Review of the Primary National Ambient Air Quality Standard (NAAQS) for Sulfur Dioxide (SO_2)

Background, Schedule, and Draft Integrated Review Plan

CASAC Review Meeting
April 22, 2014

National Center for Environmental Assessment and Office of Air Quality Planning and Standards

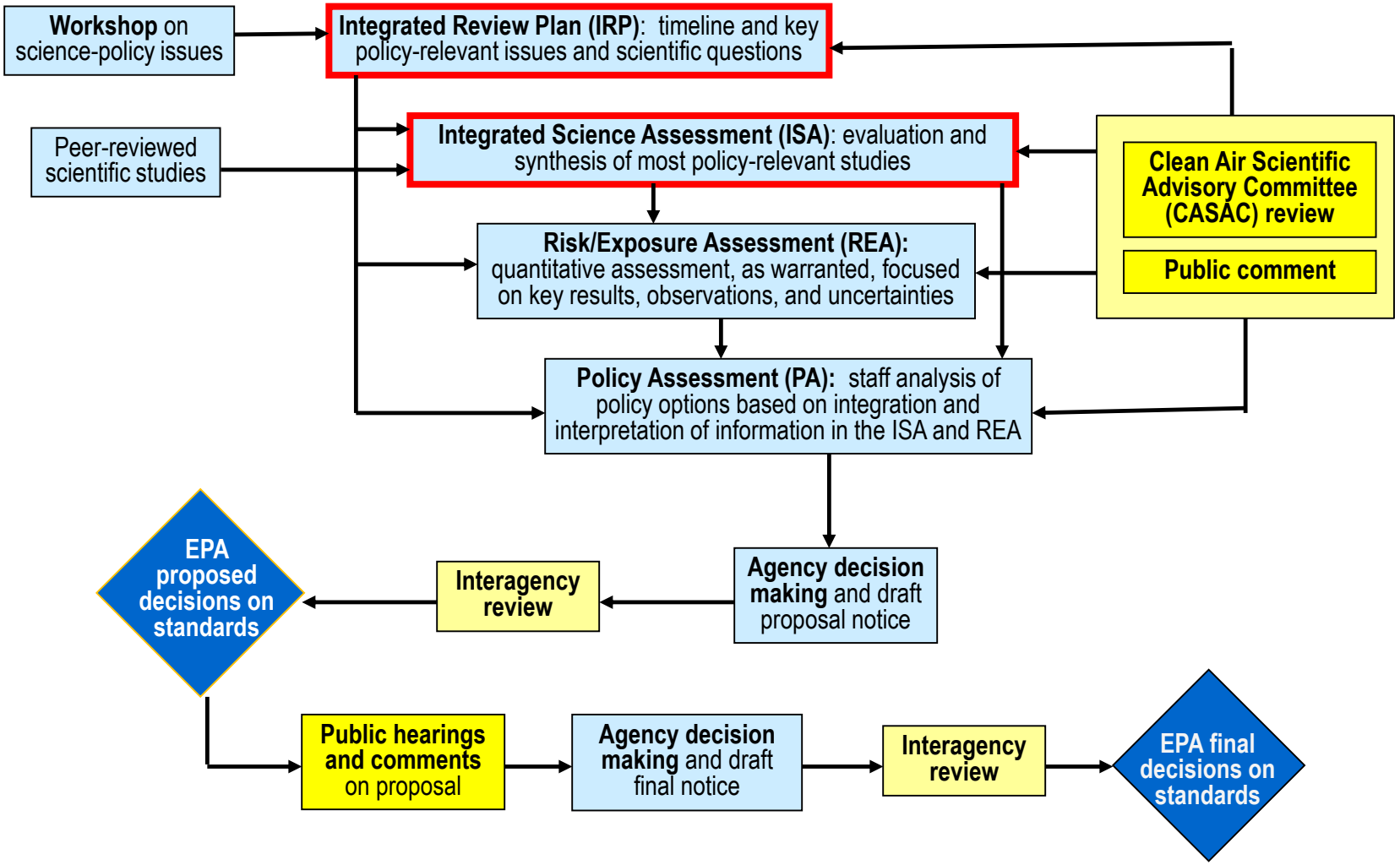
Overview

- Statutory requirements
- NAAQS review process
- Scope of current review
- Current schedule
- History of Primary SO_2 NAAQS Reviews
- Summary of last review: focus on key policy-relevant issues
- Draft Integrated Review Plan (IRP) for current review
- Primary SO_2 NAAQS team and additional information

Statutory Requirements

- 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 public health, including at-risk populations and lifestages, 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
  - **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
  - EPA is required to engage in "reasoned decision making" to translate scientific evidence into standards
  - EPA may not consider cost in setting standards (this has been upheld by the Supreme Court); however, cost is considered in developing control strategies to meet the standards (implementation phase)

NAAQS Review Process



Scope of Current Review

- Considers **gaseous** species of sulfur oxides only
  - Particulate species (e.g., sulfates) are considered in review of particulate matter (PM) NAAQS
- Focuses on **primary NAAQS** only; considers relevant scientific information related to health effects associated with exposure to sulfur oxides
  - Secondary SO_2 NAAQS are being reviewed separately, in conjunction with review of secondary NO_2 NAAQS

Anticipated Schedule for the Primary SO_2 NAAQS Review

Stage of Review	Major Milestone	Target Date for Completion	Target Date for CASAC Review/Consultation
Integrated Review Plan (IRP)	Literature Search	Ongoing	
	Call for Information	May 10, 2013	
	Workshop on Science/Policy Issues	June 12-13 2013	
	Draft IRP	**March 2014**	**April 22, 2014**
	Final IRP	July 2014	
Integrated Science Assessment (ISA)	**First draft ISA**	**October 2014**	**January 2015**
	Second draft ISA	July 2015	October 2015
	Final ISA	January 2016	
Risk/Exposure Assessment (REA)	REA Planning Document	February 2015	March 2015
	If warranted:		
	First draft REA		
	Second draft REA	TBD	TBD
	Final REA		
Policy Assessment (PA) and Rulemaking	First draft PA	September 2015	October 2015
	Second draft PA	June 2016	July 2016
	Final PA	December 2016	
	Notice of proposed rulemaking	May 2017	
	Notice of final rulemaking	February 2018	

History of Primary SO_2 NAAQS (1)

- 1971: Promulgated first NAAQS for SO_2
  - Primary NAAQS: 24-hour standard set at 140 ppb and annual standard set at 30 ppb
  - Secondary NAAQS: 3-hour standard set at 500 ppb
- 1988: Proposed not to revise the existing standards but requested comment on adding a 1-hour primary standard (400 ppb)
- 1994: Reproposed not to revise the existing standards
  - Requested comment on regulatory alternatives, including adding 5-minute standard (600 ppb) or establishing new regulatory program under section 303
- 1996: Final decision not to revise the existing standards; did not promulgate 5-minute standard or any other regulatory program
  - Challenged by American Lung Association and Environmental Defense Fund
- 1998: DC Circuit Court of Appeals remanded the decision back to EPA
  - Court required EPA to provide an adequate explanation for the conclusion that 5-minute exposures to SO_2 do not amount to a "public health" problem under the Act, given that exposure analyses show that from 68,000-166,000 asthmatics at least once each year are exposed to levels causing adverse effects ("atypical physical effects" judged by the Administrator to be adverse). See 134 F. 3d at 392.

History of Primary SO_2 NAAQS (2)

- 2010: Revised SO_2 primary NAAQS by establishing a 1-hour standard at 75 ppb
  - 1- hour standard at 75 ppb would substantially limit health effects associated with short-term (5-minute to 24-hour) exposure to SO_2
  - The then-existing 24-hour and annual standards were revoked
    - Given a 1-hour standard at 75 ppb, the then-existing 24-hour and annual standards provided little additional public health protection
- 2012: DC Circuit Court of Appeals upheld revisions to the SO_2 primary NAAQS
- 2013: Kickoff of current review

Assessments in the Last Review (1)

- **Integrated Science Assessment (ISA):** NCEA is responsible for preparing this assessment
- Purpose: critically evaluate and integrate evidence from multiple disciplines on health effects of ambient SO_X
- Builds on evidence base from the previous review, incorporating new evidence where available
- Utilizes principles of systematic review in study selection, evaluating study quality, integrating the evidence, and determining the likelihood of causality
- Classifies the weight of evidence for causality with a five-level framework
  - Causal relationship [*last review*: short-term exposure and respiratory morbidity]
  - Likely to be a causal relationship [*last review*: none]
  - Suggestive of a causal relationship [*last review:* short-term exposure and mortality]
  - Inadequate to infer a causal relationship [*last review*: short-term exposure and cardiovascular morbidity; long-term exposure and respiratory morbidity, other morbidity, and mortality]
  - Not likely to be a causal relationship [*last review*: none]

Assessments in the Last Review (2)

- ***Integrated Science Assessment (ISA)*** assessed the broad body of scientific evidence and concluded a causal relationship existed between respiratory morbidity and short-term (5-minutes to 24-hours) exposure to SO_2
  - Controlled human exposure studies of exercising asthmatics with 5-10 minute exposures provide "definitive evidence" for the causal association
    - Links 5-10 minute SO_2 exposures as low as 200-300 ppb with bronchoconstriction
    - Links 5-10 minute SO_2 exposures ≥ 400 ppb with bronchoconstriction that is frequently accompanied by respiratory symptoms
  - Epidemiologic studies of associations between 1- and 24-hour SO_2 concentrations and respiratory symptoms, emergency department visits, and hospital admissions provide "supporting evidence"
    - Over 50 U.S. and international studies, almost all new since the prior review of the SO_2 NAAQS
    - Associations found in areas meeting the existing SO_2 NAAQS

Assessments in the Last Review (3)

- ***Risk and Exposure Assessment (REA)*** characterized SO_2 air quality, exposures, and risks for recent air quality and air quality adjusted to simulate just meeting alternative standards
  - Evaluated 5-minute, 24-hour, and annual average SO_2 levels in 40 counties with ambient monitors
  - Estimated the number of exercising asthmatics in St. Louis and Greene County, MO exposed to 5-minute daily maximum SO_2 concentrations above health benchmark values (i.e., 100, 200, 300, and 400 ppb)
  - Estimated SO_2 associated risks for lung function decrements in exercising asthmatics in response to 5-minute daily maximum SO_2 exposures in St. Louis and Greene County, MO
- ***Policy Assessment Chapter of REA*** presented staff policy considerations and conclusions
  - Then-existing 24-hour and annual standards were inadequate to protect public health with an adequate margin of safety
  - 1-hour SO_2 standard in the range of 50 to 150 ppb could be considered

Last Review: Final Decision on Adequacy of then-existing 24-hour and Annual Standards

- **Conclusions:** The then-existing 24-hour and annual standards were judged not requisite to protect public health with an adequate margin of safety
- **Evidence:** A number of SO_2 epidemiologic studies reported positive associations with respiratory emergency department visits and/or hospital admissions in locations that would have met the then-existing 24-hour and annual standards
- **Air Quality, Exposure, and Risk:** Estimated that in areas just meeting the then-existing 24-hour and annual standards, large numbers of exercising asthmatics would be exposed to SO_2 concentrations above 5-minute health benchmark values
- *In light of the Administrator's conclusion regarding the then-existing SO_2 standards, the Agency considered revisions in terms of the standard indicator, averaging time, form, and level in order to set a standard that is requisite to protect public health with an adequate margin of safety*

Last Review: Final Decisions on Elements of NAAQS (1)

- **Indicator:** SO_2 remained the most appropriate indicator for a standard that is intended to address health effects associated with exposure to SO_2, alone or in combination with other gaseous SO_X
  - Most all human clinical and epidemiologic studies are in terms of exposure to SO_2
  - Measures leading to reductions in population exposures to SO_2 can generally be expected to also reduce population exposures to other gaseous SO_X
- **Averaging Time:** judged appropriate to set new standard with a 1-hour averaging time
  - Weight of evidence most directly supported an averaging time that focused protection on short-term (5-minute to 24-hour) exposures to SO_2
  - Based on analyses in the REA, a standard with a 1-hour averaging time at an appropriate level would effectively control short-term (5-minute to 24-hour) peak SO_2 concentrations

Last Review: Final Decisions on Elements of NAAQS (2)

- **Form:** 3-year average of the annual 99th percentile of 1-hour daily maximum SO_2 concentrations
  - Limit upper end of the distribution of ambient SO_2 concentrations reported in some epidemiologic studies to be associated with increased risk of SO_2-related adverse respiratory health effects (e.g., asthma emergency department visits)
  - At a given standard level, a 99th percentile form is appreciably more effective at limiting 5-minute SO_2 concentrations above benchmark levels than 98th percentile form

Last Review: Final Decisions on Elements of NAAQS (3)

- **Level:** 75 ppb provides substantial protection from 200 and 400 ppb 5-minute benchmark levels identified from controlled human exposure studies
- 75 ppb is also below SO_2 concentrations found in locations where epidemiologic evidence was judged to be the strongest
  - Three U.S. emergency department visit/hospital admission studies finding the effect of SO_2 to be robust with respect to the addition of PM in multipolllutant models (i.e., areas with 99th percentile 1-hour daily maximum SO_2 concentrations ≥ 78 ppb)
- Recognizes uncertainties associated with two U.S. emergency department visit studies in areas where 99th percentile 1-hour daily maximum SO_2 concentrations were lowest (i.e., ~50 ppb)

Last Review: Revoking the then-existing 24-hour and Annual Standards

- The previous 24-hour and annual standards were revoked:
  - Given a 1-hour standard at 75 ppb, neither the then-existing 24-hour or annual standard was expected to provide additional public health protection
    - Air quality analyses indicated that a 1-hour standard at 75 ppb would prevent SO_2 concentrations from exceeding levels allowed by the then-existing 24-hour and annual standards
    - There is no health evidence to support an annual standard to protect against health effects associated with long-term exposure to SO_2

Current Review: Overarching 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 standard**?
  - NAAQS protect public health, including the health of at-risk populations and lifestages, with an adequate margin of safety
- What **alternative standards**, if any, are supported by currently available scientific evidence and exposure/risk-based information, and are appropriate for consideration?
  - In terms of basic elements of NAAQS: indicator, averaging time, form, and level

Current Review: Key Issues (1)

- Many key issues to be addressed in the current review are based upon uncertainties in evidence and exposure/risk information identified in last review
- These key issues have guided the development of the key policy-relevant questions presented in the draft IRP
- Specific issues to be considered with regard to the **evidence** include…
  - Extent to which new evidence reinforces or calls into question the evidence presented and evaluated in the last review
    - Evidence of health effects not previously identified or stronger evidence than previously considered?
    - Evidence of effects at lower concentrations than previously observed or in areas that would likely meet current standard?
    - Expanded understanding of at-risk populations and lifestages?
  - Extent to which uncertainties in scientific evidence from last review have been reduced and/or whether new uncertainties have emerged
    - Extent to which SO_2 itself, as opposed to one or more co-occurring pollutants (e.g., $PM_{2.5}$, O_3), contributes to health effects reported in epidemiological studies?

Current Review: Key Issues (2)

- Specific issues to be considered with regard to **exposure and risk analyses** include…
  - Air quality relationships between short-term and longer-term exposures to SO_2
    - What are the important uncertainties associated with using a 1-hour NAAQS to protect against 5-minute peak concentrations of concern?
  - Extent to which risk or exposure information suggest that exposures of concern (i.e., exposures above benchmark levels) are likely to occur with recent ambient SO_2 concentrations or with concentrations that just meet the current SO_2 standard?
    - Are these estimated exposures/risks reasonably judged to be important from a public health perspective?
  - Extent to which newly available scientific evidence and tools/methodologies provide support for conducting a new REA
    - Are key uncertainties reduced by the increased availability of 5-minute SO_2 monitoring data?
    - Is there new information to improve the exposure model inputs and exposure estimates which are an important input to the risk assessment?
    - Is there new information and/or approaches that would inform simulations of current or potential alternative SO_2 standards?

Current Review: Organization of Draft IRP

1. Introduction (including regulatory history)
2. Status and Schedule
3. Key Policy-Relevant Issues
4. Science Assessment
5. Quantitative Risk and Exposure Assessment
6. Ambient Air Monitoring
7. Policy Assessment and Rulemaking
8. References

Primary SO_2 NAAQS Review Team

Health and Environmental Impacts Division

- Dr. Michael Stewart, Team Lead, PA Team Lead
- Mr. John Langstaff, REA Team Lead

Ms. Karen Wesson, Ambient Standards Group Leader

Dr. Stephen Graham, Risk Benefits Group Leader (Acting)

Dr. Bryan Hubbell, Sr. Advisor for Science & Policy Analysis (Acting)

Dr. Erika Sasser, Division Director (Acting)

Air Quality Assessment Division

- Mr. Doug Solomon, air quality analysis
- Mr. Nealson Watkins, air monitoring

Mr. James Hemby, NAAQS Coordinator

Mr. Lewis Weinstock, Ambient Air Monitoring Group Leader

Dr. Liz Naess, Air Quality Analysis Group Leader

Mr. Tyler Fox, Air Quality Modeling Group Leader

Mr. Marc Houyoux, Emissions Inventory Group Leader

Mr. Chet Wayland, Division Director

National Center for Environmental Assessment

- Dr. Tom Long, ISA Team Co- Lead
- Dr. Lisa Vinikoor-Imler, ISA Team Co- Lead

Dr. Steven Dutton, Branch Chief (Acting)

Dr. John Vandenberg, NCEA-RTP Director

Office of General Counsel

- Mr. Steven Silverman

Additional Information

- Documents from the current and previous primary SO_2 NAAQS reviews are available at: http://www.epa.gov/ttn/naaqs/standards/so2/s_so2_index.html
- Primary contact:
  - Dr. Michael Stewart, US EPA, OAQPS/HEID/ASG
  - Stewart.michael@epa.gov
  - (919) 541-7524