United States Environmental Protection Agency (US EPA)

Workshop on Ultrafine Particles: Summary and Potential Next Steps

Beth M. Hassett-Sipple

Air, Climate, and Energy Research Team
US EPA Office of Research and Development
July 1, 2015

Overview

- Background
  - US EPA particulate matter (PM) national ambient air quality standards (NAAQS) review completed in 2012
- Purpose and scope of February 2015 workshop
- Key discussion topics
- Next steps under consideration

National Ambient Air Quality Standards (NAAQS) - Statutory Requirements

- Primary (health-based) standards . . . in the "judgment of the (US EPA) Administrator" are "requisite" to protect public health with an "adequate margin of safety"
  - "Requisite" means 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
  - Includes consideration of potential impacts in at-risk populations or lifestages
- Secondary (welfare-based) standards "…specify a level of air quality the attainment and maintenance of which" in the "judgment of the (US EPA) Administrator" is "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 . . ."
  - Determining what is adverse to the public welfare requires policy judgments about the societal impact of adverse effects to crops, vegetation, etc.

US EPA Sets, then Implements, NAAQS

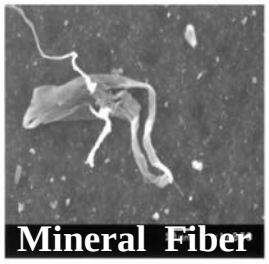
- US EPA has established national ambient air quality standards (NAAQS) for six pollutants
  - **Particulate matter**
  - Carbon monoxide
  - Nitrogen dioxide
  - Ozone
  - Lead
  - Sulfur dioxide
- US Clean Air Act outlines a 2-step process for setting and then meeting NAAQS
  - Step 1 is ***setting the standards***, which requires EPA to conduct an extensive scientific review to determine whether new standards are necessary to protect public health and welfare
    - U.S. Clean Air Act requires periodic review of the science and the standards, and bars EPA from considering cost in setting the NAAQS
  - Step 2 is ***implementing the standards***, which involves states putting measures and programs in place to reduce harmful pollution to meet the standards
    - US Clean Air Act specifies that cost, technical feasibility and the time needed to meet the standards are all factors that should be taken into account in this step

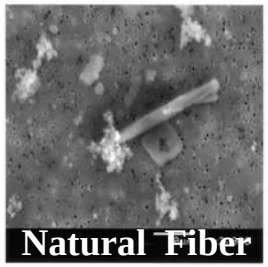
Major Elements of the NAAQS

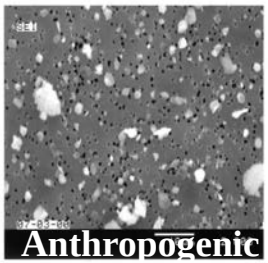
- Indicator**:** Identifies the chemical species or mixture that is to measured in ambient air (e.g., O_3, $PM_{2.5}$)
- Averaging time**:** Defines the time period over which ambient measurements are averaged (e.g., 8-hour, annual)
- Form**:** Defines the air quality statistic that is to be compared to the level of the standard in determining whether an area attains the standard (e.g., 4^{th} max, 98^{th} percentile)
- Level**:** Defined in terms parts per million (ppm), parts per billion (ppb), micrograms per cubic meter ($\mu g/m^3$)
- The **relative protection** afforded by a standard or suite of standards is a **function of all four elements**

Particulate Matter (PM) Size Range

PM is a complex mixture of solid, semi-volatile and aqueous materials of various sizes found in the air.



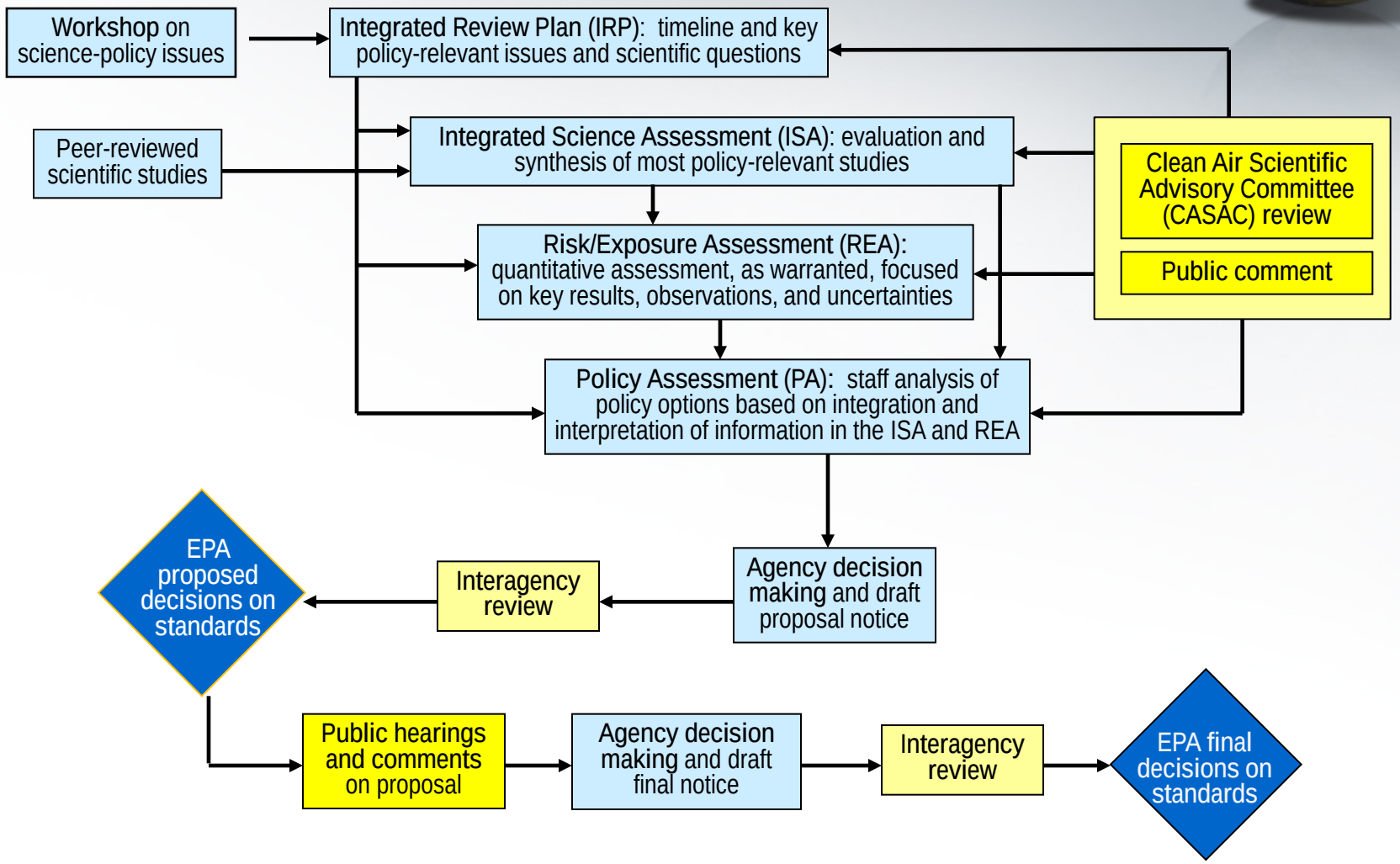




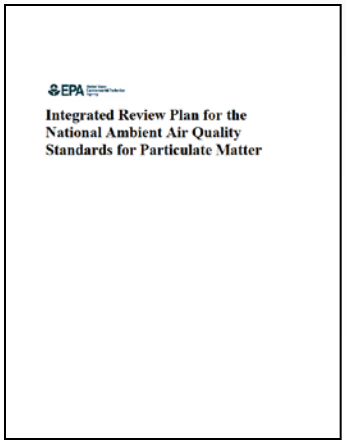
History of U.S. Particulate Matter (PM) NAAQS

- **1971:** Standards set for Total Suspended Particulates (TSP)
- **1987:** Indicator revised to PM_{10} to focus on the subset of inhalable particles small enough to penetrate to the thoracic region of respiratory tract
- **1997:** Separate standards set for fine ($PM_{2.5}$ indicator) and coarse (PM_{10} indicator) fractions
- **2006:** Revised level of 24-hour $PM_{2.5}$ standards (65 to 35 µg/m^3), retained level of annual $PM_{2.5}$ standards (15.0 µg/m^3)
- **2012:** Lowered the level of the $PM_{2.5}$ annual standard from 15.0 to 12.0 µg/m^3 and retained the 24-hour standard
  - Also, required the location of a small number of monitors to measure $PM_{2.5}$ near heavily traveled roads in areas with populations ≥1 million

Overview of the Process for Reviewing NAAQS



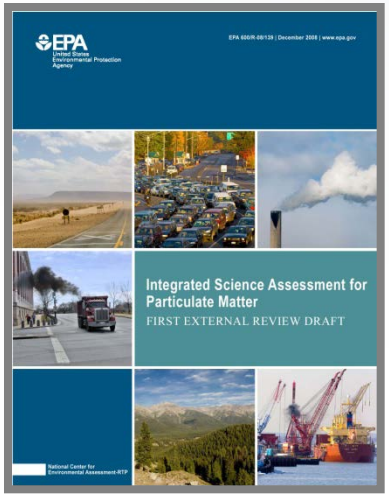
PM NAAQS Review Documents
(review completed in 2012)



Integrated Review Plan

Draft – Oct 2007

Final – Mar 2008

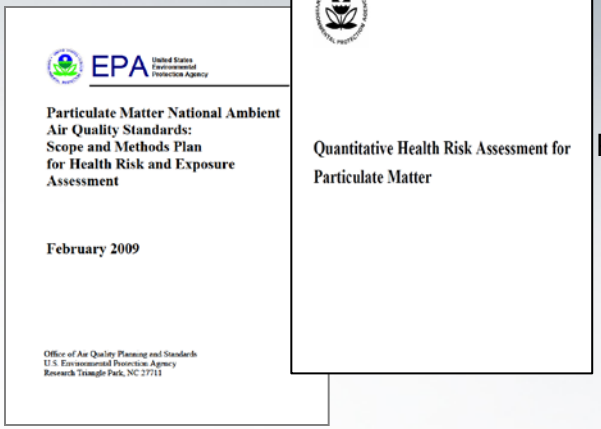


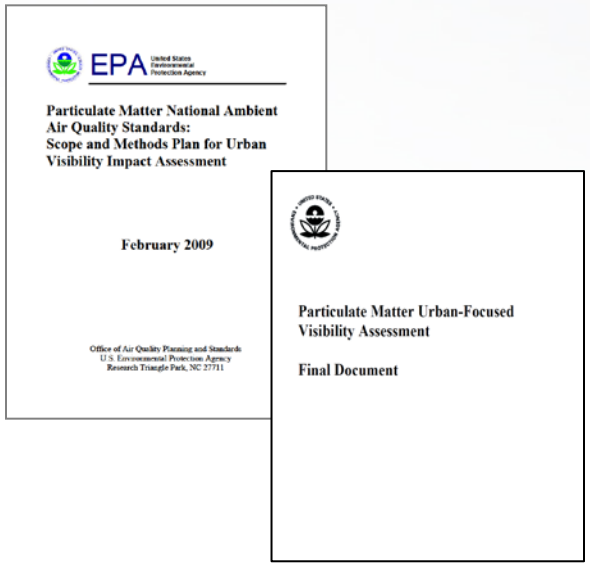
Integrated Science Assessment

1st Draft - Dec 2008

2nd Draft – July 2009

Final – Dec 2009





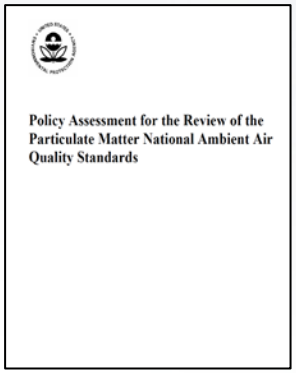
Risk/Exposure Assessments

Planning Documents - Feb 2009

1st Drafts – Sept 2009

2nd Drafts – Feb 2010

Final – Jun/Jul 2010



Policy Assessment

Preliminary Draft - Sept 2009

1st Draft – Mar 2010

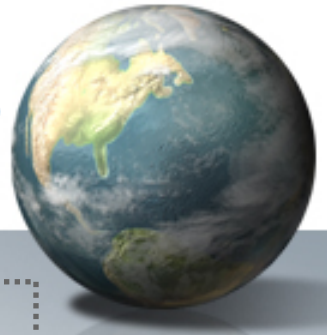
2nd' Draft – Jun 2010

Final – Apr 2011

UFPs: Key Questions Posed in PM NAAQS Review Completed in 2012

- What role does the ultrafine mode of PM play in the air pollution story?
- To what extent does the available information provide support for considering a separate indicator for ultrafine particles (UFPs)?

Integrated Science Assessments (ISAs)



ISAs consider and integrate policy-relevant information across a wide range of scientific disciplines

- Atmospheric science
- Exposure science
- Human and animal toxicology
- Epidemiology
- Ecology

- Availability and relative importance of different types of evidence varies by pollutant or assessment

ISAs: Weight-of-Evidence Approach

- *Transparency through structured framework*
- *Five categories based on weight-of-evidence*

Relevant Pollutant Exposures

- Causal relationship
- Likely to be a causal relationship
- Suggestive, but not sufficient, to infer a causal relationship
- Inadequate to infer a causal relationship
- Not likely to be a causal relationship

Health or Environmental Effects

Framework for Causal Determinations in the ISAs

Causal relationship	Evidence is sufficient to conclude that there is a causal relationship with relevant pollutant exposures (e.g., doses or exposures generally within one to two orders of magnitude of current levels). That is, the pollutant has been shown to result in health effects in studies in which chance, confounding, and other biases could be ruled out with reasonable confidence. For example: (1) controlled human exposure studies that demonstrate consistent effects; or (2) observational studies that cannot be explained by plausible alternatives or that are supported by other lines of evidence (e.g., animal studies or mode of action information). Generally, the determination is based on multiple high-quality studies conducted by multiple research groups.
Likely to be a causal relationship	Evidence is sufficient to conclude that a causal relationship is likely to exist with relevant pollutant exposures. That is, the pollutant has been shown to result in health effects in studies where results are not explained by chance, confounding, and other biases, but uncertainties remain in the evidence overall. For example: (1) observational studies show an association, but copollutant exposures are difficult to address and/or other lines of evidence (controlled human exposure, animal, or mode of action information) are limited or inconsistent; or (2) animal toxicological evidence from multiple studies from different laboratories demonstrate effects, but limited or no human data are available. Generally, the determination is based on multiple high-quality studies.
Suggestive, but not sufficient, to infer a causal relationship	Evidence is suggestive of a causal relationship with relevant pollutant exposures, but is limited, and chance, confounding, and other biases cannot be ruled out. For example: (1) when the body of evidence is relatively small, at least one high-quality epidemiologic study shows an association with a given health outcome and/or at least one high-quality toxicological study shows effects relevant to humans in animal species; or (2) when the body of evidence is relatively large, evidence from studies of varying quality is generally supportive but not entirely consistent, and there may be coherence across lines of evidence (e.g., animal studies or mode of action information) to support the determination.
Inadequate to infer a causal relationship	Evidence is inadequate to determine that a causal relationship exists with relevant pollutant exposures. The available studies are of insufficient quantity, quality, consistency, or statistical power to permit a conclusion regarding the presence or absence of an effect.
Not likely to be a causal relationship	Evidence indicates there is no causal relationship with relevant pollutant exposures. Several adequate studies, covering the full range of levels of exposure that human beings are known to encounter and considering at-risk populations and lifestages, are mutually consistent in not showing an effect at any level of exposure.

- -Rule out chance, confounding, and other biases
- -Consistency, coherence, biological plausibility, high-quality studies

- -Multiple, high-quality studies show effects
- -Some uncertainty remains overall

- -Cannot rule out chance, confounding, other biases
- -Evidence is limited but supporting
- -Evidence is sizeable and generally but not entirely consistent

- Evidence is of insufficient quantity, quality, consistency

- Multiple studies consistently show no effect

2009 PM ISA Conclusions: Short- and Long-Term UFP Exposures

	Health Category	Causality Determination
Short-term Exposure	Mortality	Inadequate
	Cardiovascular Effects	Suggestive
	Respiratory Effects	Suggestive
	Central Nervous System	Inadequate
Long-term Exposure	Mortality	Inadequate
	Cardiovascular Effects	
	Respiratory Effects	
	Reproductive and Developmental	
	Cancer	

2009 PM ISA - UFP Health Evidence: Short-Term Exposures

Cardiovascular Effects *(Suggestive)*

- Largest body of evidence from controlled human exposure studies for changes in vasomotor function, coherence with toxicological studies
- More limited evidence for other effects (e.g., systemic oxidative stress, heart rate variability)
- Inconsistent epidemiological evidence for hospital admissions/emergency department visits, some evidence for changes in subclinical measures (e.g., arrhythmias)

Respiratory Effects *(Suggestive)*

- Toxicological evidence for oxidative, inflammatory, and allergic responses; controlled human exposure studies report decreases in pulmonary function and increases in pulmonary inflammation
- Limited and inconsistent epidemiological studies – symptoms and hospital admissions/emergency department visits

2009 PM ISA - UFP Health Evidence: Uncertainties and Limitations

- Chemistry/Exposure/Epidemiological Studies
  - Lack of data on ultrafine particle (UFP) composition
  - Lack of data on spatial/temporal evolution of UFP size distribution and chemical composition
  - Lack of UFP network limits number of studies conducted, specifically in U.S.
  - Relative lack of information on the spatial and temporal variability in UFP concentrations
    - Contributes to uncertainty in associations observed in studies
- Controlled Human Exposure/Toxicological Studies
  - Most UFP evidence from diesel exhaust studies
    - Unclear if the effects observed due to UFPs, larger particles (e.g., $PM_{2.5}$) or gaseous co-pollutants
  - UFP concentrated ambient particle (CAP) systems are limited in that the composition is modified when concentrated

Consideration of UFPs: PM NAAQS Review Completed 2012

- Final decisions based on consideration of available scientific evidence, air quality information, risk assessment, CASAC advice, public comments
  - Integrated Science Assessment (ISA) causal determinations reflected the overall uncertainties and limitations in the ultrafine particle (UFP) evidence across scientific disciplines
  - US EPA recognized limited nature of the available information characterizing ambient concentrations of UFPs
- Based on uncertainties and limitations in the health evidence and monitoring information, US EPA concluded that it was not appropriate at the time of the 2012 review to set a separate standard focused on UFPs
- This issue will be revisited as part of the current review of the particulate matter (PM) national ambient air quality standards (NAAQS)
  - Kickoff workshop for current review was held February 9-11, 2015

Workshop Purpose and Scope

- Gather international experts to review current state of the science, across scientific disciplines
  - Sources and emissions
  - Ambient measurements
  - Air quality modeling
  - Control strategies
  - Health effects assessment
- Consider how information has been used within different policy contexts to date, including internationally
- Provide opportunity to explore options for future research collaborations

Key Discussion Topics

- Ultrafine particles (UFPs) represent a complex mixture derived from many sources (emitted directly or formed in the atmosphere)
  - Combustion and atmospheric chemistry constantly generate UFPs
- Regulating by mass provides significant public health protection
  - Continued evaluation of constituents and unique physical attributes of UFPs warranted
- Size makes a difference – may alter deposition site, translocate systemically
- UFPs contribute little to mass but can have high surface reactivity
- Uncertainty related to characterizing UFP exposures
  - Limited routine monitoring
  - Potentially strong spatial and temporal variability
- Need to improve our understanding of potential health effects related to UFP exposures and role the ultrafine fraction plays in the air pollution "story"
  - Evidence *suggestive* but limited for cardiovascular and respiratory effects associated with short-term exposures; inadequate to infer a causal relationship for other health effects and for long-term exposures
  - Need to expand our understanding of UFPs within broader ambient mixture; specifically, differentiating effects of UFP from $PM_{2.5}$ and other co-pollutants

Key Issue

- Methods and metrics for identifying and characterizing emissions and impacts from ultrafine particle (UFP) exposures have not been consistent
  - Size, number, surface area, mass, element carbon (EC)…???
- As a result, integrating information across studies has been difficult and not conducive to adequately assessing potential health effects attributed to UFPs
- There may be more than one “right” metric

Various Metrics and Indicators Used

Current ambient PM NAAQS

Mass

- Ultrafine particles (UFPs) contribute very little to mass of $PM_{2.5}$
- Varying fractions considered (e.g., $PM_{0.1}$; $PM_{0.25}$)
- Currently, bulk of health outcomes are tied to $PM_{2.5}$ mass

Surface Area / Reactivity

- High UFP surface area may increase toxicity

Number

- UFP's exceedingly abundant
- Different cutoff diameters used (e.g., 100 nm, 200 nm, 500 nm)
- Solid particle count >23 nm (European PMP method for emissions)

Next Steps Under Consideration

- Develop workshop summary report (in progress)
- Identify strengths and limitations of available metrics
  - Explore options for developing consensus for metric(s) that will better integrate emissions and ambient measurements with future exposure and health studies
  - Evaluate and, as needed, develop refined methods to measure ultrafine particles (UFPs)
- Consider options, as appropriate, for expanding existing ambient monitoring networks
- Promote international collaborations and information exchange to improve our understanding of:
  - Emissions and control strategies
  - Air quality
  - Exposures
  - Health impacts
  - Role of UFPs vs. co-pollutants

Additional Information

- Ultrafine particle workshop materials available at: https://sites.google.com/site/2015ufpworkshop/home\
- Particulate matter national ambient air quality standard review documents from current and previous reviews: http://www.epa.gov/ttn/naaqs/standards/pm/s_pm_index.html
- Contacts:
  - Rich Baldauf, US EPA; baldauf.richard@epa.gov
  - Beth Hassett-Sipple, US EPA; hassett-sipple.beth@epa.gov