Office of Air Quality Planning  
and Standards

U.S. EPA

March 10, 2010



# Enhancements and Modifications for the 2<sup>nd</sup> Draft RA

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- New integrated discussion (Chapter 6)
- Expanded discussion of rationale for:
  - Excluding PM<sub>10-2.5</sub> from quantitative risk assessment
  - Design elements in the core analysis (selection of epidemiology studies and specification of C-R functions)
  - Approach for qualitatively assessing variability and uncertainty
- Expand sensitivity analysis:
  - Consider impact of different lags in modeling short-term morbidity endpoints
  - Compare results of the sensitivity analysis with the magnitude of uncertainty in statistical fit of the effect estimates



# Enhancements and Modifications for the 2<sup>nd</sup> Draft RA (contd.)

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- Inclusion of peak shaving rollback method (to represent more localized patterns of reductions in ambient PM<sub>2.5</sub> levels)
- Use of composite monitor PM<sub>2.5</sub> levels as a surrogate for long-term exposure-related mortality in assessing impact of different rollback methods
- Expanded use of results of the sensitivity analysis (as an additional set of reasonable risk estimates) to inform consideration of uncertainty in core risk estimates
- Considered interplay of annual and 24-hour design values together with patterns in PM<sub>2.5</sub> monitoring data in helping to interpret patterns of risk reduction for study areas



## Requested CASAC Feedback - Chapter 3 (Urban Case Study Analysis Methods)

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- Air quality inputs – inclusion of peak shaving rollback method (along with proportional and hybrid)
  - Use of composite monitor annual-average  $PM_{2.5}$  levels as surrogate for long-term exposure-related mortality
  
- Selection of model inputs for the core analysis- expanded discussion of our rationale
  - Particularly for selection of epidemiology studies and specification of C-R functions
  
- Addressing uncertainty and variability
  - Clarified process for qualitatively assessing sources of variability
  - Added coverage for specific sources of variability in our sensitivity analysis
  - Expanded discussion of qualitative analysis of uncertainty
    - Considered pair-wise interactions of sources of uncertainty



## Requested CASAC Feedback - Chapter 4 (Urban Case Study Results)

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- Sensitivity analysis – use of results as an additional set of risk estimates to inform consideration of uncertainty
- Consideration of design values and patterns of PM<sub>2.5</sub> monitoring data across study areas in interpreting risk estimates



## Requested CASAC Feedback - Chapter 6 (Integrated Discussion)

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- Captures key policy-relevant questions in integrating results of the various analyses
- Consideration of range of factors in interpreting core risk estimates
  - Interplay of annual and 24-hour design values
  - Peakiness of PM<sub>2.5</sub> distributions within study areas
  - Application of different rollback approaches (and impacts on degree of risk reduction)
- Assessment of confidence associated with core risk estimates – based on:
  - Sensitivity analysis results
  - Consideration for qualitative analysis of uncertainty and variability
- Results of several national-scale analyses used to place risk estimates in broader national-context
  - National-scale PM<sub>2.5</sub> mortality analysis
  - Representativeness analysis
  - (new) exploration of design values and patterns in PM<sub>2.5</sub> monitoring data



## Requested CASAC Feedback - Chapter 6 (Integrated Discussion) (contd.)

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### ■ Key observations:

- Alternative annual standard levels provide more consistent level of public health protection and have higher overall confidence relative to alternative 24-hour standard levels
- Potential utility in estimating risk for alternative annual standard levels below  $12 \mu\text{g}/\text{m}^3$



## SUPPLEMENTAL INFO: Additional Preliminary Analysis: Alternative Annual Standard Level of 10 $\mu\text{g}/\text{m}^3$

- Completed preliminary estimates of long-term exposure-related mortality risk for: 10/35 and 10/25

Comparison of risk for 12/35 against 12/25 and 10/35 (percent of long-term exposure-related IHD mortality attributable to  $\text{PM}_{2.5}$  - reflects proportional rollback)

Risk Assessment Location	Percent reduction compared with 12/35		Annual average $\text{PM}_{2.5}$ (for 12/25)
	For 12/25	For 10/35	
Dallas, TX	0%	34%	12
Houston, TX	0%	37%	12
Atlanta, GA	3%	32%	11.8
Birmingham, AL	18%	36%	11.1
St. Louis, MO	22%	36%	10.8
Baltimore, MD	23%	36%	10.7
Detroit, MI	35%	39%	10.2
Philadelphia, PA	35%	35%	10
Phoenix, AZ	43%	42%	9.9
New York, NY	43%	36%	9.7
Pittsburgh, PA	42%	35%	9.7
Los Angeles, CA	63%	45%	9.2
Fresno, CA	64%	0%	7.3
Tacoma, WA	94%	0%	6.3
Salt Lake City, UT	100%	0%	5.7



# Second Draft Urban Focused Visibility Assessment (UFVA) Secondary PM NAAQS Review

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## Clean Air Scientific Advisory Committee



0 deciview –  $10 \text{ Mm}^{-1}$

25 deciview –  $122 \text{ Mm}^{-1}$



20 deciview –  $74 \text{ Mm}^{-1}$

30 deciview –  $201 \text{ Mm}^{-1}$

Office of Air Quality  
Planning and Standards

U.S. EPA

March 11, 2009



## Enhancements and Modifications in the Second Draft UFVA

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- Conducted logit regression analysis on response curves from the 4 urban area preference studies
- Conducted logit analysis comparing various components of the Washington DC focus group studies (in a supplemental document)
- Replaced the 95% relative humidity cap with a 90% relative humidity screen for all current and rollback data assessments - includes an assessment of the effectiveness of the relative humidity screen
- Added 98<sup>th</sup> percentile form to 90<sup>th</sup> and 95<sup>th</sup> percentiles for the list of LE scenarios
- Added all daylight hours analysis to the maximum daily daylight hours for scenarios, shows relationships between all hours and maximum daily daylight hour forms
- New tile plot displays of daylight hourly data for 15 cities



## Requested CASAC Feedback- Second Draft UFVA

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- Document organization and usefulness of included materials
- Logit analysis (Chapter 2) of UFVA and supplemental memorandum
- Analysis of the frequency of co-occurrences of hourly relative humidity values below and above 90 percent with other meteorological events such as rain or fog (Chapter 3, section 3.3.5; Table 3-6)
- Addition of NAAQS scenarios that considered:
  - all daylight hours
  - the 98<sup>th</sup> percentile form (along with 90<sup>th</sup> and 95<sup>th</sup> percentiles)



# National Ambient Air Quality Standards (NAAQS) for Particulate Matter (PM) Schedule and Overview of Policy Assessment (Primary Standards)



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March 10, 2010



## Chapter 2 - Primary Standards for Fine Particles Adequacy of Current Standards

*Does the currently available scientific evidence and risk-based information, as reflected in the ISA and second draft RA, support or call into question the adequacy of the protection afforded by the current suite of fine particle standards?*

- Evidence-based considerations
  - Newly available evidence of associations
  - Susceptible populations
  - Air quality data from epidemiological studies
- Risk-based considerations
  - Nature, magnitude, and uncertainties of long- and short-term exposure related-risks
  - Roles of annual and 24-hour standards
  - Representativeness of urban study areas



## Chapter 2 - Primary Standards for Fine Particles Alternative Standards

*What alternative suites of fine particle standards are supported by the currently available scientific evidence and risk-based information, as reflected in the ISA and 2<sup>nd</sup> draft RA?*

- Indicator
  - PM<sub>2.5</sub> mass-based indicator
  - Ultrafine particles
  - Components
- Averaging Times
  - Annual and 24-hour averaging times
  - Subdaily
  - Seasonal



## Chapter 2 - Primary Standards for Fine Particles Alternative Standards (cont.)

- Forms - additional air quality analyses planned to inform 2<sup>nd</sup> draft PA
  - Annual standard - discuss in conjunction with alternative levels
  - 24-hour standard - consider current form (98<sup>th</sup> percentile value)
- Levels
  - Evidence-based considerations
    - Air quality data from epidemiological studies
    - Susceptible populations
  - Risk-based considerations
    - Nature, magnitude, and uncertainties of long- and short-term exposure related risks
    - Roles of annual and 24-hour standards
  - Integration



## Chapter 3 - Primary Standard for Thoracic Coarse Particles: Adequacy of Current Standard

*Does the currently available scientific evidence, as reflected in the ISA, support or call into question the appropriateness of maintaining a standard to protect against effects associated with exposure to thoracic coarse particles and the adequacy of the protection afforded by the current 24-hour  $PM_{10}$  standard against those effects?*

- Newly available evidence of associations
- Susceptible populations
- Air quality data ( $PM_{10}$ ) from epidemiological studies
- Important uncertainties



## Chapter 3 - Primary Standards for Thoracic Coarse Particles: Alternative Standards

*What alternative standards to protect against exposures to  $PM_{10-25}$  could be supported by the currently available scientific evidence, as reflected in the ISA?*

- Indicator
  - Protection for all thoracic coarse particles
  - Urban and non-urban environments
- Averaging Time
  - Continued use of 24-hour averaging time
- Level and Form
  - Additional analyses planned to inform 2<sup>nd</sup> draft PA

# The New Process

- Detailed response to CASAC review
- Truly *integrated* synthesis
- Advancement of outcomes to REA based on strength of evidence
- Clear framework for REA
- Transparent linkages of REA to Policy Assessment