Minutes of the
U.S. Environmental Protection Agency
Clean Air Scientific Advisory Committee
Sulfur Oxides Primary NAAQS Review Panel
Public Meeting
December 5 - 6, 2007

Committee Members:	Dr. Rogene Henderson, Chair
Date and Time:	December 5 - 6, 2007
Purpose:	To discuss the draft *Integrated Science Assessment for Sulfur Oxides – Health Criteria* (Sept. 2007) and to discuss the *Sulfur Dioxide Health Assessment Plan: Scope and Methods for Exposure and Risk Assessment* (Nov. 2007). Both of these documents may be found at http://www.epa.gov/ttn/naaqs/standards/so2/s_so2_index.html.
SAB Staff:	Dr. Holly Stallworth, Designated Federal Officer Dr. Tony Maciorowski, Deputy Director, SAB Staff Office
Other EPA Staff:	Michael Stewart, EPA Harvey Richmond, EPA Stephen Graham, EPA Karen Martin, EPA Lydia Wegman, EPA Rhonda Thompson, EPA Doug Johns, EPA Ellen Korrane, EPA Ila Cote, EPA Mary Ross, EPA Tom Luber, EPA Lori White, EPA James Brown, EPA Lindsay Stark, EPA Tom Long, EPA David Svengard, EPA Jee-Young Kim, EPA Qingya Mey, EPA Debra Walsh, EPA Barbara Buckley, EPA William Wilson, EPA Rebecca Daniels, EPA Dennis Kotchman, EPA Anu Mundipalli, EPA

Chris Trent, EPA
Annie Jarabeu, EPA

Other: Kaz Ito, New York University
Bryan Baldwin, Southern Company
Greg Recer, New York State Department of Health
Cindy Langworthy, Hunton & Williams
Therese Mar, University of Washington
Aaron Flynn, Hunton & Williams

Attachments: **Attachment A:** Background and Schedule for the Review of the Primary Sulfur Dioxide NAAQS
Attachment B: Integrated Science Assessment for Sulfur Oxides (1st External Review Draft)
Attachment C: Overview of the Scope and Methods Plan Supporting the Review of Primary SO_2 NAAQS

Meeting Summary

The discussion followed the issues and general timing as presented in the meeting agenda. Dr. Stallworth convened the meeting on Wednesday, December 5, 2007 and explained the CASAC Sulfur Oxides Primary NAAQS Review Panel will operate under the Federal Advisory Committee Act. Dr. Henderson reviewed the agenda.

Dr. Ila Cote of EPA's National Center for Environmental Assessment (NCEA) and Dr. Michael Stewart of EPA's Office of Air Quality Planning and Standards (OAQPS) presented *Background and Schedule for the Review of the Primary Sulfur Dioxide NAAQS* (attached). Drs. Cote and Stewart walked panelists through the current National Ambient Air Quality Standards (NAAQS) review process via a flow chart and matrix of dates, both shown in the attached presentation, and summarized highlights from the previous assessment of sulfur dioxide (SO_2).

Drs. Jeff Arnold, Doug Johns and Jee Young-Kim of EPA's National Center for Environmental Assessment presented *Integrated Science Assessment for Sulfur Oxides* (attached). These scientists from NCEA walked panelists through the organization of the September 2007 *Integrated Science Assessment* (ISA) and covered major points, including: ambient SO_2 concentrations around the U.S., personal exposure considerations, NCEA's typology for characterizing causal relationships, SO_2 dosimetry, clinical and epidemiological studies covered in the ISA. Panelists engaged the NCEA presenters on the subject of relative risks and how to characterize causal relationships as well as the question of how to deal with multi-pollutant models in the context of the ISA. The NCEA representatives said they focused on studies with tight confidence intervals that adjusted for only one pollutant.

During the public comment period, Mr. Howard Feldman of the American Petroleum Institute presented (via phone) remarks that emphasized the inaccuracy that

was embedded in the SOx ISA due to its reliance on SO_2 measurements from ambient monitors as good surrogates for measurement of personal SO_2 exposure.

Following the public comment period, panelists addressed charge questions 1 – 3. All charge questions may be found in the draft ISA posted at http://www.epa.gov/ttn/naaqs/standards/so2/s_so2_cr_isa.html. Panelists presented their various comments captured in *12-3-07 Preliminary Draft Comments on EPA's Integrated Science Assessment for Sulfur Oxides - Health Criteria (First External Review Draft, Sept. 2007) from Clean Air Scientific Advisory Committee (CASAC) Sulfur Oxides Primary National Ambient Air Quality Standards (NAAQS) Review Panel*, posted at: http://www.epa.gov/sab/panels/casac_nox_and_sox_primary_panel.htm. Panelists stressed the following ways to improve the ISA, through: better descriptions of ship emissions; additional detail in presenting ambient data for SO_2; examination of SO_2 correlations with other co-pollutants like particulate matter, carbon monoxide, etc.; examination of correlations between 5 minute data, 24 hour data; maps, distinguishing between source monitors and population monitors; more integration of studies, acknowledgement of the role that PM plays in mediating SO_2 effects and the problems with interpreting multi-pollutant models.

Following a lunch break, panelists addressed the remaining charge questions, i.e. charge questions 5 – 8. Panelists also commended NCEA for improvements since the Panel's review of the NOx ISA in October 2007. The panelists again urged NCEA to follow a strict protocol for reviewing and evaluating each study, e.g. Hill's criteria for characterizing causation. Panelists stressed the need for a protocol that describes the approach for evidence gathering, evaluation, summarization and interpretation, including uniform criteria and language for describing the strength of the available evidence. Panelists urged NCEA to consider improvements to the ISA by presenting a compendium of the effects, emphasizing quantities needed for the risk assessment, and providing guidance on benchmarks or exposures of concern.

At the end of the day, panelists were tasked with writing brief consensus paragraphs that would go in the letter to the Administrator to be discussed the following morning.

On Thursday, December 6, 2007, the Panel discussed the draft produced in response to their assignments to write short responses to charge questions. Overnight, each draft response had been compiled into a single letter to the Administrator. Panelists discussed the language of each paragraph and offered a few revisions recorded by the Designated Federal Officer. At the end of this session, the draft letter to the Administrator, as projected on the overhead screen, was completed and ready for a final review via e-mail from the Panel. The Panel, including a quorum of the chartered CASAC, approved the draft letter projected on the screen.

After the morning break, scientists from OAQPS presented an overview of the draft *Sulfur Dioxide Health Assessment Plan: Scope and Methods for Exposure and Risk Assessment* (hereinafter, Exposure and Risk Assessment) at

http://www.epa.gov/ttn/naaqs/standards/so2/s_so2_cr_pd.html. Dr. Michael Stewart, Dr. Stephen Graham and Mr. Harvey Richmond summarized the organization of the document and discussed the objectives, scope, methods and expected output for each tier of the risk assessment. Panelists urged OAQPS to re-consider its preliminary decision not to do a Tier III analysis which would combine concentration-response or exposure-response data with exposure estimates to generate population risk estimates. One panelist in particular offered suggestions on using information on human interindividual variability for responses in order to make a tentative projection of the likely incidence of responses for asthmatics. Other panelists also urged OAQPS to consider advancing its plans for quantitative analysis of exposure levels and population effects. Panelists also weighed in on the issue of using a proportional (i.e., linear) approach to adjusting air quality to simulate just meeting potential alternative SO2 standards that are below recent air quality concentrations. Considerable discussion was devoted to understanding the extent and nature of 5 minute data available from states. One panelist offered a caution about using the cumulative density function of peak-to-mean ratios. OAQPS was also urged to validate its models.

After lunch, panelists urged OAQPS to reconsider its conclusion that insufficient information existed to do a Tier III analysis. Panelists brainstormed ways to impute the relationships between .2 and 1 ppm SO_2.

At the close of the meeting, panelists were reminded of a December 14, 2007 deadline for final revisions to both the draft letter to the Administrator and individual comments on both the ISA and Exposure and Risk Assessment document.

On Behalf of the Panel,
Respectfully Submitted,

Holly Stallworth, Ph.D. /s/
Designated Federal Officer

Certified as True:

Rogene Henderson /s/
Chair, Clean Air Scientific Advisory Committee
Sulfur Oxides Primary NAAQS Review Panel

NOTE AND DISCLAIMER: The minutes of this public meeting reflect diverse ideas and suggestions offered by committee members during the course of deliberations within the meeting. Such ideas, suggestions, and deliberations do not necessarily reflect definitive consensus advice from the panel members. The reader is cautioned to not rely on the minutes represent final, approved, consensus advice and recommendations offered to the Agency. Such advice and recommendations may be found in the final advisories, commentaries, letters, or reports prepared and transmitted to the EPA Administrator following the public meetings.

Attachment A

United States Environmental Protection Agency

Office of Air Quality Planning and Standards

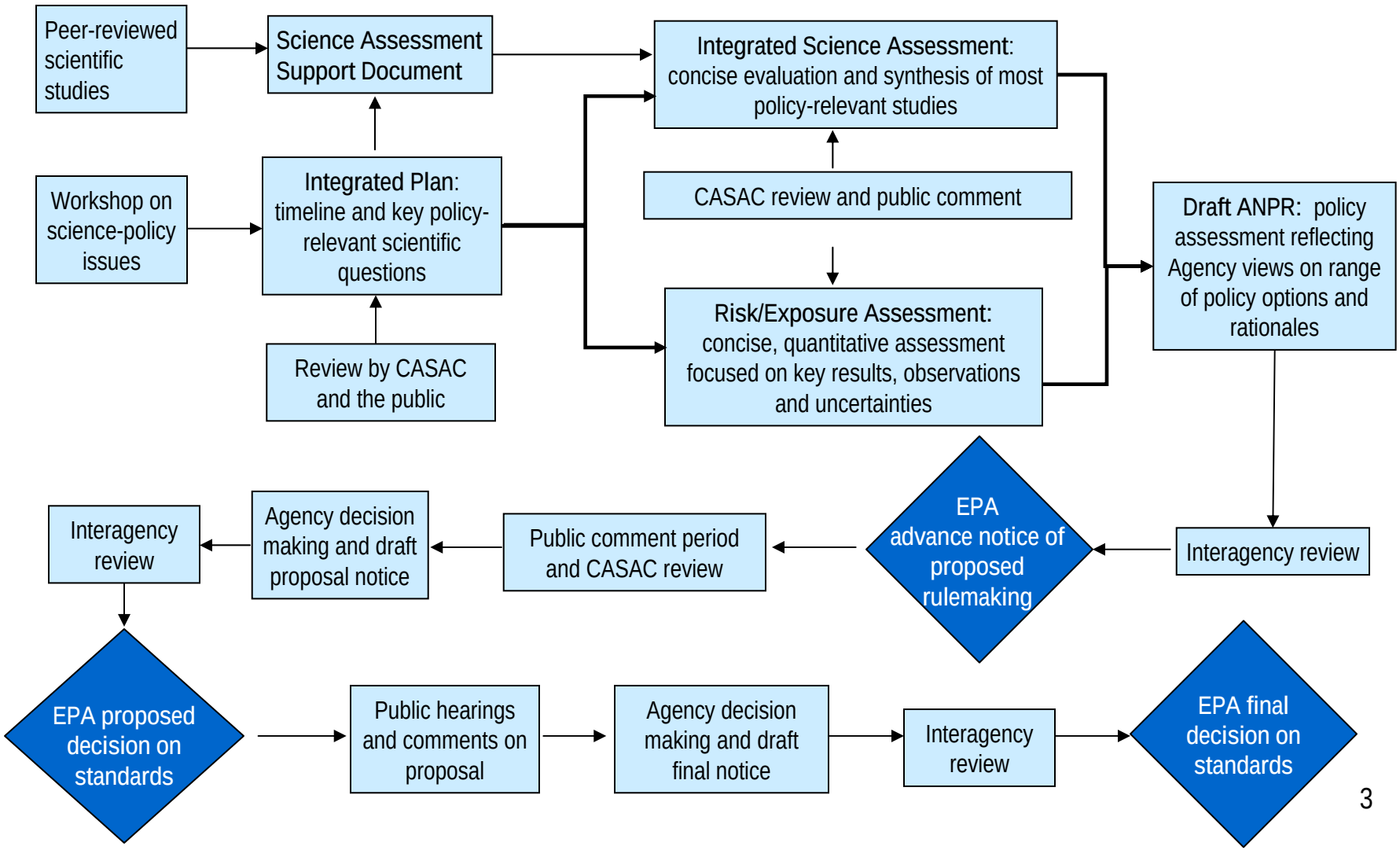
Background and Schedule for the Review of the Primary Sulfur Dioxide NAAQS:

Presentation to CASAC
December 5, 2007
Office of Air and Radiation
Office of Air Quality Planning and Standards

Overview

- Process for the current review
- Schedule for the current review
- History of the SO_2 NAAQS
- Highlights from the previous review
  - Key health effects identified in previous review
  - Administrator's conclusions from the previous review
  - SO_2 NAAQS remand
  - EPA's planned response to remand

Process for Current Review



Schedule for Current Review

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

*Indicates that a single CASAC meeting will address both documents

History of the SO_2 NAAQS

- 1971: Promulgated first NAAQS for SO_2
  - Primary NAAQS: 24-hour standard set at 0.14 ppm and annual standard set at 0.03 ppm
  - Secondary NAAQS: 3-hour standard set at 0.50 ppm
- 1988: Proposed not to revise the current standards
  - Requested comment on adding a 1-hour primary standard (0.4 ppm)
  - Based on a joint Criteria Document for PM and Sulfur Oxides (1982) and addendum (1986)
- 1994: Reproposed not to revise the current standards
  - Requested comment on regulatory alternatives, including adding 5-minute standard (0.60 ppm) or establishing new regulatory program under section 303
- 1996: Final decision not to revise the current 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
  - EPA did not adequately explain its decision not to set a 5-minute standard
- 2006: Deadline suit filed by Center for Biological Diversity (and others)
- Present: Consent decree in deadline suit entered; deadlines are now official
  - Current review will also address issues raised by the 1998 remand

Highlights from the Previous Review

- Key health effects identified in previous review
  - Increased respiratory illness and symptoms associated with *long-term* exposure to SO_2 and aggravation of bronchitis, increased mortality, and decreased lung function in children associated with *short-term* exposure to SO_2
    - Based on epidemiologic studies where it was difficult to separate the effects of SO_2 from PM
  - Transient impairment of respiratory function in a significant proportion of exercising asthmatics following 5-10 minute exposures to SO_2 at levels as low as 0.6 ppm
    - Based on controlled human exposure studies to 5-10 minute peaks of SO_2
- Administrator's conclusions from the previous review
  - The existing annual and 24-hr standards are required to protect against health effects associated with long- and short-term exposure to SO_2
  - 5-minute peak SO_2 levels do not pose a "broad public health problem when viewed from a national perspective" because they are "localized, infrequent, and site-specific" and therefore are "not the type of ubiquitous public health problem for which establishing a NAAQS would be appropriate" (61 FR at 25575); therefore, a 5-minute standard is not appropriate
    - This conclusion was based on an exposure analysis conducted by EPA

Highlights from the Previous Review (continued)

- S02 NAAQS remand:
  - In 1998, the Court of Appeals for the District of Columbia found EPA failed to adequately explain its determination that revisions to the SO_2 NAAQS were not appropriate and 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.
- EPA's planned response to remand:
  - Analyze additional 5-minute SO_2 air quality data collected since the last review
    - Much of this data comes from an increased monitoring effort that resulted from negotiations with the American Lung Association after the 1998 remand
  - Conduct a new risk/exposure analysis to better estimate the current size of the asthmatic population affected by short-term SO_2 peaks
  - Consider whether rulemaking under 303 is appropriate

- **Attachment B**

Integrated Science Assessment for Sulfur Oxides
(1st External Review Draft)

Presentation to the
Clean Air Scientific Advisory Committee

NCEA-RTP Sulfur Oxides Team
National Center for Environmental Assessment, RTP Division
Office of Research and Development

December 5, 2007

NCEA-RTP SO_x TEAM

ISA IN SUPPORT OF THE PRIMARY STANDARD

Dr. Ila Cote – Acting Division Director
Dr. Mary Ross – Branch Chief

Dr. Jee Young Kim - SO_x Team Leader

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- Dr. James Riddle, Sciences International

Overview

- Draft ISA highlights with focus on EPA charge questions
  - Source to Dose
    - Atmospheric sciences
    - Characterization of ambient concentrations
    - Exposure assessment
  - Health Effects
    - Morbidity and mortality from short-term exposures
    - Morbidity and mortality from long-term exposures

ISA Organization

- Integrated Science Assessment
  - Introduction
  - Source to tissue dose
  - Integration of health evidence
  - Public health impact
  - Key findings and conclusions
- Annexes: more detailed summaries of evidence
  - Atmospheric chemistry
  - Framework for modeling human exposures
  - Toxicology
  - 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 SO_2 NAAQS?
- Are the properties of ambient sulfur oxides appropriately characterized, including policy-relevant background, spatial and temporal patterns, and relationships between ambient sulfur oxides and human exposure?
- Is the information provided on atmospheric sciences and exposure sufficient for the evaluation of human health effects of sulfur oxides in the ISA?

Sulfur Chemistry in the Troposphere

- **Sulfur dioxide (SO_2)**: produced mainly by fossil fuel combustion (chiefly coal and oil) and metal smelting; electricity generating utilities (EGUs) are largest emitters.

- SO_2 is soluble and oxidized to sulfate (SO_4^{2-}) mainly in cloud droplets; gas-phase oxidation is less important.

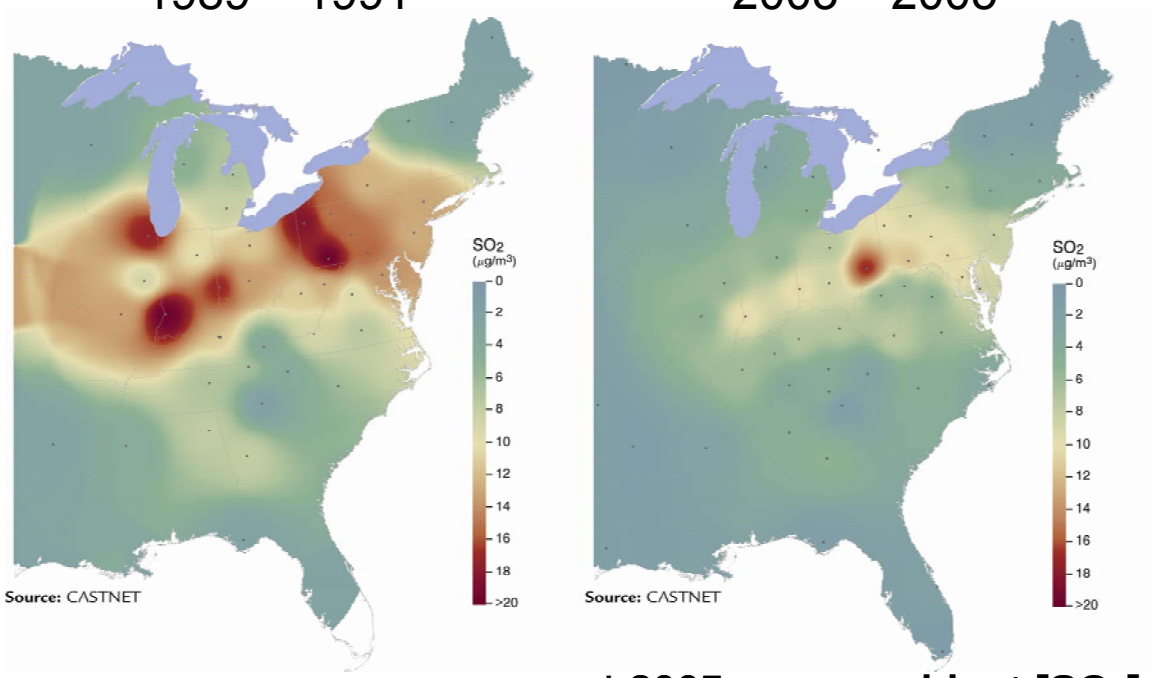
  - Dry deposition and conversion to SO_4^{2-} in cloud droplets and/or on particles removes gas-phase SO_2 within a few days.
  - Particulate SO_4^{2-} is removed from the atmosphere by wet and dry deposition in about a week.
  - Thus, SO_2 and SO_4^{2-} can be dispersed over large areas by winds aloft, resulting in largely homogeneous regional ambient exposures, except during precipitation and plume events.

Ambient SO_2 Concentrations

The national composite annual mean SO_2 ambient concentration decreased by 48% from 1990 to 2005

Annual Mean SO_2 Concentration

1989 – 1991 | 2003 – 2005



*** 2005 mean ambient [SO_2] : ~4 ppb**

Distribution of Measured SO_2 Concentrations Inside and Outside U.S. Cities as a Function of Temporal Averaging Times (2003-2005)

Averaging Time Monitor Locations	*n*	Mean	Percentiles 1	5	10	25	30	50	70	75	90	95	99	Max
1-h Maximum Concentration*														
Inside CMSAs**	332405	13	1	1	1	3	4	7	13	16	30	45	92	714
Outside CMSAs	53417	13	1	1	1	1	2	5	10	13	31	51	116	636
1-h Average Concentration*														
Inside CMSAs	7408145	4	1	1	1	1	1	2	4	5	10	15	34	714
Outside CMSAs	1197179	4	1	1	1	1	1	2	3	3	7	13	36	636
24-h Average Concentration*														
Inside CMSAs	327918	4	1	1	1	1	2	3	5	6	10	13	23	148
Outside CMSAs	52871	4	1	1	1	1	1	2	3	4	8	12	25	123
Annual Average Concentration*														
Inside CMSAs	898	4	1	1	1	1	2	4	5	6	8	10	12	15
Outside CMSAs	143	4	1	1	1	1	2	3	4	5	8	9	13	14

* Values are ppb

** CMSAs = Consolidated Metropolitan Statistical Areas

Personal Exposure Considerations

- Indoor SO_2 comes mostly from infiltration of outdoor air
- Only five studies identified since the last review that characterize personal exposures to present-day low concentrations of ambient SO_2
  - Typical 24-h SO_2 personal exposures now at or below the ~5 ppb detection limit of passive samplers; hence, ambient-to-personal exposure associations can be poorly characterized
  - Indoor-to-outdoor ratios in the U.S. range from 0.03 to 0.67; the variation due to building characteristics, indoor heating and ventilation sources varying with season, and instrument detection limit thresholds
- Studies with well-characterized personal exposures – higher concentrations; no indoor sources – demonstrated positive associations between ambient concentrations and personal exposure : *e.g.*, slope = 0.13, R^2 = 0.43 (Brauer, et al., 1989)

Charge Questions 4-6

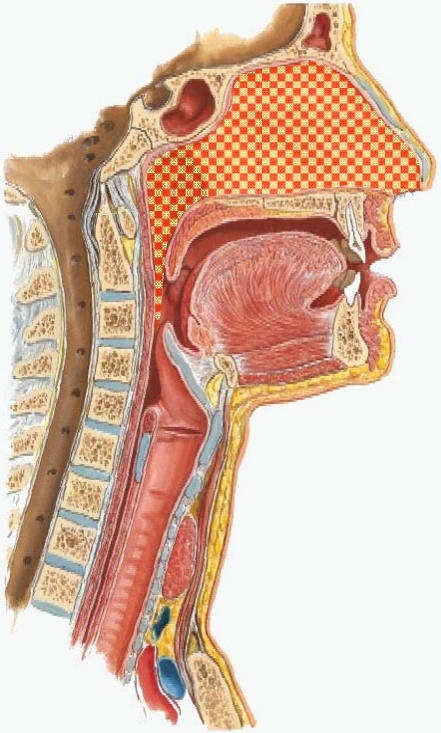
- To what extent are the discussion and integration of evidence on the health effects of sulfur oxides from the animal toxicological, human clinical, and epidemiological studies technically sound, appropriately balanced, and clearly communicated?
- To what extent does the integration of health evidence 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 health effects of sulfur oxides?

Evaluation of Health Evidence

- **Causal** – strong and consistent evidence from human clinical studies
- **Likely Causal** – strong and consistent epidemiological evidence along with coherent and plausible human clinical or animal toxicological evidence
- **Suggestive** – generally strong and consistent epidemiological evidence but limited experimental evidence for coherence and plausibility
- **Inconclusive** – epidemiological evidence not strong or consistent (or limited available evidence) and limited or no available experimental evidence for coherence and plausibility

Dosimetry

Light activity



Nasal breathing

SO_2 reaches the lower respiratory tract during exercise due to high ventilatory rates and oronasal breathing

Exercise

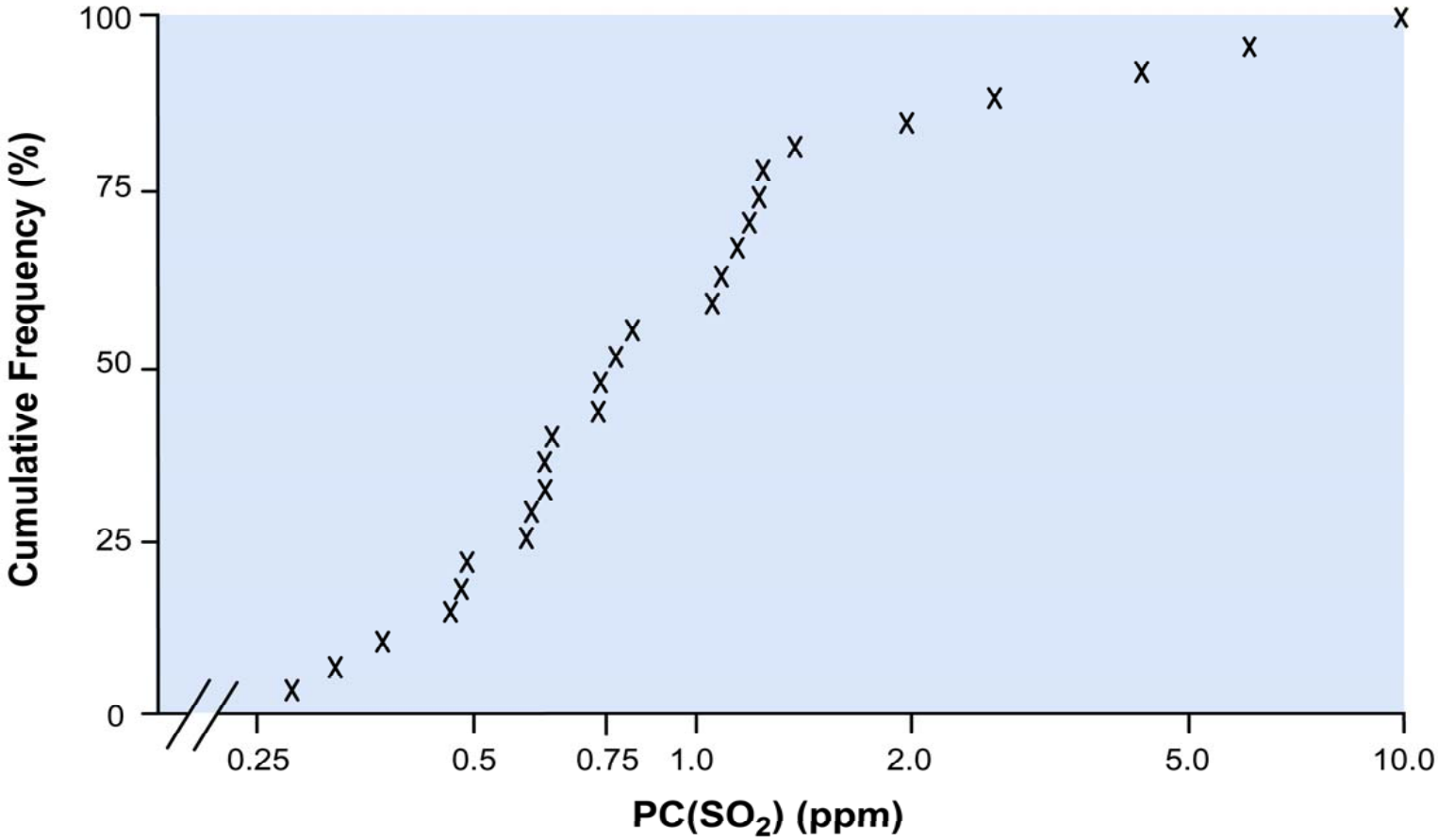
Oronasal breathing

SO_2 in the airways

Peak Exposures: Respiratory Effects

Human Clinical Studies

- SO_2-induced respiratory effects consistently demonstrated in exercising asthmatic individuals
  - 5-15 minute exposures to concentrations of 0.5-1.0 ppm
  - Lung function decrements and respiratory symptoms increase with exposure concentration
  - Effects generally not enhanced with increasing exposure duration above 10-15 minutes
- Respiratory effects not observed in exercising non-asthmatics at concentrations below 1.0 ppm



Distribution of individual airway sensitivity to SO_2 among asthmatics (n=27) following 10 min exposures with moderate levels of exercise . PC(SO_2) is the estimated SO_2 concentration needed to produce a doubling of specific airways resistance.

Source: Horstman et al. (1986)

Short-term Exposures: Respiratory Effects

Epidemiological Studies

Reference	Location	Population	Lag
Mortimer et al. (2002)	8 U.S. cities	Asthmatics (n = 846)	1-2
Schwartz et al. (1994)	6 U.S. cities	Children (n = 300)	1
*Van der Zee et al. (1999)	5 urban areas in the Netherlands	With chronic respiratory symptoms (n = 142)	0
			1
			0-4
*Roemer et al. (1993)	The Netherlands	With chronic respiratory symptoms (n = 73)	0
			1
			0-6
Hoek and Brunekreef (1994)	The Netherlands	Children (n = 1079)	0
			1
Segala et al. (1998)	Paris, France	Mild asthmatics (n =43)	1
*Schildcrout et al. (2006)	7 U.S. Cities	Asthmatics (n = 881)	0
			1
			0-2
Romieu et al. (1996)	N. Mexico City, Mexico	Mild asthmatics (n = 71)	Not stated

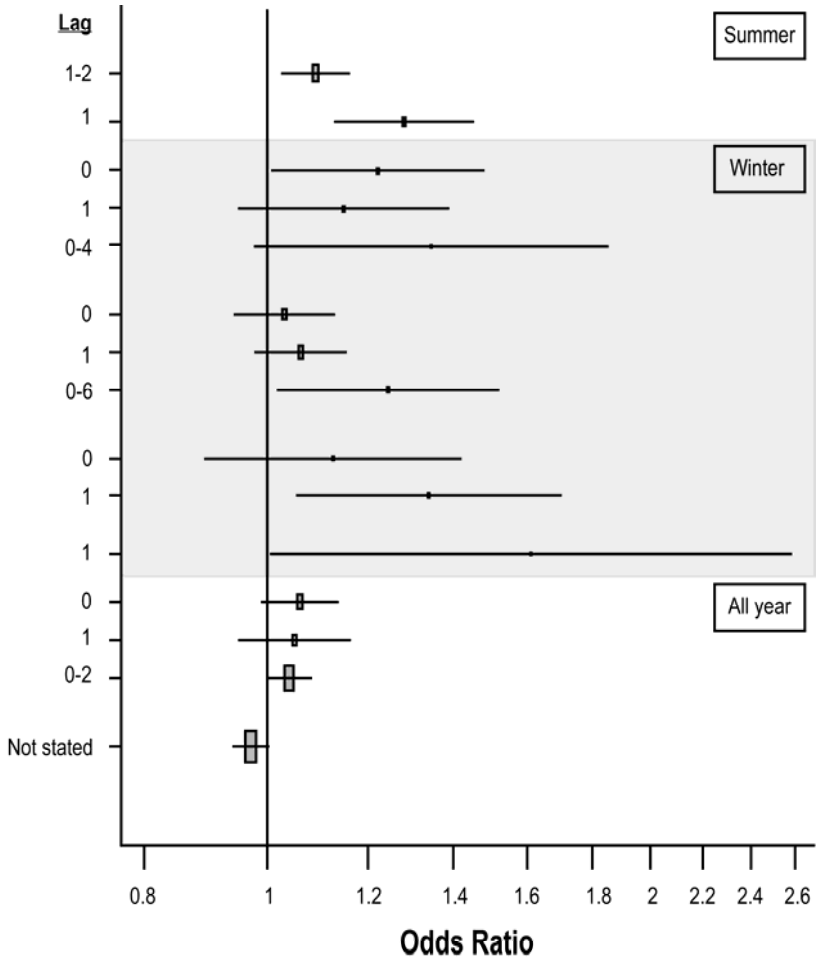
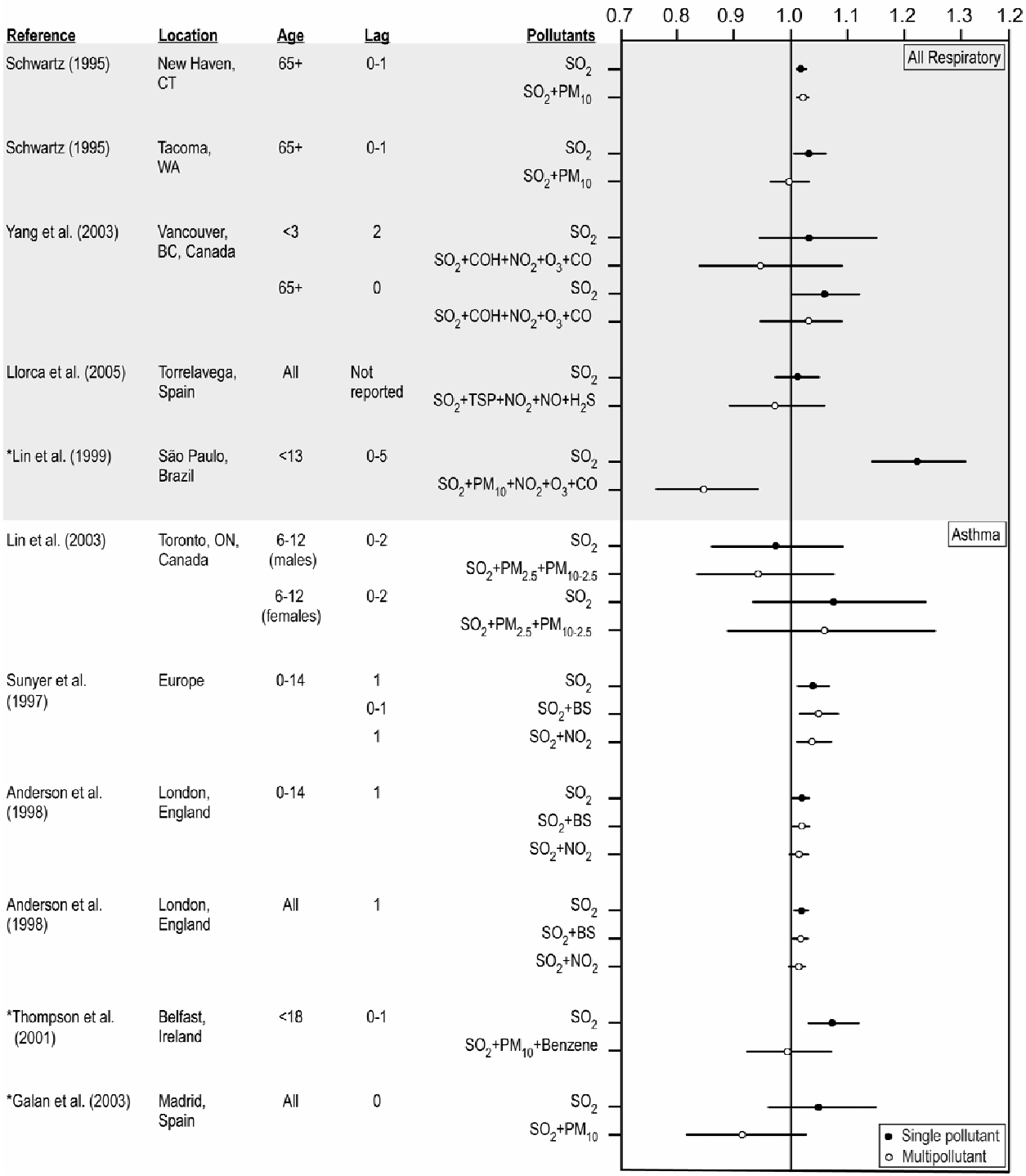


Figure 3.1-4. Odds ratios (95% CI) for the incidence of lower respiratory symptoms or asthma symptoms among children, grouped by season

*Risk estimates are standardized per 10-ppb increase in 24-h avg SO_2 level

Figure 3.1-11. Increased Risk of All Respiratory and Asthma Hospitalizations and ED Visits, with Copollutant Adjustment

Relative Risk (95% CI) for associations between hospitalizations and ED visits and 24-hour average SO_2 concentrations (per 10 ppb).



Short-term Exposures: Respiratory Effects

Respiratory symptoms

- Associations observed between ambient SO_2 concentrations and increased respiratory symptoms in children, particularly those with asthma or chronic respiratory symptoms
  - Associations observed at ambient concentrations below the current 24-h average NAAQS of 0.14 ppm

ED visits and hospital admissions

- Positive, but not always statistically significant, associations observed between ambient SO_2 concentrations and ED visits and hospitalizations for all respiratory causes and asthma, particularly among children and older adults

* **Overall, we conclude that there is a "likely causal" relationship between short-term exposure to SO2 and respiratory effects**

Short-term Exposures: Cardiovascular Effects and Mortality

Cardiovascular morbidity

- **Inconclusive evidence** from epidemiological studies and human clinical studies
  - Associations observed with ED visits and hospitalization, but lack of supportive data from panel studies and human clinical studies on cardiovascular health effects

All cause mortality

- **Suggestive evidence** from epidemiological studies
  - Positive associations in U.S. and Canadian multicity studies
  - SO_2 risk estimates generally reduced with copollutant (e.g., PM, NO_2) adjustment, suggesting some extent of confounding among these pollutants
  - Intervention study from Hong Kong supports notion that reduction in SO_2 levels results in reduction in deaths

Health Effects from Long-term Exposures

Respiratory morbidity

- **<u>Inconclusive evidence</u>** from epidemiological studies and animal toxicological studies
  - Some epidemiological studies observed positive associations of long-term exposure to SO_2 with respiratory symptoms in children; however, overall evidence limited and inconsistent

Cancer incidence

- **<u>No evidence</u>** from epidemiological studies and animal toxicological studies

Adverse birth outcomes

- **<u>Inconclusive evidence</u>** from epidemiological studies
  - Limited evidence from epidemiological studies suggested an association between SO_2 and low birth weight; however, most studies did not adjust for potential confounding factors

Mortality

- **<u>Inconclusive evidence</u>** from epidemiological studies
  - Associations observed between long-term exposure to SO_2 and mortality in some U.S. studies; however, results inconsistent across studies and assessment of potential confounding challenging

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 sulfur oxides?

- 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?

Susceptible and Vulnerable Subpopulations

Individuals with preexisting disease:

- Human clinical and epidemiological studies suggest that subjects with respiratory illnesses, particularly asthma, are more susceptible to respiratory health effects from SO_2 exposures than the general public

Age:

- Limited epidemiological evidence suggests that children and older adults (65+ years) are more vulnerable and/or susceptible to respiratory health effects from SO_2 exposures than the general public

Genetic polymorphisms:

- Only one study specifically examined variability in the effect of SO_2 by genetic polymorphisms, and found a significant association with the homozygous wild-type allele for TNF-α (Winterton et al., 2001)

Attachment C

United States Environmental Protection Agency

Office of Air Quality Planning and Standards

Overview of the Scope and Methods Plan Supporting the Review of the Primary SO_2 NAAQS

Presentation to CASAC

December 6, 2007

Office of Air and Radiation

Office of Air Quality Planning and Standards

Purpose of this Meeting

- Solicit feedback on EPA's planned approach to assessing risks and exposures associated with SO_2

Overview

- Exposure Assessment
  - Tier I
  - Tier II
- Risk Assessment
  - Tier I
  - Tier II
  - Tier III
- Charge Questions for CASAC

Exposure Assessment: Overview

- Goals of the exposure assessment:
  - Estimate frequency of short-term peak SO_2 exposures to ambient concentrations through air quality characterization and exposure modeling analyses
  - Estimate time-averaged SO_2 ambient concentrations
- Approach
  - Tier I: Air quality characterization
  - Tier II: Exposure assessment
- Populations Considered
  - Susceptible/vulnerable populations (as identified in ISA): children (birth to 18), asthmatic children (birth to 18), asthmatic adults (>19), and the elderly (>65)
- Assessment of uncertainty
  - At each analysis Tier, will progress from qualitative to quantitative depending on availability of data and anticipated magnitude of the uncertainty

Exposure Assessment: Tier I

- Objectives:
  - Estimate the number of short-term 5-minute peak concentrations at ambient SO_2 monitoring locations considering various averaging times (1-hour, 3-hour, daily, annual) and concentration levels
  - Estimate short- and long-term average concentrations using 1-hr average ambient monitoring data
  - Provide inputs to the Tier II risk assessment and a Tier III risk assessment, if performed
- Approach
  - Using 5-minute monitoring data, develop a statistical model(s) relating short-term peak concentrations (5-minute) to 1-hour average concentrations
    - Consider influential factors: temporal variability, hourly concentration levels, proximal sources of SO_2
    - Consider population demographics surrounding monitors to estimate surrogate exposures
  - Using 1-hour ambient monitoring data, estimate time-averaged ambient concentrations in urban areas consistent with time-averaging reported in relevant epidemiological studies
- Expected output
  - Number of short-term peak concentrations/potential exposures given time-averaged concentrations at ambient monitors
  - Various time-averaged ambient monitor concentrations in selected urban areas
  - Statistical relationships among 5-minute peak and 1-hr average ambient monitoring concentrations including those proximal to local emission sources
- Uncertainty
  - primarily qualitative, however may develop confidence intervals around peak estimates and perform cross-validation/sensitivity analysis of peak-to-mean ratios used in statistical model

Exposure Assessment: Tier II

- Objectives:
  - Estimate 5-minute peak exposure concentrations surrounding important local sources of SO_2
    - account for human attributes that influence short-term (e.g., 5-minute) personal exposure, including behavior (e.g., time spent outdoors) and physiology (e.g., heightened ventilation rates)
  - Provide input to the Tier II risk assessment and a Tier III risk assessment, if performed
- Approach
  - Estimate hourly concentrations at receptor locations considering important SO_2 emission sources using a dispersion model (AERMOD)
  - Estimate 5-minute concentrations at receptor locations using relationship(s) developed from ambient monitoring data (in Tier I analysis)
  - Estimate human exposure to 5-minute peak concentrations using exposure model (APEX)
- Expected output
  - Temporally and spatially resolved ambient levels of SO_2 accounting for local sources
  - Number of people exposed one or more times to selected SO_2 level(s) during elevated exertion in close proximity to modeled sources
- Uncertainty
  - Model to measured comparisons for near-source concentrations (where data are available)
  - Monte Carlo approach using specified distributions for input parameters

Risk Assessment: Overview

- Goals of risk assessment
  - To qualitatively characterize the range of health effects associated with exposure to SO_2 (e.g., weight of evidence concerning causality, nature of evidence related to concentration-response and exposure-response relationships, identification and size of susceptible and vulnerable populations, adversity)
  - To estimate number of occurrences of very short-term air quality events and number of people exposed at or above various potential health effect benchmarks while engaged in moderate or greater exertion associated with alternative SO_2 scenarios
  - To provide analysis of epidemiologic evidence reporting respiratory effects associated with 1- and 24-hr ambient concentrations in urban areas
  - To provide health risk estimates for SO_2-related health endpoints associated with alternative SO_2 scenarios (if a Tier III assessment is conducted)
  - Identify and characterize key assumptions, variability, and uncertainty associated with the assessments
- Scenarios evaluated
  - Recent air quality levels, air quality levels just meeting the current suite of standards, and air quality levels just meeting potential alternative standards
- Three-tiered approach
  - Tier I: Qualitative characterization of health effects evidence presented in the ISA
  - Tier II:
    - Potential Health effects benchmark levels (based on review of ISA) compared to very short-term (5-min) air quality and/or exposure estimates near major SO_2 sources
    - Additional analysis of epidemiologic evidence reporting respiratory effects associated with 1- and 24-hr ambient concentrations in urban areas
  - Tier III: Combine concentration-response or exposure-response data with exposure estimates to generate population risk estimates (if judged feasible and of sufficient utility)

Risk Assessment: Tier I

- Provides a qualitative assessment of the health effects evidence presented in the 1st and 2nd draft ISAs
- Determines which identified health endpoints and associated averaging times are likely candidates for progression to a Tier II or III risk characterization.

Risk Assessment: Tier II - Bronchoconstriction in Exercising Asthmatics

- Focus is on very short-term (5 minutes) air quality levels (from the Tier I exposure assessment) or estimated exposure levels (from the Tier II exposure assessment) that will be compared to potential health benchmark levels for populations living near modeled major SO_2 sources
- Health effect benchmarks will be identified from the 2nd draft ISA
  - Tentative benchmarks: 0.5 to 0.6 ppm (5-min averaging time) in asthmatics (children and adults)
    - Based on controlled human exposure studies
    - Uncertainty about health effect benchmarks will be qualitatively addressed
    - Will use alternative benchmark levels to illustrate impact of alternative choices about lowest exposure level of concern
  - Variability:
    - Geographic variability addressed by conducting analysis for modeled sources throughout the U.S.
    - Population variability in response addressed qualitatively
- Projected outcomes:
  - Number of occurrences of air quality levels at or above several potential health effect benchmarks
  - Number of times in a given year that a population or individual experiences various exposure levels of concern

Risk Assessment: Tier II – Respiratory Effects in Asthmatics (symptoms, emergency department visits, hospital admissions)

- Focus is on 1- and 24-hr SO_2 ambient concentrations in urban areas related to epidemiologic evidence reporting increased respiratory-related effects
- Gather additional information to characterize the SO_2 ambient air quality that existed at the time various key U.S. and Canadian studies addressing respiratory effects were conducted
  - To see if there are any discernable patterns regarding the effect estimates observed in these epidemiologic studies related to:
    - Particular SO_2 levels and associated averaging times (e.g., 98th and 99th percentile of daily averages)
    - Geographic location and/or season
    - Inclusion of various co-pollutants

Risk Assessment: Tier III

Based on our analysis of the first draft of the ISA…

- A Tier III risk assessment, if conducted, would focus on short-term (1- and 24-hour) ambient levels and respiratory-related effects in urban areas
  - Respiratory-related hospital admissions, especially for asthmatics
  - Respiratory-related emergency department visits, especially for asthmatic children
  - Respiratory symptoms (e.g., cough and wheeze), particularly in children and asthmatics
- Uncertainty associated with the SO_2 coefficient in the concentration-response function would be addressed by providing confidence intervals around point estimates of risk and by presenting a range of results based on different epidemiological studies from different cities
- Expected outputs (in each case central tendency and 95% confidence interval estimates would be provided)
  - Estimated incidence (number of cases)
  - Incidence per 100,000 relevant population for each health endpoint
  - Hypothetical change in incidence associated with moving from just meeting current standard to just meeting potential alternative standards

Risk Assessment: Tier III (Continued)

- If conducted, would estimate number of individuals in selected populations for several example urban areas expected to experience specified respiratory-related health effects
- Would be based on epidemiologic literature
  - Preliminary judgment that controlled human exposure studies do not provide enough information to identify credible exposure-response relationships
  - Still evaluating whether or not epidemiological evidence adequate to conduct credible quantitative risk assessment
- Criteria for determining if Tier II assessment conducted
  - Outcome of Tier II assessment
  - Availability of info and data required to conduct a Tier III assessment (e.g., adequate C-R functions, baseline incidence data for urban areas)
  - Utility or value-added to decision process, beyond insights provided by Tier II assessment
  - Feasibility of conducting a Tier III assessment within consent decree schedule and resources

Broader Risk Characterization

- Summary of U.S. air quality information and discussion of various health effects from the ISA
  - Provide context for quantitative risk estimates
  - Will include air quality statistics for all areas of U.S. with SO_2 monitoring data
- National-scale information on size of potentially susceptible populations will be presented

Charge Questions for CASAC:

Air Quality Considerations:

- Based on the low estimated contribution of policy-relevant background SO2 to overall ambient SO2 levels, staff is considering a proportional (i.e., linear) approach to adjusting air quality to simulate just meeting potential alternative SO2 standards that are below recent air quality concentrations. Do the Panel members have comments on adopting a proportional approach to simulate just meeting more stringent alternative air quality standards?

- Recognizing that current ambient air quality concentrations are lower than the current standards, the draft Health Assessment Plan discusses two alternative approaches to simulating ambient SO2 levels associated with just meeting the current SO2 standards: use of historical air quality data (e.g., possibly pre-2000) when ambient levels were at or above the current standards, or use of a proportional (i.e., linear) approach to adjust SO2 levels upward. Do the Panel members have advice or comments on these two alternative approaches to simulating air quality just meeting the current SO2 standards?

Charge Questions (continued)

Exposure Analysis

- In considering the exposure analysis broadly
  - Do Panel members have any comments on the general structure and overall two-tier approach that staff plans to use for the exposure analysis? Are the criteria that staff plans to use for deciding whether to conduct a Tier II analysis clear and appropriate?
  - Have the most important factors influencing exposure to SO2 been clearly accounted for and described?
  - The draft plan describes the basis for and selection of population groups of interest (i.e., children, asthmatics (children and adults), and the elderly) for which SO2 exposure estimates are to be developed. Do Panel members generally agree with the groups of interest identified in the draft plan?
- In considering the Tier I exposure assessment:
  - Do Panel members agree that a statistical model using available ambient 5-minute monitoring data is appropriate for estimating expected exceedances of very short-term (5-minute) potential health effect benchmarks?
  - Do Panel members agree with the approach of applying a statistical model to estimate 5-minute concentration exceedances at monitoring locations where only 1-hour monitoring was performed for evaluating the extent of 5-minute peaks associated with meeting alternative standards with longer averaging times?

Charge Questions (continued)

- In considering the Tier II exposure assessment:
  - Do Panel members agree with the combined emissions/dispersion modeling approach to estimate short-term (hourly) SO_2 concentrations in close proximity to SO_2 emission sources?
  - Do Panel members have comments or advice regarding the described binning of sources and development of prototype stacks/facilities?
  - Do Panel members agree with the approach using peak-to-mean ratio cumulative density functions (PMR CDFs) to estimate very short-term peak concentrations from the 1-hour modeled concentrations?
  - Do Panel members generally agree that the approach described using APEX is reasonable and appropriate to estimate the occurrence of very short-term (5 minute) SO_2 peak exposures?
  - Do Panel members have any comments or advice regarding the general approach to addressing uncertainty and variability in each Tier of the exposure assessment as described in the draft plan?

  <u>Health Risk Assessment</u>
  - Do Panel members have any comments on the general structure and overall three-tier approach that staff plans to use for the risk assessment? Are the criteria that staff plans to use for deciding whether to conduct a Tier III risk assessment clear and appropriate?

Charge Questions (continued)

- In considering the Tier I risk assessment:
  - Do Panel members agree with the approach of having a qualitative assessment of health endpoints to identify which are likely candidates for a more sophisticated and quantitative tier of assessment?
  - Do Panel members agree with our initial observation that controlled human exposure studies demonstrate strong evidence for bronchoconstriction in exercising asthmatics following 5-10 minutes SO_2 exposure?
  - Do Panel members agree with staff's initial observation that the strongest epidemiologic evidence for health effects related to SO_2 exposure is for respiratory symptoms in asthmatic children and respiratory-related hospital admissions and respiratory-related emergency department visits in asthmatics and others with respiratory conditions?
- In considering the Tier II risk assessment:
  - In general, are staff plans to use potential health effect benchmarks to address respiratory effects demonstrated in exercising asthmatics in controlled human exposure studies clear and appropriate?
  - Do Panel members generally agree with the tentatively identified potential health effect benchmark of 0.5 to 0.6 ppm for exercising asthmatics following 5-10 minutes SO_2 exposure?
  - Do Panel members generally agree with the staff's approach of focusing on areas around major sources of SO_2 with respect to concerns about 5-10 minute peak exposures related to the respiratory effects observed in controlled human exposure studies?

Charge Questions (continued)

- In considering the Tier II risk assessment (continued):
  - Do Panel members generally agree with staff's approach of focusing on urban areas with respect to concerns about 1- and 24-hr and annual SO_2 concentrations related to respiratory effects observed in epidemiologic studies?
  - Do Panel members have any comments or advice with respect to staff's approach of gathering additional information to characterize the SO_2 ambient air quality that existed at the time various key U.S. and Canadian studies addressing respiratory effects were conducted to see if the concentration-response relationships observed in these epidemiologic studies are related to particular SO_2 levels and associated averaging times, geographic location and/or season, and the inclusion of various co-pollutants?
- In considering the Tier III risk assessment:
  - Do Panel members generally agree that there is insufficient information to develop credible exposure-response relationships for use in a quantitative risk assessment based on the controlled human exposure evidence?
  - Do Panel members have any comments or advice with respect to the general approach or specific factors to be considered in deciding whether or not to proceed to a Tier III quantitative risk assessment for the respiratory-related health endpoints based on epidemiologic evidence discussed in the draft plan?
- In considering uncertainty and variability:

  Do Panel members have any comments or advice with respect to the general approach to addressing uncertainty and variability in each tier of the risk assessment as described in the draft plan?