

Integrated Science Assessment: Oxides of Nitrogen

Presentation to the
Clean Air Scientific Advisory Committee

NCEA-RTP Oxides of Nitrogen Team
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Office of Research and Development

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Overview

- NAAQS review process
- Current NO₂ NAAQS review
- Draft ISA highlights with focus on EPA charge questions

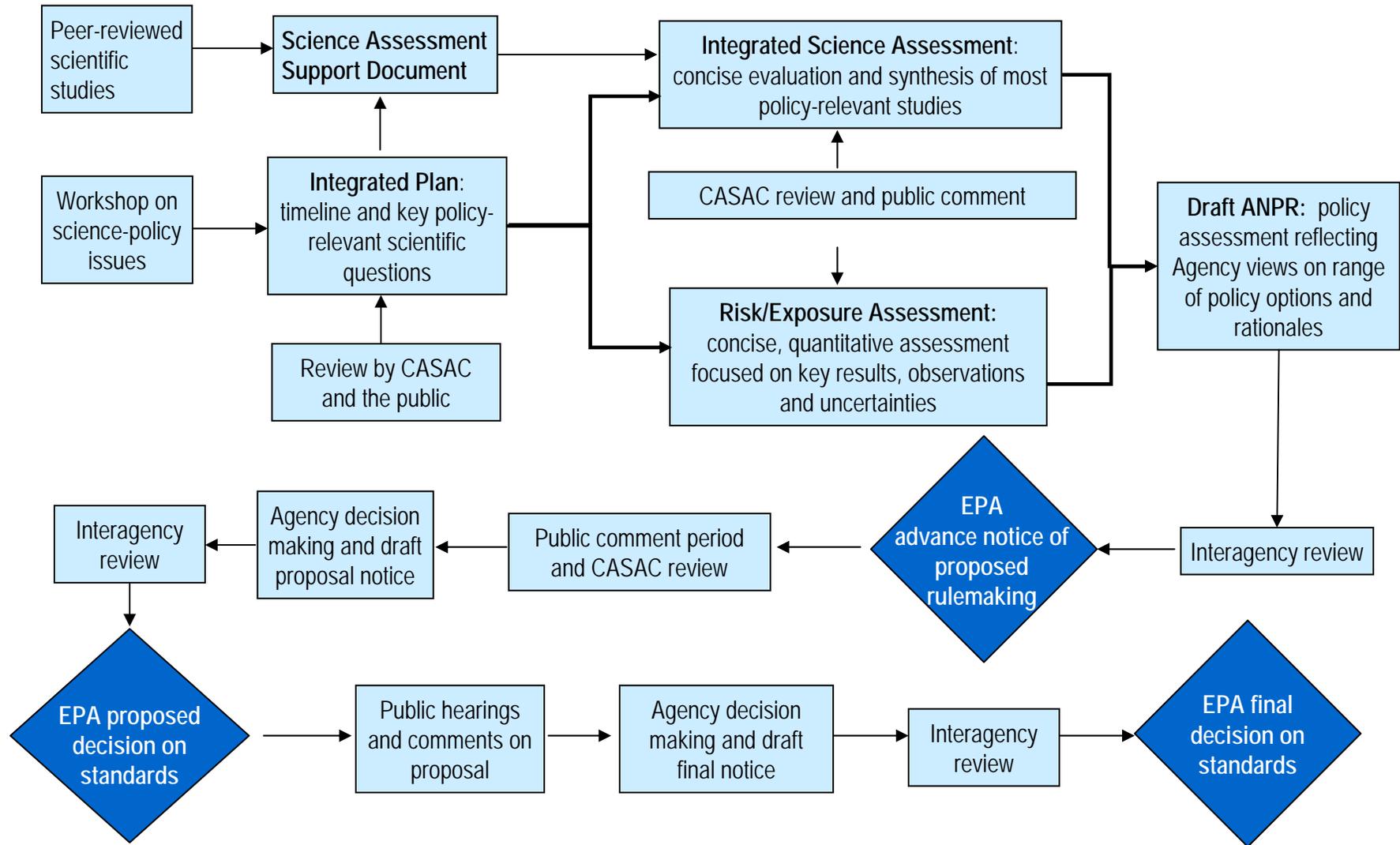


New NAAQS review process: Key steps

- **Planning:** Early in the process, NCEA/OAQPS will develop one integrated plan to guide the entire review
 - Plan will outline schedule, process, and key policy-relevant science issues
- **Science Assessment:** The Criteria Document will be replaced by a more concise evaluation and synthesis of the most policy-relevant science
 - Integrated Science Assessment (ISA): Drawing from detailed Annex chapters, provides concise evaluation and synthesis of the most policy-relevant science
 - ORD working to develop and implement process (state-of-the-art electronic database) to identify, compile, characterize, and prioritize new studies
- **Risk/Exposure Assessment:** OAQPS will develop a more concise document, informed by the ISA, that focuses on key results, observations and uncertainties
- **Policy Assessment/Rulemaking:** The Staff Paper will be replaced with an advance notice of proposed rulemaking (ANPR) containing a policy assessment that reflects Agency views, rather than staff views
 - ANPR will present a range of policy options for standard setting, and will include a description of the underlying interpretation of the scientific evidence and risk/exposure information that might support each option



New NAAQS review process



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Integrated Science Assessment Preparation

- Initial preparation of ISA annex to provide more comprehensive, detailed review of recent studies
 - Discipline-specific focus
 - Chapters on atmospheric science, exposure, toxicology, controlled human exposure studies, epidemiology with more detailed summaries of study findings
 - Workshop held in February 2007 for peer review of initial draft annex chapter materials and discussion of focus for integration of evidence
- ISA draws from annex chapters to evaluate and synthesize evidence
 - Health outcome focus
 - Evidence from different disciplines integrated and assessed
 - Strength and robustness of evidence from specific disciplines
 - Coherence and plausibility of evidence for various health outcomes
 - Recommendations and conclusions provide scientific support for future risk and exposure analyses, policy assessment



History of the NO₂ NAAQS

- **1971:** EPA promulgated first NAAQS for NO₂
 - Primary and secondary NAAQS set at 0.053 parts per million (ppm), annual average
- **1985 and 1996:** NAAQS for NO₂ reviewed and existing standards retained
- **September 2005:** Complaint filed by the Center for Biological Diversity (and others) on 5 year deadline for review of the NO₂ standards
 - February 2006: Complaint was amended to add SO₂
- **Spring 2006:** Both parties file motions for summary judgment with proposed schedules for completing reviews of NO₂ and SO₂ NAAQS
- **Fall 2006:** Briefing on motions for summary judgment completed
- **Present:** We are waiting for the judge's decision on the schedule



Schedule for the Current Review

Major Milestones		Projected Completion Date	Projected CASAC Review Date
Integrated Science Assessment	First Draft	August 2007	October 2007
	Second Draft	February 2008	Early May 2008
	Final	July 2008	
Risk/Exposure Assessment	Plan	Aug/Sept 2007	October 2007
	First Draft	March 2008	Early May 2008
	Second Draft	September 2008	November 2008
	Final	January 2009	
Policy Assessment/Rulemaking	ANPR	March 2009	April 2009
	Proposed	August 2009	
	Final	May 2010	



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NCEA-RTP NO_x TEAM

ISA IN SUPPORT OF THE PRIMARY STANDARD

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ISA organization

- Integrated science assessment
 - Introduction
 - Source to dose
 - Integration of health evidence
 - Public health impact
 - Conclusions
- Annexes: more detailed summaries of evidence
 - Atmospheric chemistry, physics
 - Measurements, sources, etc.
 - Toxicology and dosimetry
 - Controlled human exposure studies
 - Epidemiology

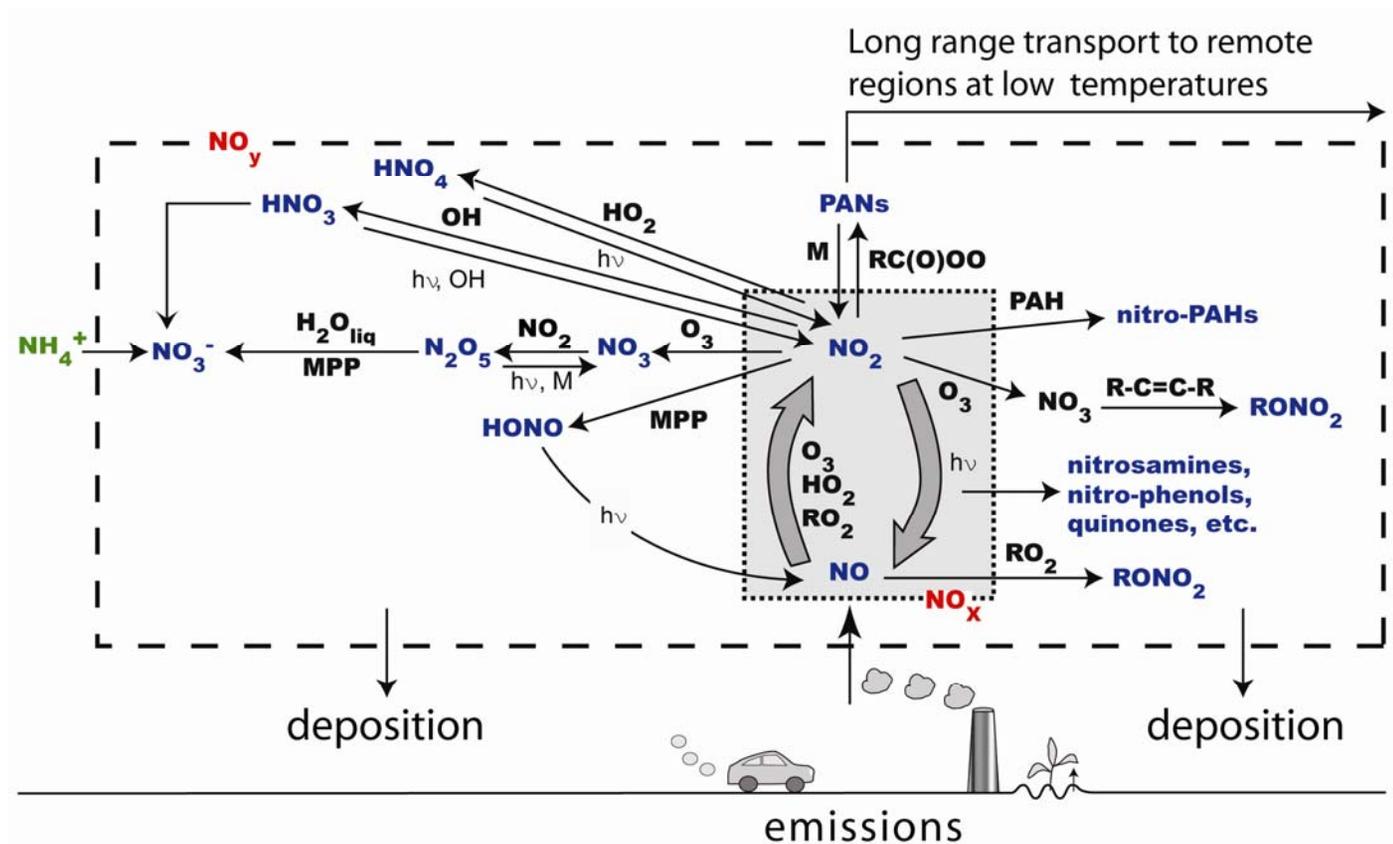


Charge Questions 1-3

- To what extent are the atmospheric chemistry and air quality characterizations clearly communicated, appropriately characterized, and relevant to the review of the primary NO₂ NAAQS?
- Are the properties of ambient oxides of nitrogen appropriately characterized, including policy-relevant background, spatial and temporal patterns, and relationships between ambient oxides of nitrogen and human exposure?
- Does the information in Chapter 2 provide a sufficient atmospheric science and exposure basis for the evaluation of human health effects presented in later chapters?



Cycle of Reactive Nitrogen Species in the Atmosphere



Oxides of Nitrogen: Definition, Measurements, Concentrations

- Atmospheric chemistry: processes involving NO_2 result in the formation of photochemical oxidants such as O_3 and PAN and the strong acid, HNO_3 , as well as compounds such as nitro-PAHs
- It has long been known that measurements of NO_2 in ambient air are subject to interference by NO_z compounds, chiefly HNO_3 and PAN
 - Measurement of NO_y (the sum of NO_x and NO_z) is a more precise measurement of oxides of nitrogen and captures more of the total mix of oxides of nitrogen than does NO_x
- Annual average concentrations of NO_2 (~15 ppb) are well beneath the level of the current NAAQS (~53 ppb). However, daily maximum 1-h average concentrations can be greater than 100 ppb in a few locations that are heavily influenced by traffic.



Personal – Ambient Exposure Relationships

- The evidence relating ambient levels of NO₂ to personal exposures is mixed
 - Many of the studies examined found that ambient levels of NO₂ were significant proxies of personal exposures to NO₂.
 - However, a number of studies did not find significant associations between ambient and personal levels of NO₂.
 - A number of factors contribute to these results.
- Epidemiologic studies often use measurements at central sites to estimate population exposures
 - Measurement error often results in underestimated risk estimates and increased standard errors



Charge Questions 4-6

- To what extent is the discussion and integration of evidence from the animal toxicology and controlled-exposure human experimental studies and epidemiologic studies, technically sound, appropriately balanced, and clearly communicated?
- To what extent does the integration of health evidence focus on the most policy-relevant studies or health findings?
- What are the views of the Panel on the conclusions drawn in the draft ISA regarding the strength, consistency, coherence and plausibility of NO₂-related health effects?



Key Conclusions: Short-term Exposures

Respiratory morbidity: likely causal

- Strongest new evidence from epidemiologic studies of ED visits and hospitalization
 - Confirm previous findings of associations with increased respiratory symptoms (cough, wheeze) especially in children and asthmatics; particularly new multicity studies with ambient NO₂ exposures, and studies of indoor/personal exposures
 - Evidence of airways hyperresponsiveness and inflammation from controlled human exposure and toxicologic studies, especially in susceptible groups
 - Limited new evidence on lung function decrements and loss of lung capacity in children from epidemiologic studies
- **Cardiovascular morbidity: inconclusive**
 - **All Cause Mortality: suggestive evidence**



Key Conclusions: Long-term Exposures

- **Respiratory morbidity: suggestive evidence**
 - Decreased lung function growth
 - Increased asthma prevalence
- **Lung cancer incidence: suggestive evidence**
 - Associations reported with NO₂ in two epidemiologic studies, but no support from animal tox studies for carcinogenicity of NO₂
 - Atmospheric reaction products of NO₂, such as nitro-PAH's, may be carcinogenic
- **Adverse birth outcomes: limited evidence**
- **Cardiovascular effects: no evidence available**
- **Mortality (including lung cancer): inconclusive evidence**



Charge Questions 7-8

- What are the views of the Panel on the appropriateness of public health impact and the characterization of groups likely to be susceptible or vulnerable to NO₂?
- What are the Panel's views on the adequacy of this first external review draft ISA to provide support for future risk, exposure and policy assessments?



Potentially Susceptible and Vulnerable Subpopulations

- Preexisting disease status
 - Respiratory diseases, especially asthma
 - Viral infections
- Age
 - Children
 - Older adults
- High exposure populations
- Genetic susceptibility

