

# Review of the Primary NO<sub>2</sub> NAAQS: Draft Policy Assessment

Presented to CASAC Oxides of Nitrogen  
Primary NAAQS Review Panel  
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# EPA Speakers

## Introduction/Background

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## Overview of the Policy Assessment

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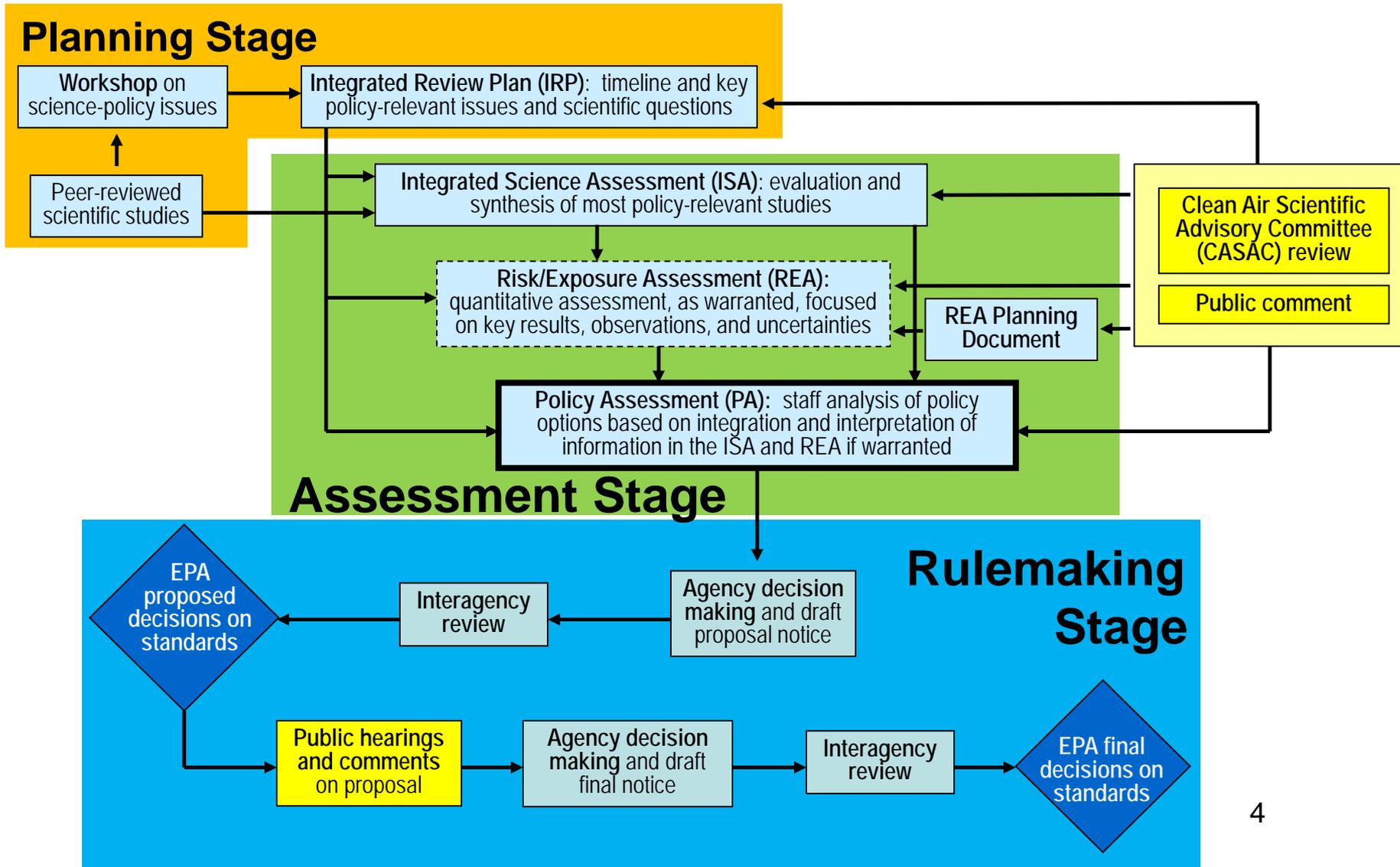


## Background and Schedule

- This public meeting is for CASAC review and discussion of the draft Policy Assessment (PA), which is intended to facilitate the CASAC's advice and public input as part of the ongoing review of the primary NAAQS for NO<sub>2</sub>
  - The draft PA presents staff's considerations and preliminary conclusions regarding what the available scientific evidence and information indicates about the adequacy of the current NO<sub>2</sub> primary standards
- In June 2015, we met with CASAC to discuss the 2<sup>nd</sup> draft ISA and the REA Planning Document
  - The final ISA was released in January 2016
  - The REA Plan presented considerations and preliminary conclusions regarding potential support for quantitative analyses. Building on these and on CASAC advice on the REA Plan, the draft PA includes quantitative analyses comparing NO<sub>2</sub> air quality to health-based benchmarks



# Overview of NAAQS Process





# Current Review of the Primary NO<sub>2</sub> NAAQS

| Stage of Review                     | Major Milestone                       | Date                  |
|-------------------------------------|---------------------------------------|-----------------------|
| Planning                            | Workshop on science/policy issues     | March 2012            |
|                                     | Final Integrated Review Plan          | June 2014             |
| Integrated Science Assessment (ISA) | 1 <sup>st</sup> draft ISA             | 2013                  |
|                                     | 2 <sup>nd</sup> draft ISA             | 2014                  |
|                                     | Final ISA                             | January 2016          |
| Risk/Exposure Assessment (REA)      | REA Planning Document                 | May 2015              |
| <b>Policy Assessment (PA)</b>       | <b>1st Draft PA with REA analyses</b> | <b>September 2016</b> |
| Rulemaking                          | Proposed                              | TBD                   |
|                                     | Final                                 | TBD                   |

- CASAC advice and public input on the draft PA will be considered in developing the final PA
- We are under litigation on the schedule, and we anticipate that this litigation will result in court-ordered deadlines for completion of the review



# Purpose and Organization of the Draft Policy Assessment

- **Purpose:** The PA is intended to help bridge the gap between the relevant scientific information and assessments and the judgments required of the EPA Administrator in determining whether it is appropriate to revise the primary NAAQS for NO<sub>2</sub>.
- Organization of the draft PA:
  - **Chapter 1:** Introduction and overview of document; general approach to reviewing standards
  - **Chapter 2:** Overview of NO<sub>2</sub> emissions, monitoring, and air quality trends and relationships
  - **Chapter 3:** Consideration of evidence for NO<sub>2</sub>-related health effects from epidemiologic, controlled human exposure, and animal toxicology studies
  - **Chapter 4:** Consideration of support for conducting/updating quantitative analyses; results from analyses comparing NO<sub>2</sub> air quality to health-based benchmarks
  - **Chapter 5:** Preliminary conclusions on adequacy of the current primary NO<sub>2</sub> standards



# Background

- Current NO<sub>2</sub> primary (health-based) standards (2010)
  - Annual standard: 53 ppb, annual average
  - 1-hr standard: 100 ppb, 3-year average of the 98% of daily maximum 1-hour NO<sub>2</sub> concentrations
    - This standard was added in the 2010 review to increase protection against respiratory effects related to short-term exposures
    - The 2010 rulemaking also required states to locate monitors near heavily trafficked roadways in large urban areas and in other locations where maximum NO<sub>2</sub> concentrations can occur
- NO<sub>2</sub> monitoring network:
  - Approximately 462 monitors in operation in 2015
  - 65 of these monitors are in the near-road monitoring network, phased into operation between 2013-2015
  - Current NO<sub>2</sub> design values (2013-2015) indicate that no area is at or above either of the current standards; there have been no nonattainment areas since 1998.



# NO<sub>2</sub> Air Quality

- General focus is on NO<sub>2</sub>, as this is the current indicator for oxides of nitrogen and most relevant to the evaluation of health evidence
- Ambient concentrations of NO<sub>2</sub> are influenced by both direct NO<sub>2</sub> emissions and by emissions of NO, with the subsequent chemical conversion of NO to NO<sub>2</sub>
- National average NO<sub>2</sub> concentrations have declined substantially in recent years, reflecting significant emissions reductions in NO and NO<sub>2</sub>.
- Emissions from mobile sources still remain a dominant source of NO<sub>2</sub> and some of the highest NO<sub>2</sub> concentrations are measured near roads
  - NO<sub>2</sub> concentrations in the past decades were considerably higher near roadways compared to concentrations measured further from roadways
  - Early data from the near-road monitoring network indicate that NO<sub>2</sub> concentrations are generally higher at near-road monitors than other monitors in the same CBSA
- Analyses of the air quality relationships between the 1-hour and annual standards suggest that meeting a 1-hour standard of 100 ppb generally maintains annual NO<sub>2</sub> concentrations well below the annual standard of 53 ppb (generally < ~35 ppb)



# Consideration of Evidence for NO<sub>2</sub>- Related Health Effects

- Consideration of evidence in the draft PA is focused on the extent to which the evidence calls into question the adequacy of the current standards
  - Does evidence substantively alter conclusions from the last review? Have uncertainties been reduced or have new uncertainties been identified?
  - Are effects observed with exposure concentrations lower than those previously identified or that would be allowed by the current standards?



## Consideration of Evidence for NO<sub>2</sub>- Related Health Effects: **Short-Term Exposure**

- ISA concludes that the evidence indicates a “causal” relationship for respiratory effects; consistent with evidence in the last review
- Strongest evidence comes from controlled human exposure studies
  - Demonstrate increases in airway responsiveness (AR) in people with asthma following 30-60 min exposures to 100-530 ppb NO<sub>2</sub>; all studies of exposures conducted at rest were available in the last review. Uncertainty regarding lack of a dose-response relationship and potential adversity of AR.
  - New meta-analysis demonstrates that a significant fraction of study subjects with asthma experience increases in AR following NO<sub>2</sub> exposures; increases in some volunteers were large enough to have potential clinical relevance.
  - Evidence supports the consideration of the potential for exposures to NO<sub>2</sub> concentrations at or above 100-300 ppb, though uncertainties become increasingly important at lower concentrations where evidence from individual studies is less consistent.



# Consideration of Evidence for NO<sub>2</sub>- Related Health Effects: **Short-Term Exposure**

- Supporting evidence from epidemiologic studies for various respiratory endpoints
  - Associations across U.S. and Canadian studies of emergency department visits and hospital admissions are generally positive, but are not significant and relatively imprecise in locations having NO<sub>2</sub> concentrations at or below the current NAAQS.
  - Evidence partially reduces some uncertainty from the previous review as there is expanded examination of copollutant confounding and improvement in exposure metrics. Additional uncertainty in whether study areas would have met the NAAQS as monitors for study locations/years do not reflect NO<sub>2</sub> concentrations near roads.



# Consideration of Evidence for NO<sub>2</sub>- Related Health Effects: Long-Term Exposure

- ISA concludes that the evidence indicates there is “likely to be a causal relationship” for respiratory effects; evidence is stronger than in previous reviews
- Strongest evidence is from epidemiologic studies
  - Studies demonstrate generally positive associations for asthma incidence in children. Important uncertainties to consider including the potential for exposure measurement error and copollutant confounding.
  - Locations of epidemiologic studies generally do not have NO<sub>2</sub> concentrations below the current NO<sub>2</sub> standards for the study periods; monitors in operation during study periods do not reflect the highest NO<sub>2</sub> concentrations occurring near roadways
- Supporting evidence from experimental studies (short and long-term) provides biological plausibility in demonstrating a mode of action by which NO<sub>2</sub> exposure can be linked to asthma development
  - Suggest potential for repeated, short-term peak exposures to play a role in asthma development



# Consideration of Quantitative Risk and Exposure Analyses

- Quantitative analyses of air quality, exposure, and risk can inform judgments about public health impacts of NO<sub>2</sub>-related health effects and put scientific evidence into broader public health context
- REA Plan evaluated the potential support for conducting new or updated quantitative analyses and considered the likelihood that quantitative analyses would add substantially to our understanding of NO<sub>2</sub> exposures and risk. Types of analyses considered included:
  - Comparisons of air quality (1-hour concentrations) to health-based benchmarks
  - Model-based exposure assessment
  - Risk assessment based on information from controlled human exposure studies
  - Epidemiologic based risk assessment (for short and/or long-term exposures)
- Draft PA further evaluates potential support for such analyses



# Comparison of Air Quality to Health-Based Benchmark Concentrations

- To what extent are the current standards estimated to allow 1-hour ambient NO<sub>2</sub> concentrations that may be of public health concern?
- Approach:
  - Focused on 23 CBSA case study areas, with the majority having new near-road monitoring data available
  - Analyzed 1-hour NO<sub>2</sub> concentrations for current air quality and air quality adjusted upwards to simulate just meeting the 1-hour standard (100 ppb) and the potential for these concentrations to exceed relevant health-based benchmarks (i.e., 100-300 ppb)
- Results:
  - Analyses of recent ambient measurements indicate little or no potential for 1-hour exposures at or above benchmarks
  - Air quality adjusted to simulate meeting the current 1-hour standard also indicates:
    - Virtually no potential for exposures to NO<sub>2</sub> concentrations that have been shown to most consistently result in increases in AR in people with asthma (i.e., above 200 ppb)
    - Limited potential for exposures to 100 ppb NO<sub>2</sub>, a level at which uncertainties in the evidence become increasingly important



## Consideration of Other Quantitative Analyses

- Model-based exposure assessment was not conducted as comparisons of air quality to health-based benchmarks indicate little potential for exposures to ambient NO<sub>2</sub> concentrations that would be of public health concern; refined estimates of personal exposures would be of limited additional value
- Short-term epidemiologic risk assessment was conducted in the last review; new evidence does not warrant conducting an updated risk assessment for short-term exposures
- In response to CASAC advice, EPA staff gave thorough consideration to evidence available to inform an epidemiologic risk assessment for long-term NO<sub>2</sub> exposures and concluded such an assessment is not warranted
  - Overall, there are important limitations in the epidemiologic evidence (i.e. lack of copollutant models and baseline incidence data)
  - Results of risk assessment would be subject to considerable uncertainty and not informative for evaluating adequacy of the current standards



## Preliminary Staff Conclusions on the Adequacy of the Current Primary NO<sub>2</sub> NAAQS

- We reach the preliminary conclusion that the available evidence, including uncertainties, does not support the need for increased protection against short- or long-term NO<sub>2</sub> exposures, beyond that provided by the existing standards.
- Analyses comparing air quality to health-based benchmarks do not demonstrate the potential for exposures that are of public health concern.
- Overall, the combined evidence and quantitative information in the current review do not call into question adequacy of the current standards. Thus, no alternative standards have been identified for consideration.



## Data Gaps and Areas for Future Research

- More thorough examination of the potential for co-occurring pollutants to confound health effect associations with NO<sub>2</sub>, particularly for traffic-related pollutants in epidemiologic studies of long-term NO<sub>2</sub> exposures
- Improved understanding of short-term NO<sub>2</sub> exposures, particularly those that occur in locations near important sources of NO<sub>x</sub> emissions such as on and near heavily trafficked roads
- Additional research into the potential for increased AR or other effects following NO<sub>2</sub> exposures at 100 ppb (and below); improved understanding of the potential adversity of these effects



Questions?