



# REVIEW OF THE NATIONAL AMBIENT AIR QUALITY STANDARDS FOR PARTICULATE MATTER

BACKGROUND, ANTICIPATED SCHEDULE, AND DRAFT  
INTEGRATED REVIEW PLAN

Presented to the CASAC PM Panel

May 23, 2016

# Outline of Presentation

## Background and History

- Overview of NAAQS statutory requirements, review process, schedule and purpose of the IRP
- Overview of current PM NAAQS and key decisions made in the last review

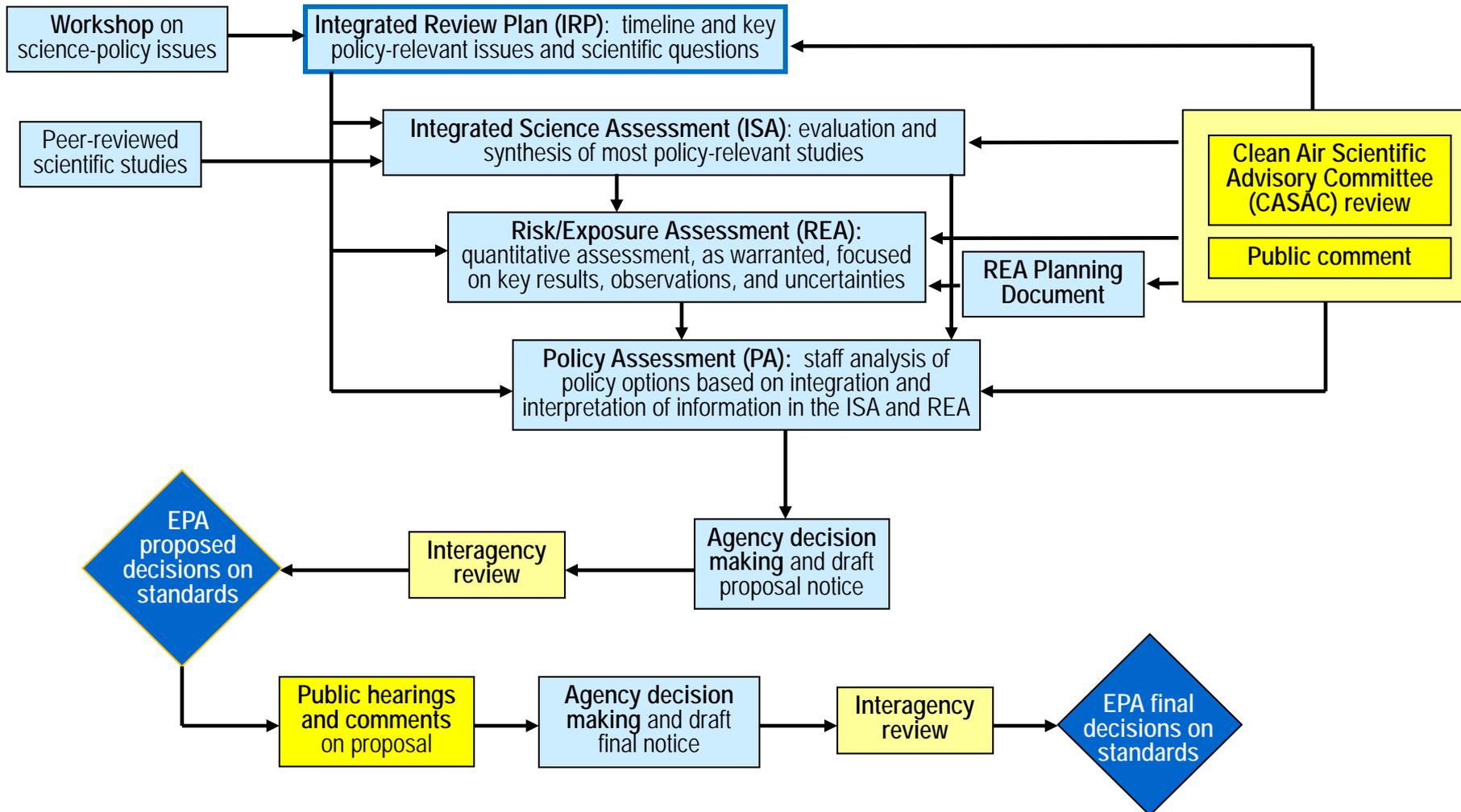
## Current Review

- Scope and overarching policy-relevant questions
- Integrated Science Assessment (ISA)
- Health and Welfare Risk and Exposure Assessments (HREA, WREA)
- Policy Assessment (PA)

# 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” means sufficient but not more than necessary
  - “Adequate margin of safety” is 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 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 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 whether the societal impacts of effects on visibility, ecosystems, materials etc. are adverse
- CAA does not require the elimination of risk; EPA is required to engage in “reasoned decision making”
- In setting NAAQS, the EPA may not consider implementation costs (*Whitman v. American Trucking Associations*)
  - In addition, “[a]ttainability and technological feasibility are not relevant considerations in the promulgation of national ambient air quality standards” (*American Petroleum Institute v. Costle*)

# Overview of the Process for Reviewing NAAQS



# Anticipated Schedule for Current Review of PM NAAQS

Stage of Review	Major Milestone	Target Date
Planning	Release Final IRP	September 2016
Science Assessment	Release First Draft ISA for CASAC/public review	Spring 2017
	CASAC Review Meeting for First Draft ISA	Summer 2017
	Release Second Draft ISA for CASAC/public review	Winter 2018
	CASAC Review Meeting for Second Draft ISA	Spring 2018
	Release Final ISA	Spring 2019
Risk/Exposure Assessments	Release REA Planning Document(s) for CASAC/public review	Spring/Summer 2017
	CASAC Review Meeting for REA Planning Document(s)	Summer 2017
	Develop REA(s)	2018 to 2019
Policy Assessment/ Rulemaking	Develop PA	2018 to 2020
	Proposed Rulemaking	2020
	Final Rulemaking	2021

# Purpose and Organization of the IRP

- Purpose of the IRP
  - Provides an overview of the history of the PM NAAQS and of the key policy-relevant issues that will guide the current review
  - Outlines the process for developing key assessment documents (ISA, HREA, WREA, PA), including the process for obtaining CASAC review and public input
  - Presents the anticipated schedule for the entire review
- The IRP **does not** present detailed assessments of the scientific evidence; detailed discussions of technical approaches for assessing exposures or risks or for adjusting air quality; or conclusions regarding the appropriateness of existing or potential alternative standards
- Organization of the draft IRP
  - Chapter 1: Background and review process; history; scope of review
  - Chapter 2: Decisions in last review; key issues in the current review; overview of PM monitoring networks
  - Chapter 3: Plan for the assessment of the scientific evidence in the ISA
  - Chapters 4 and 5: Considerations for the quantitative assessment of PM risks and exposures (chapter 4 - health; chapter 5 - welfare)
  - Chapter 6: Overview of the PA and the rulemaking phase of the review

# Overview of Current PM NAAQS

Current Standards					Decisions in 2012 Review
Indicator	Averaging Time	Primary/Secondary	Level	Form	
PM <sub>2.5</sub>	Annual	Primary	12.0 µg/m <sup>3</sup>	Annual arithmetic mean, averaged over 3 years	Revised level from 15 to 12 µg/m <sup>3</sup> *
		Secondary	15.0 µg/m <sup>3</sup>		Retained*
	24-hour	Primary and Secondary	35 µg/m <sup>3</sup>	98th percentile, averaged over 3 years	Retained
PM <sub>10</sub>	24-hour	Primary and Secondary	150 µg/m <sup>3</sup>	Not to be exceeded more than once per year on average over a 3-year period	Retained

\*EPA eliminated spatial averaging for the annual standards

# Overview of Decisions in the 2012 Review: Primary Standards

- **PM<sub>2.5</sub>**: Revised the level of the annual standard from 15 to 12.0  $\mu\text{g}/\text{m}^3$  and retained the 24-hour standard with its level of 35  $\mu\text{g}/\text{m}^3$ 
  - Strongest evidence was for premature mortality, cardiovascular effects, and respiratory effects; consistent evidence in epidemiologic studies with long-term average ambient PM<sub>2.5</sub> concentrations below 15.0  $\mu\text{g}/\text{m}^3$
  - 12.0  $\mu\text{g}/\text{m}^3$  was below the long-term mean concentrations in key epidemiology studies and corresponded to lower portions of distributions in studies for which population information was available
  - 24-hour standard retained to provide supplemental protection, particularly in areas with high peak-to-mean ratios of PM<sub>2.5</sub> concentrations
- **PM<sub>10</sub>**: Retained the existing PM<sub>10</sub> standard, with its level of 150  $\mu\text{g}/\text{m}^3$ 
  - PM<sub>10</sub> standard is meant to protect against PM<sub>10-2.5</sub> exposures; health evidence for PM<sub>10-2.5</sub> was considerably more uncertain than for PM<sub>2.5</sub>
  - Final decision to retain the existing PM<sub>10</sub> standard recognized important uncertainties in the extent to which additional public health benefits would be achieved by revising the existing PM<sub>10</sub> standard

# Overview of Decisions in the 2012 Review: Secondary Standards

- Retained the annual\* and 24-hour  $PM_{2.5}$  standards, and the 24-hour  $PM_{10}$  standard, based on visibility impairment and non-visibility effects
- **Visibility impairment:** The 24-hour  $PM_{2.5}$  standard “provides sufficient protection in all areas against the effects of visibility impairment” and “adoption of...a distinct secondary standard is not needed to provide sufficient protection from visibility impairment”
  - To reach this conclusion, EPA identified a target level of protection in terms of a  $PM_{2.5}$  visibility index (24-hour averaging time, 90<sup>th</sup> percentile form, 30 deciview level)
  - An analysis of  $PM_{2.5}$  air quality indicated that all areas meeting the existing 24-hour  $PM_{2.5}$  standard had visual air quality at least as good as that target level of protection
- **Non-visibility effects:** Appropriate to retain existing secondary standards to protect against PM-related non-visibility welfare effects; final decision noted the lack of information supporting different standards to protect against such effects
  - Non-visibility effects included ecological effects in plant and animal species, materials effects (damage, soiling) and climate effects

\*EPA eliminated spatial averaging for the annual standard

# Current Review: General Scope

- This review focuses on the air quality criteria for PM and on the primary and secondary NAAQS for PM<sub>2.5</sub> and PM<sub>10</sub>
  - Health and welfare effects associated with size fractionated PM mass; focus is on PM<sub>2.5</sub> and PM<sub>10-2.5</sub>
  - As available, we will also consider evidence for additional size fractions (e.g., ultrafine particles) and PM components
- This review of the secondary PM NAAQS will focus on visibility impairment, climate effects, materials damage and soiling (i.e., materials effects) and certain ecological effects
  - Specifically, the review of the secondary NO<sub>x</sub> and SO<sub>x</sub> NAAQS is addressing the ecological effects of ecosystem loading of oxides of nitrogen and oxides of sulfur, which includes particulate nitrogen and sulfur compounds

# Current Review: Policy-Relevant Questions

- Does the currently available scientific evidence and exposure/risk information support or call into question the **adequacy of the protection afforded by the current primary standards**?
  - IRP includes a list of more specific policy-relevant questions focused on the strength of the evidence for PM-attributable effects, at-risk populations, PM concentrations at which adverse effects occur, and uncertainties in the evidence
- What **alternative standards**, if any, are supported by currently available scientific evidence and exposure/risk-based information, and are appropriate for consideration?
  - IRP includes more specific policy-relevant questions focused on the basic elements of the NAAQS
  - Questions focus on the extent to which the science supports existing and/or alternative indicators, averaging times, forms, and levels

# ISA: Purpose and Scope

- **Purpose:** The ISA is intended to be a systematic and comprehensive, but also concise, evaluation of the science adequate to support the NAAQS review process
- **Scope:** The ISA is tasked with answering the question “Is there an independent effect of PM on health and welfare at relevant ambient concentrations?”
  - Studies will be considered if they include a composite measure of PM (e.g., PM<sub>2.5</sub> mass, PM<sub>10-2.5</sub> mass, ultrafine particle (UFP) number)
  - Studies on sources of PM (e.g., diesel exhaust, wood smoke, etc.) will be considered if they measured PM mass and examine effects with and without particle trap to assess particle effect
  - Studies of components of PM will be considered if they include a measure of PM mass to assess toxicity of component in comparison to mass (the current indicator)
  - Studies will be considered if PM exposures are relevant to ambient concentrations (< 2 mg/m<sup>3</sup>; 1 to 2 orders of magnitude above ambient concentrations)
  - For some welfare effects, additional nuances in the type of literature considered for inclusion:
    - Effects on Materials: include consideration of impacts of gaseous and particulate nitrogen and sulfur
    - Ecological Effects: deposited components of PM, but not nitrogen- and sulfur-containing compounds or their transformation products

# ISA: General Approach

- Applying the concepts of systematic review, the ISA will focus on health and welfare effects for which the evidence in the 2009 PM ISA was less certain (i.e., effects where the causality determination was “likely to be causal”, “suggestive”, or “inadequate” and where there is now a larger body of evidence)
  - For effects where a “causal relationship” was concluded in the 2009 PM ISA the discussion will be more streamlined, replacing text with tables and figures when warranted
    - However, if new lines of evidence are available (e.g., specific cardiovascular effect), an in-depth assessment of the new information will be conducted
  - Causality determinations will be made for short- and long-term exposures to PM<sub>2.5</sub>, PM<sub>10-2.5</sub>, and UFPs for the following health categories:
    - Cardiovascular Effects
    - Respiratory Effects
    - Central Nervous System Effects
    - Reproductive and Developmental Effects
    - Cancer, Mutagenicity, and Genotoxicity
  - Causality determinations will be made for the following welfare categories:
    - Effects on Visibility
    - Effects on Climate
    - Effects on Materials
    - Ecological Effects

# ISA: General Approach (cont.)

- Evaluation of PM<sub>10</sub> Evidence
  - Consistent with 2009 PM ISA, discussion of PM<sub>10</sub> studies will be focused on whether the evidence informs either PM<sub>2.5</sub> or PM<sub>10-2.5</sub>; no causal determinations will be made for PM<sub>10</sub>
- Evaluation of Cancer
  - Epidemiology
    - Evaluation of studies examining lung cancer mortality or lung cancer incidence and a composite metric of PM (i.e., PM<sub>2.5</sub>, PM<sub>10-2.5</sub>, etc.)
    - Studies of individual components of PM and cancer will not be included
  - Toxicology
    - In vitro studies will be discussed in the Mode of Action chapter
    - In vivo studies will be discussed in the Health Effects chapters
    - More environmentally relevant concentrations (i.e., < 2 mg/m<sup>3</sup>) are emphasized
    - More emphasis will be placed on studies using relevant exposure routes (e.g., inhalation)
    - Less emphasis will be placed on studies using PM extracts (bioavailability issue)
    - Studies of individual components of PM and cancer will not be included, except possibly in Mode of Action chapter
- CASAC reviews one or more drafts prior to EPA releasing a final ISA

# REA: Purpose and General Approach

## Purpose

- Drawing upon the information in the ISA, the REA(s) will present quantitative assessments of risks and exposures, as warranted, under various air quality scenarios
- The REA(s) will not present conclusions on the adequacy of existing or potential alternative standard(s)

## General Approach

- Prior to conducting quantitative analyses, we will release Health and Welfare REA (HREA, WREA) planning documents
  - Planning Documents will provide detailed consideration of, and preliminary conclusions regarding, the quantitative analyses that are warranted in this review, including the planned scope and approaches for any such analyses
- Planning Documents will be reviewed by CASAC and the public
  - EPA does not produce final Planning Documents, but instead considers CASAC recommendations and public comments in the design and when conducting the quantitative assessments
- If REAs are developed, CASAC reviews one or more drafts prior to EPA releasing the final REA(s)

# REA: Scope of Assessments to Be Considered

- Health (HREA): We will consider the extent to which the available information supports conducting an updated quantitative PM health risk assessment based on information from epidemiologic studies and/or a PM exposure assessment
  - For the epidemiology-based risk assessment, we will consider policy-relevant issues such as the shape of the C-R function and confidence in PM-attributable health effects at low ambient concentrations
  - In considering potential support for an exposure assessment, we will consider the insights that could be gained and the uncertainties that would be associated with PM exposure estimates
  - We will consider the extent to which quantitative analyses are warranted for PM<sub>2.5</sub> and PM<sub>10-2.5</sub>, as well as other potential PM metrics
- Welfare (WREA): We will consider the extent to which available information supports conducting quantitative analyses of PM-related visibility and non-visibility effects
  - Visibility: We will consider whether updated assessments of light extinction and/or of visibility preference studies are warranted in this review
  - Non-visibility: We will consider whether quantitative assessments of climate, ecological effects, and/or materials effects are warranted for this review

# PA: Purpose and General Approach

- **Purpose:** The PA will present staff considerations and conclusions regarding the adequacy of the existing PM standards and the potential alternatives, if any, appropriate to consider in the current review
  - The PA will integrate the information from the ISA and, as available, REA(s) to frame policy options for consideration by the Administrator
  - The PA is also intended to facilitate CASAC's advice to the Agency, and recommendations to the Administrator
- **Approach:** The general approach in the PA will be based on characterizing:
  - The range of PM concentrations over which the evidence indicates the greatest confidence in the occurrence of PM-attributable adverse effects of public health or welfare importance
  - The PM concentrations at which that confidence becomes appreciably lower
- The PA will recognize that final decisions will reflect public health and welfare policy judgments drawing upon available scientific information, including judgments about the uncertainties inherent in that information
- CASAC reviews one or more drafts prior to EPA releasing a final PA

# Additional Information

Documents from the current and previous PM NAAQS reviews are available at:  
[https://www3.epa.gov/ttn/naaqs/standards/pm/s\\_pm\\_index.html](https://www3.epa.gov/ttn/naaqs/standards/pm/s_pm_index.html)