



# **Integrated Review Plan for Review of the Ozone National Ambient Air Quality Standard**

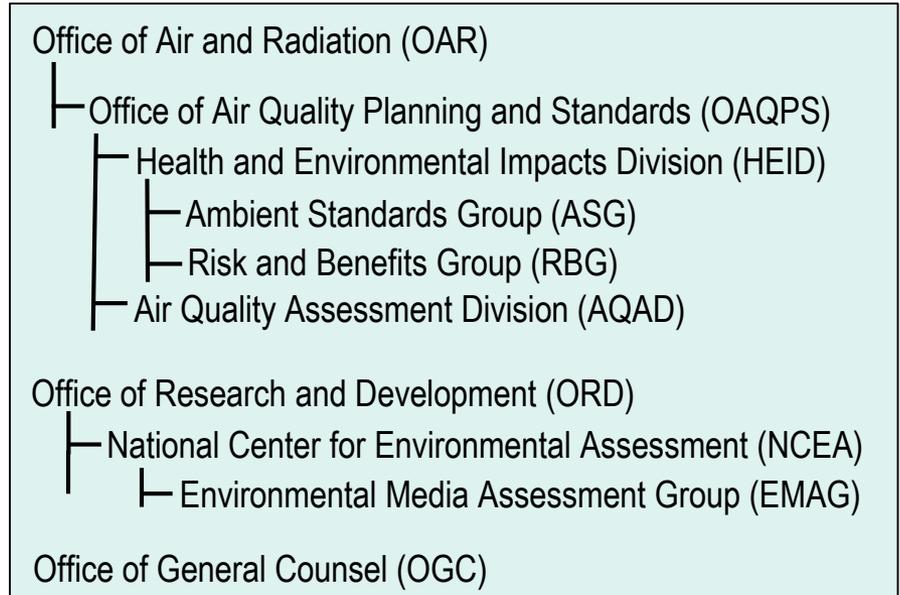
## **External Review Draft**

Office of Air Quality Planning and Standards  
and  
National Center for Environmental Assessment  
U.S. Environmental Protection Agency

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Clean Air Scientific Advisory Committee

# EPA Speakers

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- ORD/NCEA
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# Outline for Presentation

- Introduction and Background
  - Statutory Requirements
  - Initiation of Expedited Review
  - CASAC Role and Timeline in this Expedited Review
- Planning for this Review of the Ozone NAAQS
  - Current Ozone NAAQS: primary and secondary
  - Current Air Quality
  - Role of the Integrated Review Plan
  - Integrated Science Assessment (ISA)
  - Quantitative Risk and Exposure Assessment (REA analyses)
  - Policy Assessment (PA)
- Organization of Integrated Review Plan and Consultation Areas

# Statutory Requirements for the NAAQS

- EPA sets national ambient air quality standards (NAAQS) for six pollutants
  - Ground-level ozone
  - Carbon monoxide
  - Nitrogen dioxide
  - Particulate matter
  - Lead
  - Sulfur dioxide
- Sections 108 and 109 of the Clean Air Act govern the establishment, review, and revision (as appropriate) of NAAQS, including:
  - **Primary (health-based) standards** which in the “judgment of the Administrator” are “requisite to protect the public health”, including at-risk populations, with an “adequate margin of safety”
  - **Secondary (welfare-based) standards** which 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 . . .”
- The law requires EPA to review the scientific information and NAAQS for each criteria pollutant every five years, and to obtain advice from the Clean Air Scientific Advisory Committee (CASAC) on each review.
- Court decisions provide additional guidance on aspects of EPA decision-making
  - EPA is required to engage in “reasoned decision making” to translate scientific evidence into standards
  - EPA may not consider cost in setting standards; however, cost is considered in developing control strategies to meet the standards (implementation phase)

# Statutory Requirements for the NAAQS: CASAC

- Section 109(d)(2) addresses the appointment and advisory functions of an independent scientific review committee
  - Section 109(d)(2)(B) provides that, at 5-year intervals, this committee “shall complete a review of the criteria...and the national primary and secondary ambient air quality standards...and shall recommend to the Administrator any new...standards and revisions of existing criteria and standards as may be appropriate...”.
  - Section 109(d)(2)(C) reads: “Such committee shall also
    - (i) advise the Administrator of areas in which additional knowledge is required to appraise the adequacy and basis of existing, new, or revised national ambient air quality standards,
    - (ii) describe the research efforts necessary to provide the required information,
    - (iii) advise the Administrator on the relative contribution to air pollution concentrations of natural as well as anthropogenic activity, and
    - (iv) advise the Administrator of any adverse public health, welfare, social, economic, or energy effects which may result from various strategies for attainment and maintenance of such national ambient air quality standards.

# Initiation of Expedited Review (May 2018 memo)

## May 9, 2018 memo from the EPA Administrator:

- Directed the initiation of an expedited review of ozone NAAQS, targeting completion within statutorily-specified timeframe
  - Also specified expedited review of NAAQS for particulate matter
- Identified ways to streamline the review process (e.g., increased focus on policy-relevant information and avoiding multiple drafts of documents)
  - If efficiencies prove successful in ozone review, EPA should follow in future NAAQS reviews
- Identified standardized set of charge questions for CASAC including:
  - General charge questions for NAAQS reviews, to be supplemented with more detailed requests as necessary
  - Two additional charge questions that may elicit information not relevant to the standard-setting process.
    - EPA may consider an appropriate mechanism, including after receiving CASAC's final advice on the standards, to facilitate robust feedback on these topics

# Timeline and CASAC Role

Key Milestones in the Ozone NAAQS Review		
Date	EPA	CASAC
June 2018	Call for Information	
Fall 2018	Draft IRP	<b>Consultation</b> on plans for the review, including plans for ISA, REA analyses and PA
Early 2019	Final IRP	
Spring 2019	<b>Draft ISA</b>	<b>Review</b> of draft ISA, which provides an assessment of the currently available scientific information on public health and welfare effects of ozone and is the science foundation for the review ( <i>the air quality criteria</i> )
Fall 2019	<b>Draft PA</b> (with REA analyses)	<b>Review</b> of draft PA, which presents an evaluation of the policy-relevant aspects of the current scientific evidence and quantitative exposure, risk and air quality analyses, focusing on implications with regard to the adequacy of the current standards and, as appropriate, potential alternatives
	<b>Final ISA</b>	
	<b>Final PA</b>	
Spring 2020	<b>Proposed decision</b>	
Late 2020	<b>Final decision</b>	

# Planning for this Review: Current Ozone NAAQS

- **Primary standard** protects public health with an adequate margin of safety
  - 70 ppb, as the annual 4<sup>th</sup> highest daily maximum 8-hour average concentration, averaged over three years
  - Established with particular consideration of respiratory effects documented in controlled human exposure studies involving continuous exposure during quasi-continuous exercise, and quantitative estimates of exposure and risk
    - Supported by epidemiologic studies of association of array of health outcomes (including mortality) with ambient air concentrations, and mode of action information from toxicological studies in multiple species
- **Secondary standard** protects public welfare from known or anticipated adverse effects
  - 70 ppb, as the annual 4<sup>th</sup> highest daily maximum 8-hour average concentration, averaged over three years
  - Established with particular consideration of growth-related impacts on vegetation, ecosystems and their related services, and analyses of cumulative, seasonal exposures occurring in sites that would meet this standard
    - Additionally provided increased protection for other effects documented by the evidence base, such as visible foliar injury.

# Planning for this Review: Current Air Quality

- Ozone concentrations have trended downward over the past several decades in response to reductions in precursor emissions
  - For example annual 4<sup>th</sup> highest daily maximum 8-hour average concentrations have declined by 17% on average since 2000 at U.S. trends sites
  - Highest concentrations are in California, with recent concentrations at sites in Texas, the Northeast Corridor, along Lake Michigan and some western U.S. urban areas also exceeding the standard
- Anthropogenic emissions of nitrogen oxides and volatile organic compounds have declined by more than 40% and 15%, respectively, since 2002
- EPA continues efforts to improve estimation of natural and anthropogenic sources of precursor emissions and characterization of their impact on ozone concentrations nationally
  - Activities planned for the current review include updated state-of-the-science modeling for a more recent model year (e.g., 2016) to estimate relative contributions of natural and anthropogenic sources to ozone concentrations in the U.S.

# Planning for this Review: Role of the Integrated Review Plan

- Integrated Review Plan (IRP)
  - Describes process and schedule for the review
  - Identifies key policy-relevant issues that will guide the review
  - Provides context/background related to previous review
    - Key scientific issues, uncertainties, and decisions (and their rationales)
  - Describes planning for new/updated assessments (based on currently available information) to inform the Administrator's decisions in the review
    - Integrated Science Assessment (ISA)
    - Risk and Exposure Assessment (REA analyses)
    - Policy Assessment (PA)

Final IRP is prepared in consideration of comments from CASAC and the public

# Planning for this Review: Integrated Science Assessment

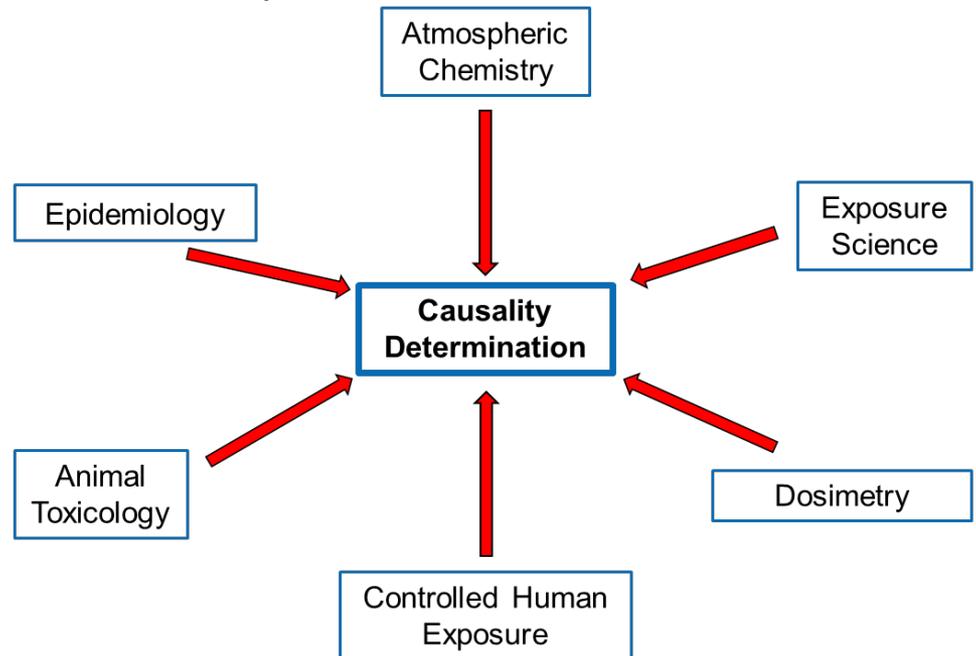
- **Purpose:** ISA is intended to be a comprehensive, but also concise evaluation that is adequate to support the NAAQS review process; provides the scientific foundation for each NAAQS review
- **Scope:** ISA is tasked with answering the question “Is there an independent effect of ozone on health and welfare (e.g., ecological effects and effects on climate) at relevant ambient concentrations?”
  - PECOS Statements: Used to guide:
    - Literature search strategy
    - Criteria for inclusion/exclusion
    - Type of data extracted
    - Integration
    - Synthesis of results

**P** = Population  
**E** = Exposure  
**C** = Comparison  
**O** = Outcome  
**S** = Study Design

# Developing the ISA: Example for Health Criteria

- Organize relevant literature for broad health outcome categories
- Evaluate studies, characterize results, extract relevant data
- Integrate evidence across disciplines for health outcome categories
- Develop causal determinations using established framework
- Evaluate evidence for populations potentially at increased risk
- Consideration of evidence spans many scientific disciplines from source to effect:

- Atmospheric chemistry
- Exposure
- Controlled human exposure studies
- Epidemiologic studies
- Animal toxicology studies
- At-risk populations/lifestages



# Framework for Causality Determinations in ISAs

- Promote consistency and transparency
- Emphasize synthesis of evidence across scientific disciplines
- Weight of evidence categories:
  - Causal relationship
  - Likely to be a causal relationship
  - Suggestive of, but not sufficient to infer, a causal relationship
  - Inadequate to infer a causal relationship
  - Not likely to be a causal relationship
- ISA Preamble describes this framework
  - Preamble is now stand-alone document (<http://www.epa.gov/isa>)
- CASAC supported development and use of this framework in many ISAs over the last 10 years



# Framework for Causality Determinations in the ISA

	Health Effects	Ecological and Other Welfare Effects
<b>Causal relationship</b>	<p>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 recent concentrations) that have been shown to result in health effects and other biases could be ruled out with reasonable confidence. (1) controlled human exposure studies that demonstrate consistent effects, or (2) observational studies that cannot be explained by chance, confounding, and other biases. Generally, the determination is based on multiple high-quality studies conducted by multiple research groups.</p>	<p>Evidence is sufficient to conclude that there is a causal relationship with relevant pollutant exposures. That is, the pollutant has been shown to result in health effects and other biases could be ruled out with reasonable confidence. Controlled exposure studies (laboratory studies) provide the strongest evidence for causality, but the scope of inference may be limited. Generally, the relationship is usually obtained from the joint consideration of many lines of evidence that reinforce each other.</p>
<b>Likely to be a causal relationship</b>	<p>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. For example: (1) observational studies where exposures are difficult to address and/or other lines of evidence 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.</p>	<p>Evidence is sufficient to conclude that there is a likely causal association with relevant pollutant exposures. That is, an association has been observed between the pollutant and the outcome in studies in which chance, confounding, and other biases are minimized but uncertainties remain. For example, field studies show a relationship, but suspected interacting factors and other lines of evidence are limited or inconsistent. Generally, the determination is based on multiple studies by multiple research groups.</p>
<b>Suggestive of, but not sufficient to infer, a causal relationship</b>	<p>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 study shows an association with a given 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.</p>	<p>Evidence is suggestive of a causal relationship with relevant pollutant exposures, but chance, confounding, and other biases cannot be ruled out. For example, at least one high-quality study shows an effect, but the results of other studies are inconsistent.</p>
<b>Inadequate to infer a causal relationship</b>	<p>Evidence is inadequate to determine that a causal relationship exists with relevant pollutant exposures. The available studies are of insufficient quality, consistency, or statistical power to permit a conclusion regarding the presence or absence of an effect.</p>	<p>Evidence is inadequate to determine that a causal relationship exists with relevant pollutant exposures. The available studies are of insufficient quality, consistency, or statistical power to permit a conclusion regarding the presence or absence of an effect.</p>
<b>Not likely to be a causal relationship</b>	<p>Evidence indicates there is no causal relationship with relevant pollutant exposures. Several adequate studies examining relationships with relevant exposure that human beings are known to encounter and considering at-risk populations and lifestyles, are mutually consistent in failing to show an effect at any level of exposure.</p>	<p>Evidence indicates there is no causal relationship with relevant pollutant exposures. Several adequate studies examining relationships with relevant exposure are consistent in failing to show an effect at any level of exposure.</p>

# Planning for this Review: Risk and Exposure Assessment

- In each NAAQS review, analyses of exposures, risk and air quality draw on information in ISA and prior assessments
- Considerations that shape the planning for updated/new quantitative analyses include:
  - Analyses from last review, associated uncertainties and ramifications on interpretation of results;
  - Newly available information, including health/welfare effects evidence, tools and methods; and,
  - What is indicated regarding types of analyses for which updates would be most informative
- Chapter 5 of draft IRP includes preliminary planning for this review of the O<sub>3</sub> primary and secondary standards
  - Overview of main analyses from last review
  - Summary of extent and type of uncertainties in quantitative analyses developed to inform decisions for each of the standards, and potential for newly available information, tools and methods to appreciably affect results (details in Appendices 5-A, 5-B)
  - Identification of the types of analyses for which updates may be most informative in this review
- The PA will consider new analyses, as well as prior analyses that remain informative in the current review
  - New/updated analyses will be documented in PA, including appendices and supplemental materials, as needed

# Planning for this Review: Policy Assessment

- In each review, the policy assessment (PA) presents a transparent evaluation of policy implications of the currently available scientific information and quantitative analyses pertaining to the existing standards for consideration by Agency
- This evaluation is framed by and organized around a set of policy-relevant questions which are summarized in the IRP (Chapter 3)
  - Do the currently available scientific evidence and exposure- and risk-based information support or call into question the adequacy of the public health/welfare protection afforded by the current primary/secondary O<sub>3</sub> standard?
    - Is there newly available evidence that may alter our understanding of key health/welfare effects, at-risk populations/ecosystems, exposures of potential concern?
      - Are previously identified uncertainties in the evidence reduced or do important uncertainties remain? Have new uncertainties emerged?
    - What are the nature and magnitude of O<sub>3</sub> exposures and associated health/welfare risks associated with air quality conditions just meeting the current standard? To what extent are the estimates reasonably judged important from a public health/welfare perspective?
      - What are the important uncertainties associated with any risk/exposure estimates?
- Review of the draft PA facilitates CASAC advice to the Agency on adequacy of current standards, and on revisions, as appropriate

# Organization of Integrated Review Plan

- Chapter 1: Introduction
  - Legislative requirements, NAAQS process, timeline
- Chapter 2: Background
  - Prior O<sub>3</sub> NAAQS reviews, air monitoring, data analysis, air quality overview
- Chapter 3: **Key Policy-relevant Issues for the Current Review**
  - General approach for current reviews of primary and secondary standards
  - Identification of key policy-relevant questions for review, which PA will initially consider
- Chapter 4: **Science Assessment**
  - ISA organization, assessment approach, areas of specific focus
- Chapter 5: **Quantitative Risk and Exposure Assessments**
  - Assessments in last review, considerations for any assessments in this review
- Chapter 6: **Policy Assessment**
  - Short overview of purpose, scope and development process
- Chapter 7: Proposed and Final Decisions
  - Short overview of process

# Focus for CASAC Consultation

## ***Overall organization, clarity and appropriate description of introductory, background and explanatory material:***

### Chapters 1 Introduction and 2 Background:

- Chapter 1 summarizes the legislative requirements (section 1.1), general NAAQS review process (section 1.2) and specific process and projected timeline for this review (section 1.3).
- Chapter 2 summarizes the history of O<sub>3</sub> NAAQS reviews (section 2.1), describes the O<sub>3</sub> air monitoring requirements (section 2.2.1), and summarizes the data analysis performed for comparison to the standards (section 2.2.2). Section 2.3.4 also provides an overview of current O<sub>3</sub> air quality and plans for further characterization in this review.

### Chapter 6 Policy Assessment and Chapter 7 Proposed and Final Decisions:

- Chapter 6 describes the role of and process for developing the Policy Assessment for the review. Chapter 7 summarizes the EPA's processes for the proposed and final decision-making steps in the review.

# Focus for CASAC Consultation (continued)

## ***Characterization of the key scientific issues for consideration in the current review:***

### Chapter 3 Key Policy-Relevant Issues for the Current Review:

- Section 3.1.1 summarizes key policy-relevant issues and the general approach for the current review of the primary standard. To provide context, section 3.1.2 additionally summarizes considerations and conclusions underlying the final decision in the last review.
- Section 3.2.1 summarizes the general approach and key policy-relevant issues for the current review of the secondary standard. To provide context, section 3.2.2 additionally summarizes considerations and conclusions underlying the final decision in the last review.

## ***The scope, approach, and identification of specific issues to be considered in the Integrated Science Assessment:***

### Chapter 4 Science Assessment:

- Chapter 4 describes the plan for the ISA, which will critically evaluate and integrate the scientific evidence on health and welfare effects of ozone in ambient air. Section 4.2 describes the ISA organization; section 4.3 describes the assessment approach.

# Focus for CASAC Consultation (continued)

***The key issues, uncertainties and limitations for consideration in decisions regarding quantitative analyses to be conducted in the current review:***

**Chapter 5 Quantitative Risk and Exposure Assessments:**

- Section 5.1.1 summarizes the human exposure and health risk assessments developed in the last review, and section 5.1.2 identifies key considerations for decisions on quantitative assessments to be conducted in the current review.
- Section 5.2.1 summarizes the air quality, exposure and risk assessments developed in the last review of the secondary standard; section 5.2.2 identifies key considerations for decisions on quantitative assessments to be conducted in the current review.



# Supplemental Material

# PECOS- Example (Experimental)

Exposure Duration and Health Effect	Population, Exposure, Comparison, Outcome, Study Design (PECOS) Statements
<p>Short-term exposure and respiratory, cardiovascular, metabolic, nervous system, reproductive or developmental effects</p>	<p>Among the study population of any controlled human exposure or animal toxicological study of mammals at any lifestage (P), of interest are the studies of the relationship between short-term (in the order of minutes to weeks) inhalation exposure to relevant O<sub>3</sub> concentrations (i.e., 0.4 ppm or below for humans, 2 ppm or below for other mammals) (E) and respiratory, cardiovascular, metabolic, nervous system, reproductive or developmental effects (O) when human subjects serve as their own controls with an appropriate washout period or when comparison to a reference population exposed to lower levels is available, or, in toxicological studies of mammals, an appropriate comparison group is exposed to a negative control (i.e., clean air or filtered air control) (C).</p>
<p>Long-term exposure and respiratory, cardiovascular, metabolic, nervous system, carcinogenic, reproductive or developmental effects</p>	<p>Among the study population of any animal toxicological study of mammals at any lifestage (P), of interest are the studies of the relationship between long-term (in the order of months to years) inhalation exposure to relevant O<sub>3</sub> concentrations (i.e., 2 ppm or below) (E) and respiratory, cardiovascular, metabolic or nervous system, carcinogenic, reproductive or developmental effects (O) when an appropriate comparison group is exposed to a negative control (i.e., clean air or filtered air control) (C).</p>

*Draft example PECOS statement*

# May 2018 Memo: Standardized Charge Questions for CASAC

- The May 2018 memo identified general charge questions for CASAC in NAAQS reviews, to be supplemented with more detailed requests as necessary.
  - Are there areas in which additional knowledge is required to appraise the adequacy and basis of existing, new, or revised NAAQS? Please describe the research efforts necessary to provide the required information.
  - What scientific evidence has been developed since the last review to indicate if the current primary and/or secondary NAAQS need to be revised or if an alternative level or form of these standards is needed to protect public health and/or public welfare? Please recommend to the Administrator any new NAAQS or revisions of existing criteria and standards as may be appropriate. In providing advice, please consider a range of options for standard setting, in terms of indicators, averaging times, form, and ranges of levels for any alternative standards, along with a description of the alternative underlying interpretations of the scientific evidence and risk/exposure information that might support such alternative standards and that could be considered by the Administrator in making NAAQS decisions.
  - Do key studies, analyses, and assessments which may inform the Administrator's decision to revise the NAAQS properly address or characterize uncertainty and causality? Are there appropriate criteria to ensure transparency in the evaluation, assessment and characterization of key scientific evidence for this review?
- Two additional charge questions may elicit information not relevant to the standard-setting process. EPA may consider an appropriate mechanism, including after receiving CASAC's final advice on the standards, to facilitate robust feedback on these topics.
  - What is the relative contribution to air pollution concentrations of natural as well as anthropogenic activity? In providing advice on any recommended NAAQS levels, please discuss relative proximity to peak background levels.
  - Please advise the Administrator of any adverse public health, welfare, social, economic, or energy effects which may result from various strategies for attainment and maintenance of such NAAQS.