

Review of the O₃ NAAQS: First Draft Policy Assessment

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Overview of Briefing: Structure of 1st Draft Policy Assessment

- **Chapter 1:** Introduction and overview of document

Part I: Primary Standard

- **Chapter 2:** Overview of health evidence from 3rd draft ISA
- **Chapter 3:** Overview of human exposure and risk results from 1st draft REA
- **Chapter 4:** Staff's preliminary conclusions on adequacy of current primary O₃ NAAQS and alternatives appropriate for analysis in 2nd draft REA

Part II: Secondary Standard

- **Chapter 5:** Overview of vegetation effects evidence from 3rd draft ISA
- **Chapter 6:** Overview of vegetation exposure and risk results from 1st draft REA
- **Chapter 7:** Staff's preliminary conclusions on adequacy of current secondary O₃ NAAQS and alternatives appropriate for analysis in 2nd draft REA



Chapter 1: Introduction and Overview

- Purpose, legislative requirements, history through reconsideration and current review
- Overview of monitoring network and air quality, with a focus on background O₃
 - Background contributions to ambient O₃ are relatively low across much of the U.S., including heavily populated areas in the eastern U.S. and California
 - Anthropogenic emission sources are the dominant contributors to 8-hr daily max O₃ concentrations on days with highest total O₃ concentrations
 - In areas where background O₃ concentrations are highest (i.e., western U.S. and at high elevations), the key sources contributing to episodic high background concentrations include wildfires, stratospheric intrusions, and intercontinental transport



Chapter 2: Weight-of-Evidence Conclusions and Controlled Human Exposure Studies

Weight-of-evidence conclusions regarding causality

- Primary focus on effects for which the ISA concludes the relationship is causal or likely to be causal (i.e., respiratory effects following short- and long-term exposures; mortality following short-term exposures)

Controlled human exposure studies, with a focus on:

- Large body of evidence available in last review
 - Lung function decrements, respiratory symptoms, airway inflammation, airway hyperresponsiveness, and decreased lung host defense following exposures at or above 80 ppb
 - Lung function decrements following exposures as low as 60 ppb
- New studies conducted at O₃ exposure concentrations below current standard level
 - Additional evidence for lung function decrements following exposures to 60 ppb
 - Airway inflammation and respiratory symptoms following exposures to 60 and 70 ppb, respectively
 - Consider group mean FEV₁ decrements, and proportion of subjects who experience decrements (≥ 10%) that could be clinically relevant to people with lung disease
- Studies conducted in healthy adults, likely underestimate magnitude and seriousness of such effects in at-risk populations



Chapter 2: Epidemiologic Studies

- **Short-term (i.e., hours to weeks)**
 - Studies in last review reported associations with lung function decrements, respiratory symptoms, medication use, and respiratory emergency department visits and hospital admissions
 - New multi-city and single-city studies reinforce previous evidence, reporting O₃-associated mortality and respiratory effects (respiratory-related emergency department visits, hospital admissions, mortality)
 - Recent studies continue to report no evidence for discernible threshold within range of concentrations common in U.S. O₃ season (i.e., > 20 ppb), supporting associations at O₃ concentrations below current standard
 - Key issues related to the interpretation of epidemiologic studies include confounding by copollutants, effect modification, lag structure, shape of concentration-response relationships, and potential for thresholds
- **Long-term (i.e., ≥ 30 days)**
 - Limited evidence for O₃-related respiratory effects, including reduced lung function growth, available in last review
 - New studies report associations with range of respiratory effects, including new onset asthma, 1st asthma hospital admission, decrements in pulmonary function, and respiratory mortality
 - Several studies report important gene-environment interactions
 - Toxicology studies support biological plausibility of associations and coherence of evidence



Chapter 2: Public Health Implications

- Characterization of public health implications includes discussion of:
 - Adversity of effects
 - Identification of at-risk populations
 - Size of at-risk populations
 - Averting behavior
- Adversity criteria drawn from 2008 review (ATS 1985, 2000; and CASAC advice from previous reviews)
- Discussion of populations at risk focuses on factors for which the ISA concludes evidence “adequate” for increased risk
 - Asthma, lifestages (i.e., children and older adults), diet, and working outdoors
 - Estimates of sizes of at-risk populations based on data from 2010 Census and Bureau of Labor Statistics data on outdoor workers
 - Children and older adults alone total > 110 million people, or about 37% of population
- New evidence for impact of averting behaviors, based on AQI reporting, suggests they may affect risk estimates in short-term U.S. epidemiologic studies



Chapter 3: Exposure and Risk Results

- Focus is on preliminary estimates of O₃-related exposures and health risks remaining after simulating just meeting the current primary NAAQS, from the 1st draft REA
 - Estimated exposures at and above benchmark O₃ concentrations of 60, 70, 80 ppb
 - Estimated O₃-attributable mortality based on C-R relationships from epidemiologic studies
 - Estimated O₃-attributable respiratory hospital admissions and emergency department visits based on epidemiologic studies
 - Estimated O₃-attributable respiratory symptoms based on epidemiologic studies
- Second draft PA will also focus on:
 - Estimates of population at risk for O₃-induced lung function decrements
 - Estimates of exposures and risks remaining after simulating just meeting alternative standards
 - Estimates of incremental reductions in risk across alternative standards



Chapter 4: Staff's Preliminary Conclusions on Adequacy of Current Primary O₃ NAAQS

- Scientific evidence and exposure/risk information clearly calls into question adequacy of current standard, and does not support retaining current standard
 - Evidence for respiratory effects and mortality following exposures to O₃ concentrations well below the current standard
 - Based on preliminary exposure and risk information from the first draft REA, risks remaining may reasonably be judged important for public health
- In the 2008 review and reconsideration, CASAC unanimously recommended a more protective standard
- Evidence, information, and CASAC advice supports consideration of revising current standard to increase public health protection against short-term exposures, especially for at-risk populations
- Second draft Policy Assessment will also consider extent to which current standard protects against effects of long-term O₃ exposures



Chapter 4: Staff's Preliminary Conclusions Regarding Additional Analyses for 2nd Draft REA

- First draft PA presents staff's preliminary conclusions regarding the range of alternative O₃ levels appropriate for analysis in the 2nd draft REA
 - In the 2nd draft PA, staff will reach preliminary conclusions regarding the range of alternative standards appropriate for consideration by the Administrator
- Averaging time: Appropriate to analyze alternatives with 8-hr averaging time
- Levels: In identifying a range of levels for analysis, staff considered the scientific evidence and the advice received from CASAC in the last review
 - *In the last review and in the reconsideration*, CASAC recommended a focus on levels from 70 to 60 ppb
 - *In the current review*, staff reached the preliminary conclusion that the new evidence reinforces support for analyzing levels from 70 to 60 ppb
 - In addition, staff reached preliminary conclusion that the new evidence also supports analyzing standard levels somewhat below 60 ppb



Chapter 4: Considerations in Translating Epidemiologic Evidence

- Ozone design values in study locations, with particular emphasis on studies conducted in locations likely to have met the current and/or alternative standards
- Ozone air quality distributions in locations where studies have evaluated C-R relationships
 - First draft PA presents two examples, drawn from analyses in review of PM_{2.5} NAAQS
 - CASAC has provided extensive input on analyses of the PM_{2.5} epidemiologic evidence
- Several issues complicate the consideration of air quality distributions and C-R relationships:
 - Interpretation of confidence intervals, given that statistical precision decreases with decreasing data density
 - Interpretation of associations based on O₃ concentrations averaged across monitors, given that attainment is based on 4th highest concentrations measured at highest monitor
 - For some studies, lack of available data necessitates use of surrogates for study areas and air quality metrics
- For considering alternative standards in 2nd draft PA:
 - Consideration of short-term studies can be refined and expanded
 - Protection against long-term exposures will be evaluated



Chapter 5: Environmental Effects Evidence

- Weight-of-evidence conclusions regarding causality
 - Primary focus on vegetation and ecosystem-level effects for which the ISA concludes the relationship is **causal** (e.g., visible foliar injury, reduced growth/productivity, reduced yield, effects on below-ground biogeochemical cycles, and radiative forcing) or **likely to be causal** (e.g., reduced carbon sequestration, alteration of ecosystem water cycling, alteration of community composition; effects on climate)
- New vegetation effects evidence:
 - Supports, strengthens, and is consistent with key conclusions drawn from previous reviews regarding visible foliar injury, growth, productivity, and carbon storage
 - Increases coherence in weight of evidence based on new mechanistic studies
 - Reinforces previous conclusions about importance of cumulative, seasonal, peak-weighted exposures in selecting biologically/ecologically relevant exposure indices



Chapter 5: Environmental Effects Evidence (cont.)

- Vegetation effects evidence useful for assessing the adequacy and appropriateness of the current standard and consideration of potential alternative standards
 - Biologically/ecologically-relevant forms
 - Averaging times (exposure periods, such as diurnal, seasonal and annual):
 - Level
- Adversity paradigm from last review still appropriate with inclusion of ecosystem services impacts
- Information on other welfare effects (e.g., climate, UV-B) insufficient to inform judgments regarding adequacy of current standard



Chapter 6: Risk and Exposure

- Primary focus is on 1st draft REA preliminary estimates of O₃-related exposures and vegetation risks that remain after simulating just meeting the current secondary NAAQS
 - 1st draft REA estimated national scale exposures and relative biomass loss (RBL) for studied tree species
 - Assessment of visible foliar injury and other effects are ongoing and will be more fully addressed in 2nd draft REA
- The 2nd draft PA will also consider the preliminary results of analyses that used the Forest and Agriculture Services Optimization Model – Green House Gas (FASOMGHG) and iTree models
 - These analyses assess the incremental effects of O₃-induced biomass loss on associated ecosystem services in timber/agriculture markets and urban forest systems, respectively



Chapter 7: Staff's Preliminary Conclusions on the Adequacy of Current Secondary O₃ NAAQS

- Scientific evidence and preliminary exposure/risk results clearly call into question adequacy of protection and does not support retention of the current 8-hr standard
 - Evidence of vegetation effects occurring in the field resulting from ambient cumulative, seasonal exposures allowed by the current standard
 - National scale exposures and estimated risks of relative biomass loss (RBL) that could reasonably be anticipated to cause adverse effects are likely to remain in substantial geographic areas across the country upon just meeting the current standard
- Evidence clearly calls into question the appropriateness of the form and averaging time of the current 8-hr standard
 - Available information supports consideration of revising current standard to afford more appropriate protection, by selecting a biologically/ecologically relevant standard form
 - In the 2008 review and 2010 reconsideration, CASAC unanimously concluded that it is not appropriate to protect vegetation by promulgating identical primary and secondary standards and encouraged the Administrator to establish an alternative cumulative standard distinctly different in form, averaging time and level than the primary standard



Chapter 7: Staff's Preliminary Conclusions Regarding Additional Analyses for 2nd Draft REA

- First draft PA presents staff's preliminary conclusions regarding the range of alternative O₃ standards appropriate for analysis in the 2nd draft REA
 - In the 2nd draft PA, staff will reach preliminary conclusions regarding the range of alternative standards appropriate for consideration by the Administrator
- **Form:** Continue focus on the cumulative, peak-weighted W126 exposure index
- **Averaging time(s):** Continue focus on 12-hr daytime diurnal exposure period (8 am to 8 pm), maximum consecutive 3-month seasonal exposure period, and 3-year average
- **Level:** In identifying a range of levels for analysis, staff considers the scientific evidence and the advice received from CASAC in the last review
 - *In last review and in the reconsideration, CASAC recommended range of 7-15 ppm-hrs*
 - *In the current review, staff reaches preliminary conclusion that the new evidence reinforces support for analyzing levels within that same range (7–15 ppm-hrs)*