

**U.S. Environmental Protection Agency
Clean Air Scientific Advisory Committee (CASAC)
Ozone Review Panel
Public Meeting**

**EPA Presentation of Revisions
to Draft Ozone Integrated Science Assessment**

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**Durham, NC
January 9-10, 2012**

Timeline for Ozone ISA

- 1st Draft ISA – March 2011
- CASAC meeting – May 19-20, 2011
- 2nd Draft ISA – September 2011
- CASAC meeting – January 9-10, 2012
- Final ISA – Feb/Mar 2012 target



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Major Revisions to ISA in Response to CASAC Comments

- Executive Summary – added as new Chapter 1
- Original Chapter 1 – parsed out
 - Preamble: ISA development and causality framework
 - Preface: O₃ NAAQS legislative / historical background
 - Chapter 2: introductory material specific to this ISA
- Chapter 2 – increased focus on integration
- Chapter 3 – new background O₃ modeling
- Chapter 8 – focus on “at-risk” populations

Second External Review Draft Ozone ISA - Chapters

Preamble

Preface

1. Executive Summary
2. Integrative Health and Welfare Effects Overview
3. Atmospheric Chemistry and Ambient Concentrations
4. Exposure to Ambient O₃
5. Dosimetry and Mode of Action
6. Integrated Health Effects of Short-term O₃ Exposure
7. Integrated Health Effects of Long-term O₃ Exposure
8. Pop. Potentially at Increased Risk for O₃-related Health Effects
9. Environ. Effects: O₃ Effects on Veg. and Ecosystems
10. Role of Tropospheric O₃ in Climate Change and UV-B Effects

Charge Questions

Preface, Preamble, Chapters 1 (Executive Summary) and 2 (Integrative Overview)

1. The CASAC panel offered a number of recommendations to enhance the organization and presentation of the evidence in the ISA. An Executive Summary has been prepared and is put in the place of Chapter 1. As part of the development of the Executive Summary and restructuring of the integrative overview chapter, Chapter 1 materials have been revised and moved, specifically: (a) the more general sections on the development of the ISA and the causality framework are being placed in a Preamble that can support all ISAs; (b) the introductory sections specific to this ISA are placed at the beginning of Chapter 2; and (c) sections on legislative background and history of previous reviews are contained in a Preface in the front matter of the ISA. The intent was to bring the integrative overview discussion to the front of the document, thus making it more accessible to the reader.

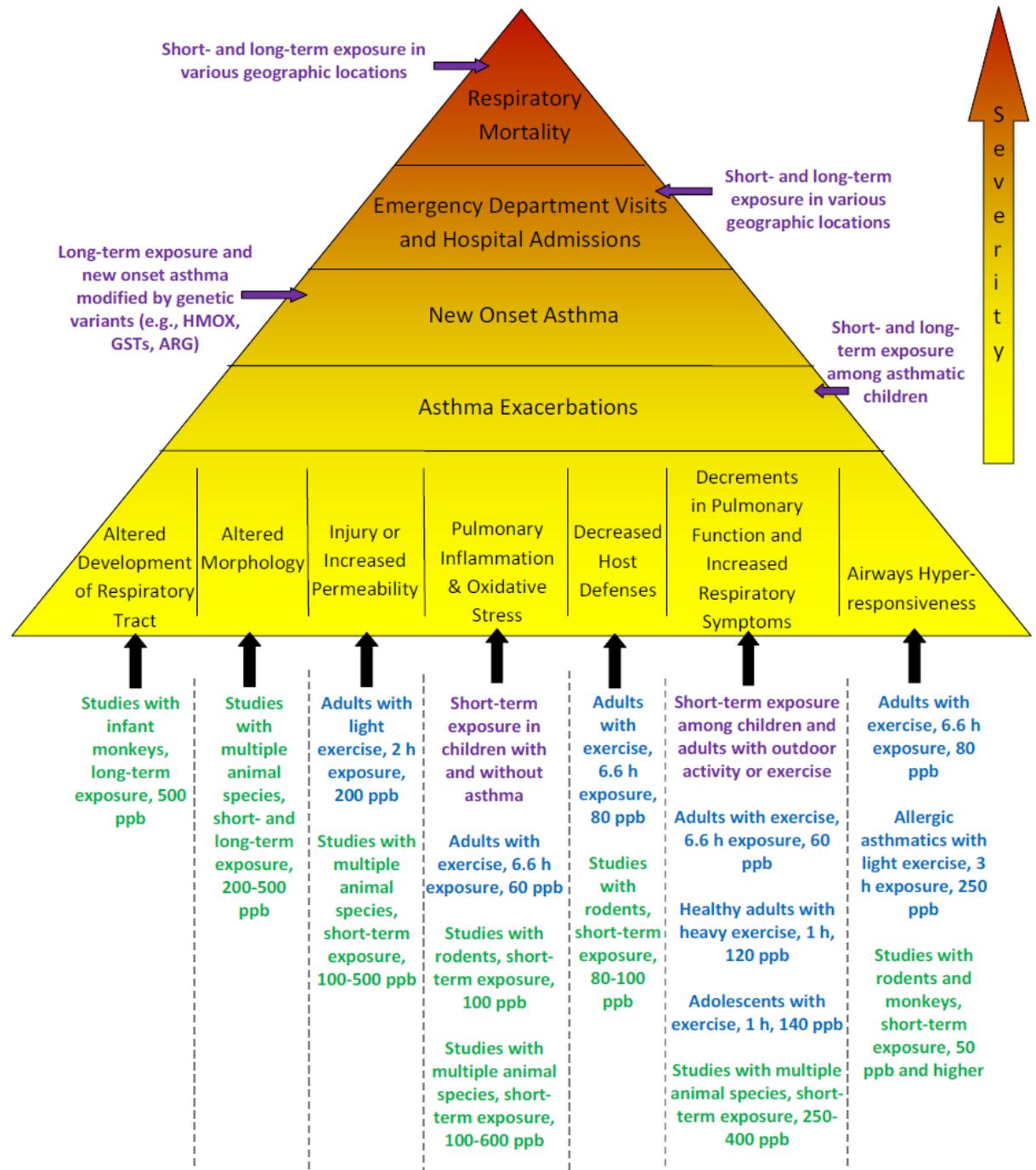
Please review and comment on the effectiveness of these revisions. Please comment on the extent to which Chapters 1 and 2 comprise a useful and effective approach for presenting this summary information and conclusions. Please recommend any revisions that may improve the scientific accuracy of these summary sections and the conclusions therein.

Second External Review Draft Human Health Causal Determinations

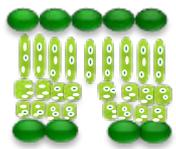
Health Outcome	Conclusions from Previous Review	Conclusions from 2011 2nd Draft ISA
Short-Term Exposure to O₃		
Respiratory effects	The overall evidence supports a causal relationship between acute ambient O ₃ exposures and increased respiratory morbidity outcomes.	Causal Relationship
Cardiovascular effects	The limited evidence is highly suggestive that O ₃ directly and/or indirectly contributes to cardiovascular-related morbidity, but much remains to be done to more fully substantiate the association.	Suggestive of a Causal Relationship
Central nervous system effects	Toxicological studies report that acute exposures to O ₃ are associated with alterations in neurotransmitters, motor activity, short and long term memory, sleep patterns, and histological signs of neurodegeneration.	Suggestive of a Causal Relationship
Mortality	The evidence is highly suggestive that O ₃ directly or indirectly contributes to non-accidental and cardiopulmonary-related mortality.	Likely to be a Causal Relationship
Long-term Exposure to O₃		
Respiratory effects	The current evidence is suggestive but inconclusive for respiratory health effects from long-term O ₃ exposure.	Likely to be a Causal Relationship
Cardiovascular Effects	No studies from previous review.	Suggestive of a Causal Relationship
Reproductive and developmental effects	Limited evidence for a relationship between air pollution and birth-related health outcomes, including mortality, premature births, low birth weights, and birth defects, with little evidence being found for O ₃ effects.	Suggestive of a Causal Relationship
Central nervous system effects	Evidence regarding chronic exposure and neurobehavioral effects was not available.	Suggestive of a Causal Relationship
Cancer	Little evidence for a relationship between chronic O ₃ exposure and increased risk of lung cancer.	Inadequate to infer a Causal Relationship
Mortality	There is little evidence to suggest a causal relationship between chronic O ₃ exposure and increased risk for mortality in humans.	Suggestive of a Causal Relationship

Continuum of Respiratory Effects

New Figure 2-3



O₃ exposure



O₃ uptake & physiology (Fig 9-2)

- Antioxidant metabolism up-regulated
- Decreased photosynthesis
- Decreased stomatal conductance or sluggish stomatal response



Effects on leaves

- Visible leaf injury
- Altered leaf production
- Altered leaf chemical composition



Plant growth (Fig 9-8)

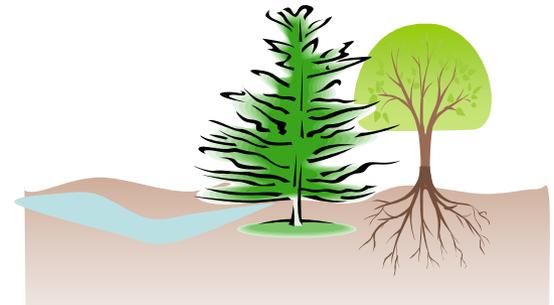
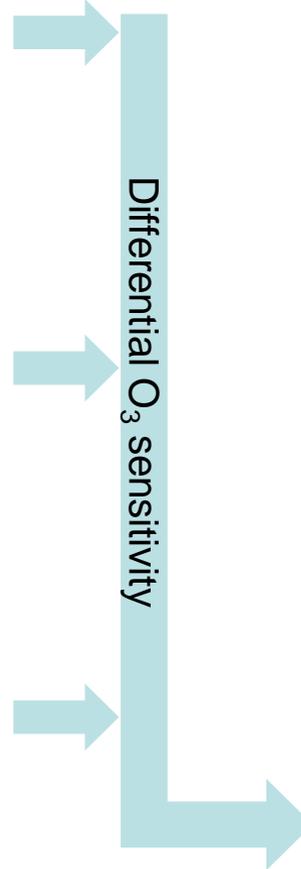
- Decreased biomass accumulation
- Altered reproduction
- Altered carbon allocation
- Altered crop quality



Belowground processes (Fig 9-8)

- Altered litter production and decomposition
- Altered soil carbon and nutrient cycling
- Altered soil fauna and microbial communities

New Figure 2-4 and 9-1



Affected ecosystem services

- Decreased productivity
- Decreased C sequestration
- Altered water cycling (Fig 9-7)
- Altered community composition (i.e., plant, insect & microbe)

Charge Questions

Chapter 3 - Atmospheric Chem. and Ambient Conc.

2. Pertaining to estimates of background O₃ concentrations, Sections 3.4 and 3.9 were updated and expanded to more fully describe the scientific issues associated with estimating background concentrations as well as the limitations and uncertainties of the methods used to estimate them. Section 3.6 on ambient O₃ concentrations was revised to improve the description of variability in O₃ concentrations attributed to diurnal and seasonal patterns, and spatial differences in urban and non-urban locations.

Please comment on the adequacy of these and other changes to the chapter and recommend any revisions to improve the discussion of key information. In relation to ambient and background O₃ concentrations, is material clearly, succinctly, and accurately provided? Where appropriate, please provide guidance that may refine the scientific interpretation and/or improve the representation of the science.

Background Ozone

Historically - Policy
Relevant Background is ozone concentrations that would exist in the absence of anthropogenic emissions of ozone precursors in the U.S., Canada and Mexico (North American Background)

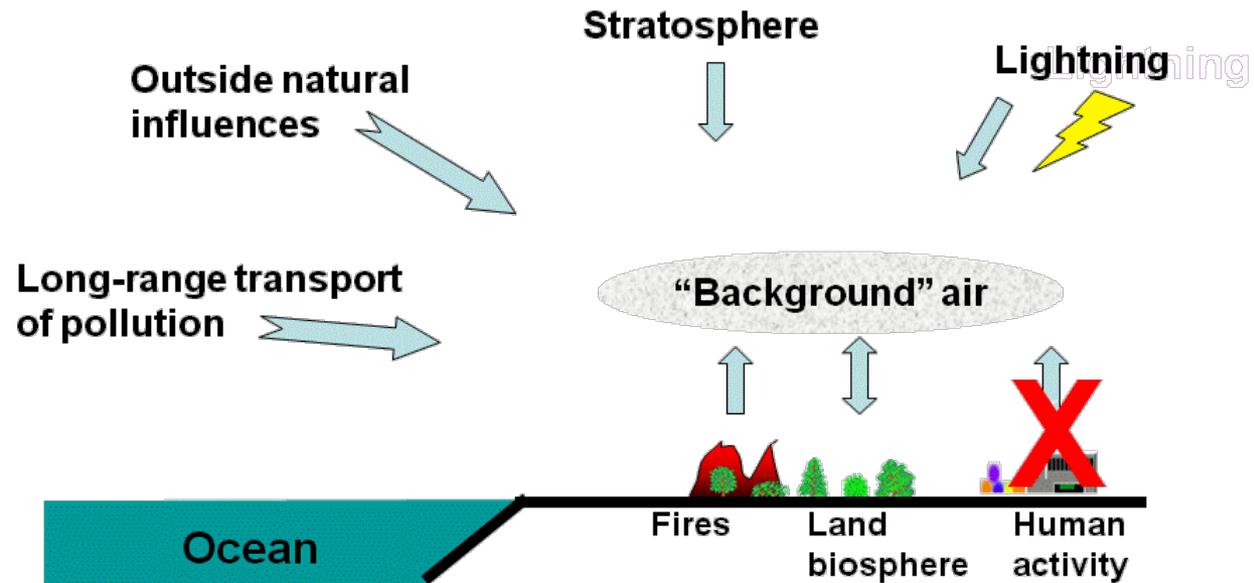


Fig. 3-7

Background O₃ is not directly observable → Must be estimated with models

New: Alternative Definitions

“Ozone concentrations that would exist in the absence of anthropogenic emissions of ozone precursors in _____”

- “the world” - Natural Background
- “the U.S., Canada and Mexico” - North American Background (historically PRB)
- “the U.S. only” - U.S. Background

Charge Questions

Chapter 4 – Exposure to Ambient Ozone

3. Revisions made to Chapter 4 in response to CASAC comments include clarifying the discussion of the relevance of central-site monitoring data for epidemiologic studies, together with potential bias and uncertainty due to exposure error; revising the summary section to be more concise and focused on the main points of the chapter; and preparing tables to summarize field study data and facilitate comparison of exposure models. In addition, material has been added discussing averting behavior on high-O₃ concentration days.

Please comment on the adequacy of these and other changes in responding to the Panel's comments. Please provide comment on revisions that may further improve the utility of discussion for characterizing personal-ambient exposure relationships and for interpretation of epidemiologic results in subsequent chapters.

New: Human Averting Behavior in Response to High O₃ Concentrations

Behavior Evidence

- People may alter their behavior (e.g., spend less time outdoors) in response to public health alerts for high O₃ concentrations
- A limited number of studies report evidence of averting behavior among:
 - Asthmatics (both children and adults)
 - Individuals that experience symptoms on smoggy days
 - Certain age groups (children and older adults)
- Averting behavior less in the general adult population and commuters than the individuals described above

Health Evidence

- Preliminary epidemiologic evidence indicates that not accounting for averting behavior may result in an underestimate of associations between O₃ exposure and asthma HA's for children and older adults
- However, the studies that found evidence for this phenomenon were conducted:
 - In one location (i.e., Los Angeles)
 - During years (1989-97) when the level of the 1-h NAAQS was 120 ppb and air quality alerts were issued at 200 ppb O₃
- More evidence is needed to determine the potential for averting behavior to affect risk estimates at concentrations in the range of the current standard

Charge Questions

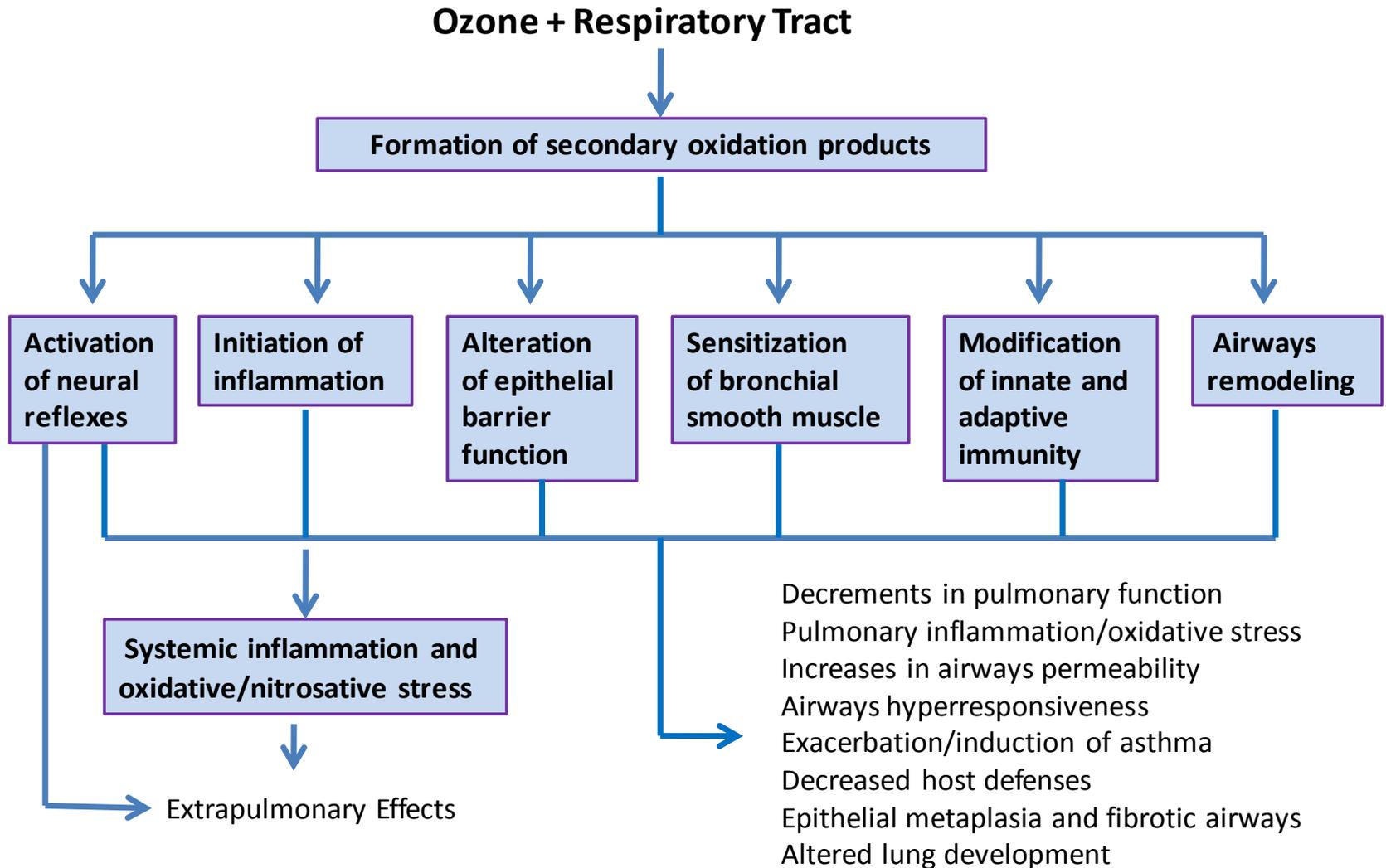
Chapter 5 - Dosimetry and Mode of Action

4. Chapter 5 was reorganized and updated in response to CASAC comments, including clarification of the linkage between dosimetry and mode of action, expanded discussion of species homology and key principles of O₃ uptake, increased emphasis on underlying mechanisms which link to effects discussed in Chapters 6 and 7, and expansion of summary sections.

Please comment on the extent to which these revisions help Chapter 5 provide the underlying mechanistic and dosimetric information for interpretation of effects evidence in later chapters and recommend any revisions to improve the discussion of key information.

Mode of Action/Possible Pathways

New Figure 5-9



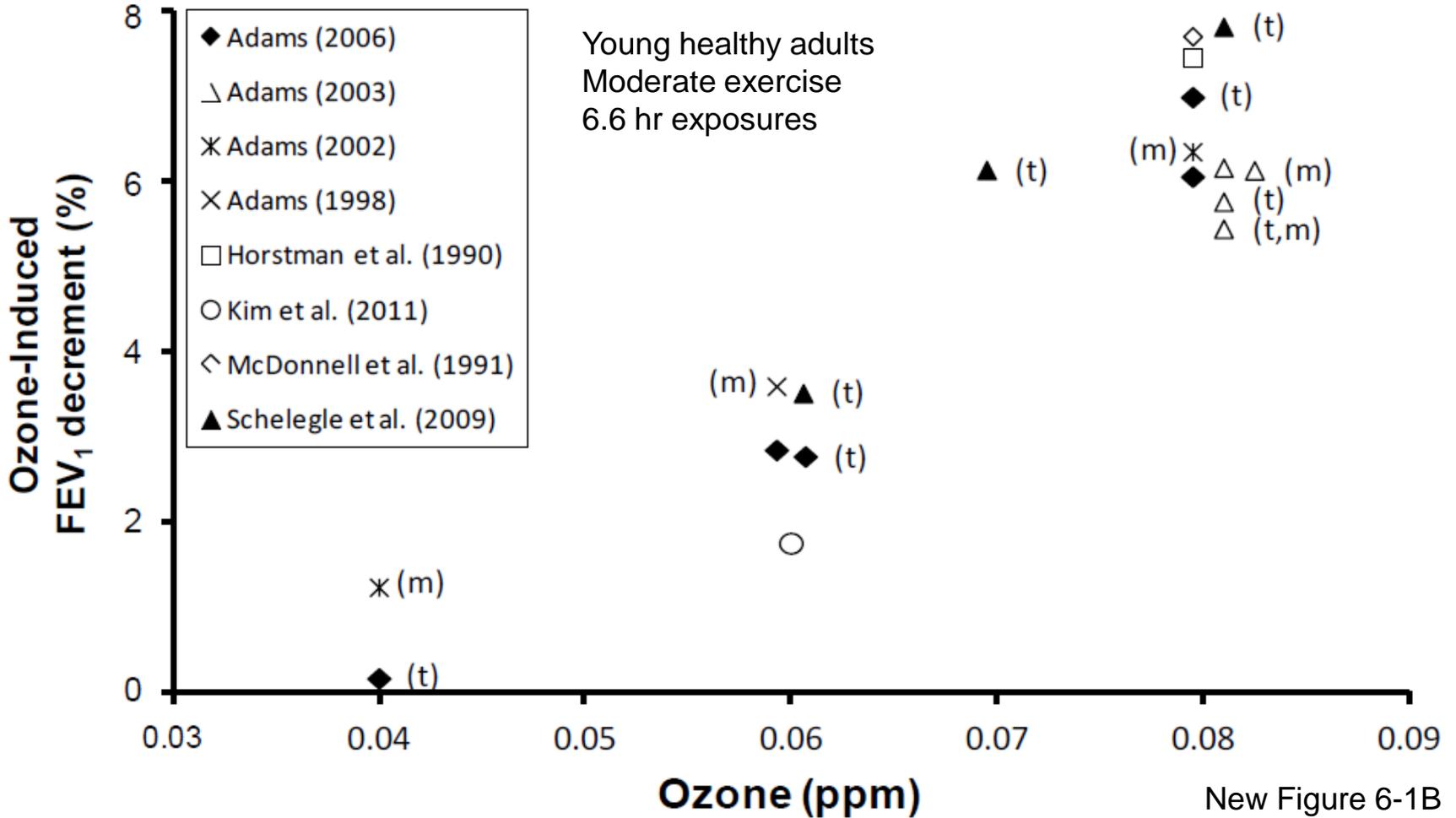
Charge Questions

Chapters 6-7 - Integrated Health Effects of Short- and Long-Term Ozone Exposure

5. In Chapters 6 and 7, references to and incorporation of information from previous assessments were expanded so that the evaluation of new health evidence is more clearly integrated with the substantial existing body of evidence on ozone-related health effects. Tables, figures, and text were revised and/or created to provide additional details related to design and results of studies. In Chapter 7, the discussion of long-term exposure and mortality has been expanded with the addition of new study findings that provide additional evidence for this association.

Please comment on the extent to which there is sufficient clarity in the presentation of study designs and results. Please provide guidance where the interpretation of the scientific evidence may be improved as well as on the soundness of conclusions in these chapters.

Controlled Human Exposure Studies Decrements in Lung Function



New Figure 6-1B

Data are group mean responses; **m**, exposure via facemask;
t, triangular (ramp up, ramp down) exposure concentration profile.

Charge Questions

Chapter 8 - Populations Potentially at Increased Risk for Ozone-Related Health Effects

6. The introduction to Chapter 8 has been revised with expanded discussion to better capture the intricacies associated with characterizing populations potentially at greater risk for O₃-related health effects, utilizing the terms identified by the CASAC panel (i.e. intrinsic, extrinsic, increased dose, greater exposure).

Please comment on the adequacy of these revisions to clarify the consideration of potential at-risk populations, and recommend any revisions to improve the characterization of key findings and scientific conclusions.

Charge Questions

Chapter 9 - Environmental Effects: Ozone Effects on Vegetation and Ecosystems

7. The discussion of effects in Chapter 9 has been reorganized and consolidated into fewer, but more integrated sections to lessen repetition and improve the clarity of presentation. More discussion of ecosystem modeling approaches and more consideration of ozone impacts on stomatal conductance and water cycling have been added to the chapter.

Please comment on the reorganization and content of this chapter and the adequacy, scientific soundness, and usefulness of the material presented. Please recommend any revisions to improve the discussion of key information.

New Causality refinement

Vegetation and Ecosystem Effects	Conclusions from 2011 2nd Draft ISA
Reduced Vegetation Growth	Causal Relationship
Alteration of Vegetation Reproduction	Causal Relationship
Visible Foliar Injury Effects on Vegetation	Causal Relationship
Alteration of Leaf Gas Exchange in Vegetation	Causal Relationship
Reduced Yield and Quality of Agricultural Crops ¹	Causal Relationship
Reduced Productivity in Terrestrial Ecosystems ²	Causal Relationship
Reduced Carbon (C) Sequestration in Terrestrial Ecosystems	Likely to be a Causal Relationship
Alteration of Terrestrial Ecosystem Water Cycling ²	Likely to be a Causal Relationship
Alteration of Below-ground Biogeochemical Cycles	Causal Relationship
Alteration of Terrestrial Community Composition ¹	Likely to be a Causal Relationship

¹ incorporated Alteration of Vegetation Reproduction

² incorporated Alteration of Leaf Gas Exchange in Vegetation

Meeting Agenda

- 8:50 am EPA Revisions to Draft ISA
EPA Update on Risk and Exposure Assessment and Policy Assessment
- 9:45 am Public Comments
- 10:30 am Break
- 10:45 am Public Comments (continued)
- 11:30 am Discussion of EPA Charge Questions
- 11:40 am Atmospheric Chemistry and Ambient Concentrations (Chapter 3)
- 12:05 am Lunch
- 1:00 pm Exposure to Ambient Ozone (Chapter 4)
- 1:25 pm Dosimetry and Mode of Action (Chapter 5)
- 1:50 pm Integrated Health Effects – Short-Term and Long-Term (Chapter 6 - 7)
- 2:45 pm At Risk Populations (Chapter 8)
- 3:10 pm Break
- 3:25 pm Ozone Effects on Vegetation and Ecosystems (Chapter 9)
- 4:05 pm Role of Tropospheric Ozone in Climate Change and UV-B Effects (Chapter 10)
- 4:45 pm Preface, Preamble, Executive Summary (Chapter 1)
and Integrative Overview (Chapter 2)