EPA
United States
Environmental Protection
Agency

Policy Assessment for the Review of the Ozone National Ambient Air Quality Standard

External Review Draft

Staff from the
Office of Air Quality Planning and Standards
U.S. Environmental Protection Agency

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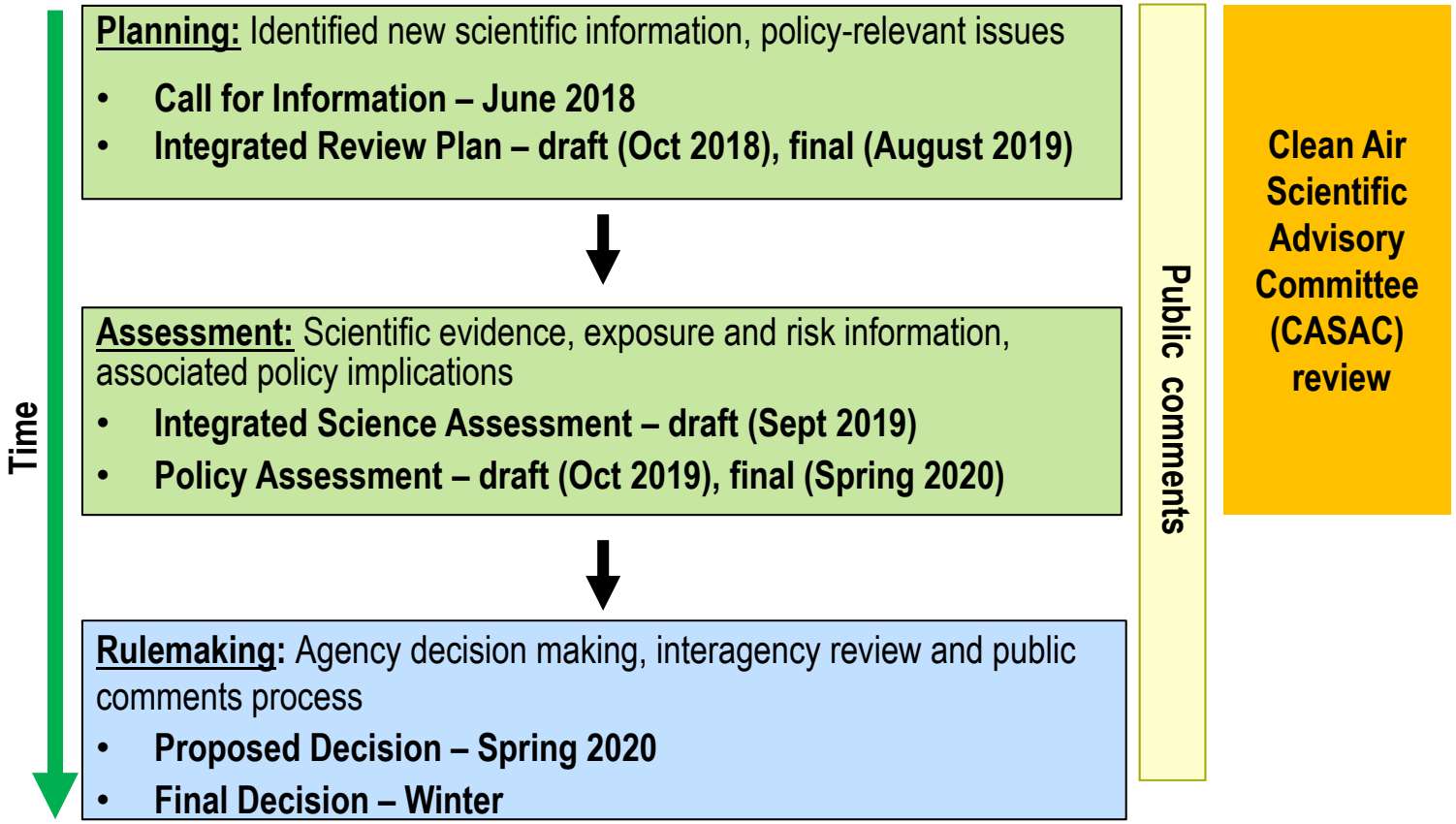
Clean Air Scientific Advisory Committee

Background and Statutory Requirements

- EPA sets National Ambient Air Quality Standards (NAAQS) for six criteria pollutants, including photochemical oxidants (which includes ozone)
- Primary (health-based) standards are those that, in the "judgment of the Administrator" are "requisite" to protect public health with an "adequate margin of safety"
  - The term "requisite" means sufficient, but not more than necessary
  - By requiring an "adequate margin of safety," Congress was directing EPA to build a buffer to protect against uncertain and unknown dangers to human health
- Secondary (welfare-based) standards are those that "…specify a level of air quality the attainment and maintenance of 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 . . ."
- In setting NAAQS, EPA is barred from considering the cost of implementing the standards or adjusting a requisite standard solely on the basis of attainability in light of background concentrations of the pollutant

Process and Schedule for this Review of the Ozone NAAQS



Purpose of the Policy Assessment (PA)

- The PA provides staff evaluations to help bridge the gap between the relevant scientific information and assessments and the judgments required of the EPA Administrator in determining whether to retain or revise the current standard.
- The draft PA draws on the draft ISA and additional policy-relevant quantitative air quality exposure and risk analyses
  - The draft PA also facilitates advice to the EPA and recommendations to the Administrator from CASAC
- The final PA will be based on the final ISA and informed by the advice and recommendations from CASAC and public comments on both draft documents.

Primary Standard: Overarching Policy-Relevant Question

- Staff evaluation in the draft PA is focused on consideration of the following overarching question:
  - **Do the currently available scientific evidence and exposure/risk-based information support or call into question the adequacy of the protection afforded by the current primary O_3 standard?**
    - Current standard is 70 ppb in terms of a 3-year average of the annual 4th highest daily maximum 8-hour average O_3 concentration

Primary Standard: Health Effects Evidence

- With regard to the currently available scientific evidence, the draft PA addresses the overarching question by considering a series of specific questions, including:
  - Importance of photochemical oxidants other than ozone (O_3) with regard to abundance in ambient air, and potential for human exposures and health effects
  - Health effects associated with exposure to O_3
  - Public health implications, at-risk populations and their sizes in the U.S.
  - Exposure concentrations associated with health effects
  - Important uncertainties, new or remaining from the last review

Primary Standard: Overview of Health Effects Evidence

- The health effects evidence continues to be strongest for respiratory effects
  - Causal relationship between short-term O_3 exposure and respiratory effects, likely causal relationship* for such effects with longer-term exposure
    - Strongest evidence comes from controlled human exposure studies, with epidemiologic studies also reporting associations between short-term O_3 and respiratory hospital admissions and emergency department visits (and other respiratory health outcomes)
  - Key effects in controlled human exposure studies of healthy adults, exposed during exercise, are lung function decrements and respiratory symptoms
    - Statistically significant findings for both endpoints for 6.6-hour exposures (5 hours of exercise) at and above 70 ppb, and statistically significant decrements at 60 ppb
    - Studies of 6.6-hour exposures at/above 80 ppb document greater lung function decrements and respiratory symptom scores, and also other respiratory response indicators
  - At-risk populations include people with asthma, children, as well as outdoor workers
    - ~8% of U.S. population has asthma, with much higher rates in some population groups
  - Uncertainties still remain from the last review regarding the population groups that may be at greatest risk and the extent of effects at low concentrations

* The draft ISA also concludes there to be likely causal relationships for short- and long-term O_3 with metabolic effects.

Primary Standard: Exposure/Risk Information

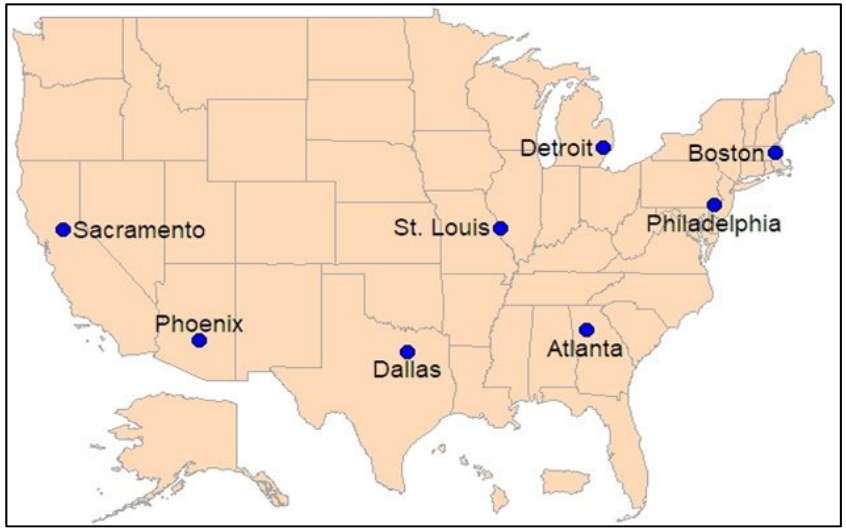
- With regard to the current draft quantitative analysis of estimated population exposure and risk, the draft PA addresses the overarching question by considering a series of specific questions:
  - What is the magnitude of population exposure and risk estimated in different study areas under conditions just meeting the current standard; and portion of the at-risk populations estimated to be affected?
  - What are key uncertainties associated with exposure/risk estimates?
  - What is the public health importance of estimated exposures and risk for at-risk populations under conditions just meeting the current standard?

Primary Standard: Exposure and Risk Analysis - Features of Study Areas

- Study Area Selection Criteria (PA, section 3D.2.1)
  - Have at least 10 ambient air O_3 monitors for the 2015-2017 period;
  - Combined statistical area (CSA)/metropolitan statistical area (MSA) ambient air monitor design values between 60-80 ppb
  - CSA/MSA population between 2 to 10 million;
  - Anticipated reasonable air quality model performance; and
  - Reasonable geographic distribution across continental U.S.

Modified from Draft PA, Appendix 3D, Table 3D-1. Study area features.

Study Area	U.S. Climate Region	CSA/MSA Population (millions)	Ambient Air Monitors (n)	Design Values (ppb)	
				2017	2008, 2010
Atlanta	Southeast	6.6	11	75	95, 80
Boston	Northeast	8.3	22	73	82, 76
Dallas	South	8.0	20	79	91, 86
Detroit	Upper Midwest	5.4	11	73	82, 75
Philadelphia	Northeast	7.2	19	80	92, 83
Phoenix	Southwest	4.9	28	76	81, 77
Sacramento	West	2.6	18	86	99, 99
St. Louis	Ohio Valley	2.9	12	72	82, 77

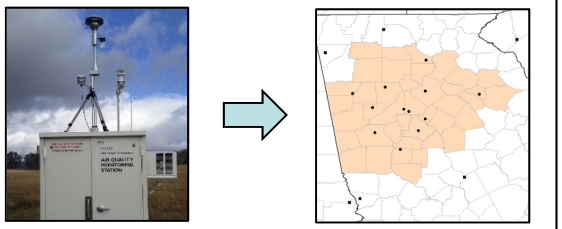


Draft PA, Appendix 3D, Figure 3D-1. Location of eight study areas.

Primary Standard: Exposure and Risk Analysis - Ambient Air Concentrations

- Objectives
  - Address fine-scale temporal and spatial variability in ambient air O_3 concentrations
  - Reflect specific air quality scenarios
- Approach to estimating concentrations (e.g., for scenario just meeting current standard)
  - Ambient air monitoring data (PA, section 3C.3)
    - O_3 measurements provide fine-scale temporal (hourly) and broad spatial variability
  - Air quality modeling (PA, section 3C.4 and 3C.5)
    - Hourly concentrations observed at monitor sites adjusted with spatially/temporally varying model-based factors such that highest study area DV met air quality scenario target
  - Spatial Interpolation (PA, section 3C.6)
    - Inverse distance weighting using nearest neighbor monitors to estimate O_3 concentrations for fine-scale (census tract) spatial variability

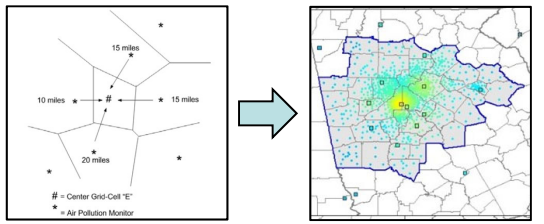
Ambient Air Monitor Data [1]



Air Quality Modeling [2]

Urban Area	75 ppb	70 ppb	65 ppb
Atlanta	0%	25%	44%
Boston	+7%	14%	40%
Dallas	15%	32%	45%
Detroit	+18%	21%	47%
Philadelphia	23%	43%	53%
Phoenix	14%	49%	68%
Sacramento	45%	58%	72%
Saint Louis	+11%	13%	38%

Spatial Interpolation [3]



[1] Draft PA, Appendix 3C, Figure 3C-3. Map of the Atlanta study area monitoring sites. (as an example)
[2] Draft PA, Appendix 3C, Table 3C-19. Percent NOx emissions changes used for each urban area to just meet each of the air quality scenarios evaluated.
[3] Draft PA, Appendix 3C, Figure 3C-91. Annual 4th highest MDA8 O_3 based on HDDM adjustments in Atlanta. (70 ppb as an example)

Primary Standard: Exposure and Risk Analysis - Estimating Exposure

- Approach uses Air Pollution Exposure Model (APEX) (PA, section 3D.2)
  - Population-based human inhalation exposure and risk model that links fine spatial and temporal scale ambient air O_3 concentrations with study area population demographics, human activity data, and physiological attributes of study populations
  - Estimates the complete time-series of O_3 exposures and simultaneously occurring breathing rates for simulated individuals as they perform activities within the microenvironment they visit
    - This is key to both the exposure and risk estimation because the adverse health effect depends on the exposed individuals having an elevated ventilation rate
- Outputs (PA, section 3D.2.7)
  - Counts of simulated people experiencing O_3 exposures at selected levels and at particular exertion rates of interest
  - Complete time-series of O_3 exposures (and ventilation rates) for simulated individuals (minute-by-minute, hourly, daily etc.)

Primary Standard: Exposure and Risk Analysis - Estimating Risk

- Comparison to Benchmarks (PA, section 3D.2.8.1)
  - Outputs: The number and percent of the simulated populations in each study area experiencing exposures at or above benchmarks (60, 70, 80 ppb)
  - Approach: Estimated daily maximum 7-hour average exposures while at elevated ventilation compared to benchmark concentrations based on controlled human exposure studies
    - Considers potential for array of effects observed in controlled human exposure studies

Primary Standard: Exposure and Risk Analysis - Estimating Risk

- Lung Function Risk (PA, section 3D.2.8.2)
  - Outputs: the number and percent of simulated populations in each study area experiencing lung function decrements (FEV_1 reductions of 10%, 15%, 20%)
    - Approach 1: Exposure-response (E-R) function estimated lung function decrement occurrence and magnitude based on observed response in 6.6-hour studies and simulated population distribution of daily maximum 7-hour exposures occurring at elevated ventilation
      - Does not address potential for decrements elicited by shorter-duration exposures at/above target ventilation
    - Approach 2: McDonnell, Stewart, Smith (MSS) model estimated lung function decrements related to estimated accumulated dose based on interpretation of controlled human exposure studies of varying durations and simulated individual's time-series of exposure and breathing rates.
      - Greater contribution to risk (compared to E-R function) from relatively lower O_3 exposures and ventilation rates below the target
      - Decrement occurrence estimated in risk analysis may be somewhat greater than expected based on 6.6-hour controlled human exposure study observations

Primary Standard: Exposure & Risk Analysis – Risk Estimates

- Comparison to Benchmarks - current standard (PA, section 3D.3.2.1)
  - % of children with asthma experiencing a day with 7-hour exposure at/above benchmark, while at elevated exertion
    - 80 ppb benchmark: At most, 0.1% in any year in any study area (zero children estimated to experience more than one day)
    - 70 ppb benchmark: At most, 1% in any year in any study area (0.1% estimated to experience more than one day)
    - 60 ppb benchmark: Less than 9%, on average across years and study areas (less than 5% estimated to experience more than one day)
- Lung Function Risk – current standard, via E-R function approach (PA, section 3D.3.3)
  - % of children with asthma experiencing a day with a FEV_1 reduction of at least:
    - 20% Decrement: At most, 0.4% in any year in any study area (0.2% estimated to experience more than a day)
    - 15% Decrement: At most, 1% in any year in any study area (0.6% estimated to experience more than a day)
    - 10% Decrement: At most 3.3%, on average across years and study areas (<3% estimated to experience more than a day)
  - Higher estimates using the MSS model, with increased uncertainty

Primary Standard: Exposure and Risk Analysis - Key Uncertainties

- Analysis aspects that reduce uncertainty since last review (PA, section 3D.3.4):
  - Closer linking of O_3 exposure averaging period for simulated individuals (7-hour) to controlled human exposure study subjects (6.6-hour)
  - Improved estimation of elevated exertion threshold based on ventilation across study duration (both exercise and rest periods) and inter-personal variability in human studies
  - Smaller air quality adjustments needed for current standard scenario
  - Improved statistical model fit and predictions for estimating ventilation and resting metabolic rate
- Remaining uncertainties (PA, section 3D.3.4):
  - Modeling longitudinal activity patterns
  - Estimating short-term energy expenditure based on longer-term average information
  - Extrapolating from controlled human exposure study conditions to lower/higher O_3 exposures, lower/higher ventilation rates, and for shorter/longer exposure periods
  - Lack of evidence from controlled human exposure studies of 6.6-hour duration for people with asthma and children, and on susceptibility factors for O_3-responding individuals
  - Lung function risk and potential for effects in population groups and at exposure concentrations/circumstances not studied

Primary Standard: Exposure & Risk Analysis - Main Findings

- Overall key observations regarding estimated percentages of each population with exposure/risk at/above benchmarks
  - Higher for children than adults
    - Due to greater frequency and amount of time outdoors at elevated exertion
  - Similar estimates for people with asthma and all people
    - Due to similar activity patterns (time outdoors and at elevated exertion)
- While there are differences between 2014 REA and current analyses, the current exposure and risk estimates for air quality conditions just meeting the current standard generally reflect the ranges of estimated exposures and risks from the last review.

Primary Standard: Preliminary Conclusions

- Health effects evidence newly available in this review is generally consistent with evidence base in last review.
- Exposure and risk estimates for air quality conditions just meeting the current standard generally reflect the ranges of estimated exposures and risks from the last review.
- Preliminary PA conclusion is that the available evidence and quantitative information, including uncertainties, do not call into question the adequacy of protection provided by the current standard, and thus, support consideration of retaining the current standard, without revision.
- Accordingly, the draft PA does not identify alternative standards for further evaluation.

Secondary Standard: Overarching Policy-Relevant Question

- Staff evaluation of the secondary standard in the draft PA* is focused on consideration of the following overarching question:
  - **Do the currently available scientific evidence and air quality and exposure information support or call into question the adequacy of the protection afforded by the current secondary O_3 standard?**
    - Current standard is 70 ppb in terms of a 3-year average of the annual 4th highest daily maximum 8-hour average O_3 concentration

* We are also considering the August 2019 court decision on the 2015 standard, recognizing that issues raised by the court in its remand of the secondary standard will be considered over the course of this review.

Secondary Standard: Welfare Effects Evidence & Air Quality/Exposure Information

- The draft PA addresses the overarching question by considering a series of specific questions related to the evidence and air quality/exposure information, including:
  - Importance of photochemical oxidants other than ozone (O_3) with regard to abundance in ambient air, and potential for welfare effects
  - Nature of welfare effects associated with exposure to O_3
  - Public welfare implications of such effects
  - Exposures and potential for public welfare effects under conditions that meet current standard
    - Metric(s) and quantitative relationships with O_3 for the various welfare effects
    - Air quality and exposures in areas meeting the current standard and potential for effects
  - Important uncertainties, new or remaining from the last review

Secondary Standard: Overview of Welfare Effects Evidence

- Nature of effects (PA, section 4.3.1), generally consistent with last review:
  - Visible foliar injury and effects on plant growth and reproduction; crop yield and quality, terrestrial ecosystem productivity, terrestrial community composition, belowground biogeochemical cycles, and radiative forcing concluded to be causally related to O_3
  - Effects on carbon sequestration in terrestrial ecosystems and on ecosystem water cycling, as well as on temperature, precipitation and related climate variables concluded likely to be causally related to O_3
    - In an expansion from the last review, draft ISA also finds increased tree mortality, altered plant-insect signaling, and altered insect herbivore growth and reproduction likely causally related to O_3
- Public welfare significance considerations include type of effect, public uses of potentially impacted areas and associated public values, extent of potentially impacted areas, severity and extent of potential impacts (PA, section 4.3.2)
- Array of effects varies with regard to availability of established, robust quantitative relationships with O_3 exposure metrics that inform understanding of risk under conditions meeting current standard (PA, section 4.3.3)
  - Well-established relationships for plant growth impacts with cumulative, concentration-weighted exposure index, W126 (PA, section 4.3.3.1, Appendix 4A)
- Uncertainties remain from the last review and with new evidence (PA, section 4.3.4)

Secondary Standard: Quantitative E-R Relationships with O_3

- **Growth-related effects** (PA, sections 4.3.3.1.2, 4.3.4, 4.5.1 and Appendix 4A)
  - Evidence continues to support use of reduced growth in tree seedlings, in terms of relative biomass loss (RBL), as proxy/surrogate for full range of growth-related effects from organism level to ecosystem level (as was used in 2015 decision)
    - W126 index as exposure metric (cumulative, concentration-weighted function)
    - In light of CASAC advice, 2015 standard focused on generally limiting cumulative exposures to those for which median RBL estimate would be somewhat below 6% (3-year average W126 index of 19 ppm-hrs)
  - Well-established quantitative E-R relationships are available for seedlings of 11 species, based on studies involving multiple-exposure concentrations and statistical analyses to identify appropriate mathematical functions
    - Uncertainties/limitations in the available data contribute imprecision to associated RBL estimates
    - Draft PA analyses find little difference in impacts on changes in biomass when W126 levels vary across three years compared to a constant W126 value across 3-years (PA, Appx 3A)
    - E-R functions also available for 10 crops, but focus is on tree seedlings as extensive management practices employed to optimize crop quality and yield complicate reliance on crop functions

Secondary Standard: Air Quality/Exposure Information

- Air quality analyses of recent 3-year period and historical record of last 17 3-year periods at U.S. O_3 monitoring sites (draft PA, section 4.4, Appendix 4D)
  - Clear relationship between W126 and design values (DVs) for current standard documents that reductions in DVs are associated with reductions in W126 index (single-year as well as 3-year average)
  - At monitoring sites, including Class I sites, that met the current standard across the U.S., W126 values (3-year average and single-year) rarely approached W126 associated with 6% RBL (median)
    - Average W126 exposures during the most recent 3-year design period were at/below 17 ppm-hrs
    - Average W126 during all 3-year design periods at/below 19 ppm-hrs, with highest values in the earlier years

Secondary Standard: Quantitative E-R Relationships with O_3 (continued)

- **Visible foliar injury** (PA, sections 4.3.3.2, 4.3.4, 4.5.1, and Appendix 4C)
  - A quantitative relationship of severity or incidence across sites has not been established with a specific O_3 metric
    - Studies of relationships between O_3 exposure and incidence/severity of leaf injury suggest role for peak concentration occurrence (e.g., N100 metric), as well as cumulative exposures (e.g. W126)
    - PA analyses of dataset developed from 6 years of U.S. Forest Service scores at biosites in 39 states and W126 index and soil moisture estimated for the sites
      - Visible foliar injury, of some extent, was observed across range of W126 index estimates
      - Across W126 bins, biosite scores and incidence is variable, with incidence and severity visibly increased at highest W126 estimates (e.g., >25 ppm-hrs)
        - » Such W126 index values not observed at locations that meet the current standard
  - Current evidence is also limited with regard to considering/judging public welfare significance of different levels of severity or extent of injury
    - While appreciably severe and extensive damage is reasonably considered significant, and a single leaf injury is reasonably considered not, evidence to inform consideration/judgments for intermediate levels of severity/extent of injury is unclear.

Secondary Standard: Evidence of quantitative relationships (continued)

- **Climate effects (e.g., radiative forcing and effects on temperature, precipitation)**
  - While O_3 abundance in the troposphere is causally related to radiative forcing and likely causally related (via radiative forcing) to effects on temperature, precipitation and related variables, the extent of such impacts of regional ground-level O_3 concentrations are uncertain and there are limitations in relevant estimation tools (draft PA, sections 4.3.3.3, 4.3.4, 4.5.1.2)
    - "Current limitations in climate modeling tools, variation across models and the need for more comprehensive observational data on these effects represents sources of uncertainty in quantifying the precise magnitude of climate responses to ozone changes, particularly at regional scales." [2013 ISA and 2019 draft ISA]
- **Newly identified vegetation-related effects,** e.g., plant-insect signaling, insect herbivore effects (draft PA, sections 4.3.3.3, 4.3.4))
  - Lack of information on relevant exposure metric and quantitative E-R relationships
    - Inconsistent directionality of associations for some effects

Secondary Standard: Preliminary Conclusions

- Welfare effects evidence is generally consistent with evidence base in last review.
  - Growth-related effects: Exposure estimates for air quality conditions meeting the current standard virtually all at/below 19 ppm-hrs (the W126 index associated with 6% RBL for median species).
    - Focus on RBL as surrogate for other vegetation-related effects continues to be supported by the current information as approach for judging adequacy of protection provided by the current standard
  - Visible foliar injury: Current evidence does not indicate the occurrence of elevated severity or extensive leaf damage in areas that meet current standard
  - Climate effects: Evidence does not support climate risk estimation for O_3 concentrations that meet current standard.
- Preliminary conclusion is that the available evidence and quantitative information, including uncertainties, do not call into question the adequacy of protection provided by the current standard, and thus, support consideration of retaining the current standard, without revision.
  - Accordingly, the draft PA does not identify alternative standards for further evaluation.

Additional Information

NAAQS for Photochemical Oxidants

Final Decision	Primary/ Secondary	Indicator	Averaging Time	Level (ppm)	Form
1971	Primary	Total photochemical oxidants	1 hour	0.08	Not to be exceeded more than one hour per year
	Secondary				
1979	Primary	Ozone	1 hour	0.12	Attainment is defined when the expected number of days per calendar year, with maximum hourly average concentration greater than 0.12 ppm, is equal to or less than 1
	Secondary				
1993	EPA decided that revisions were not warranted at the time.				
1997	Primary	**Ozone**	**8 hours**	0.08	**Annual fourth-highest daily maximum 8-hr average concentration, averaged over 3 years**
	Secondary				
2008	Primary			0.075	
	Secondary				
2015	**Primary**			**0.070**	
	Secondary				

Primary Standard: Exposure & Risk Analysis - Main Findings (continued)

- Comparison to Benchmarks - Current Standard (PA, section 3D.3.2.1)

Children with asthma (% simulated population)				
Benchmark Concentration (ppb)	One or more days		Two or more days	
	Average per year	Highest in a single year	Average per year	Highest in a single year
≥ 80	0 – <0.1	0.1%	0	0
≥ 70	0.2 – 0.7	1.0%	<0.1	0.1
≥ 60	3.3 – 8.8	11.2	0.6 – 3.2	4.9

- Lung Function Risk - Current Standard, via E-R function approach (PA, section 3D.3.3)

Children with asthma (% simulated population				
Lung Function Decrement	One or more days		Two or more days	
	Average per year	Highest in a single year	Average per year	Highest in a single year
≥ 20%	0.2 – 0.3	0.4	0.1 – 0.2	0.2
≥ 15%	0.5 – 0.9	1.0	0.3 – 0.6	0.6
≥ 10%	2.3 – 3.3	3.6	1.5 – 2.4	2.6

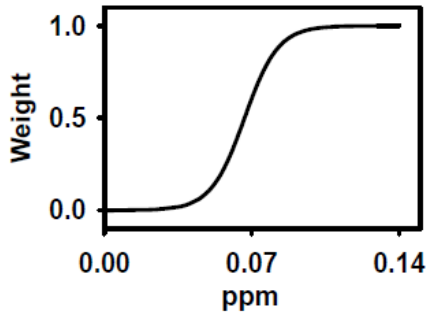
From PA, Tables 3-3 and 3-4.

How is the W126 value calculated?

The 3-year average W126 value is calculated by

1. Summing the weighted* hourly concentrations between 8:00 a.m. to 8:00 p.m. each day during each month.
2. Identifying the consecutive 3-month period within the ozone monitoring season with the maximum index value. *[This is a single-year value.]*
3. Averaging the maximum 3-month sum from each year in a 3-year period.

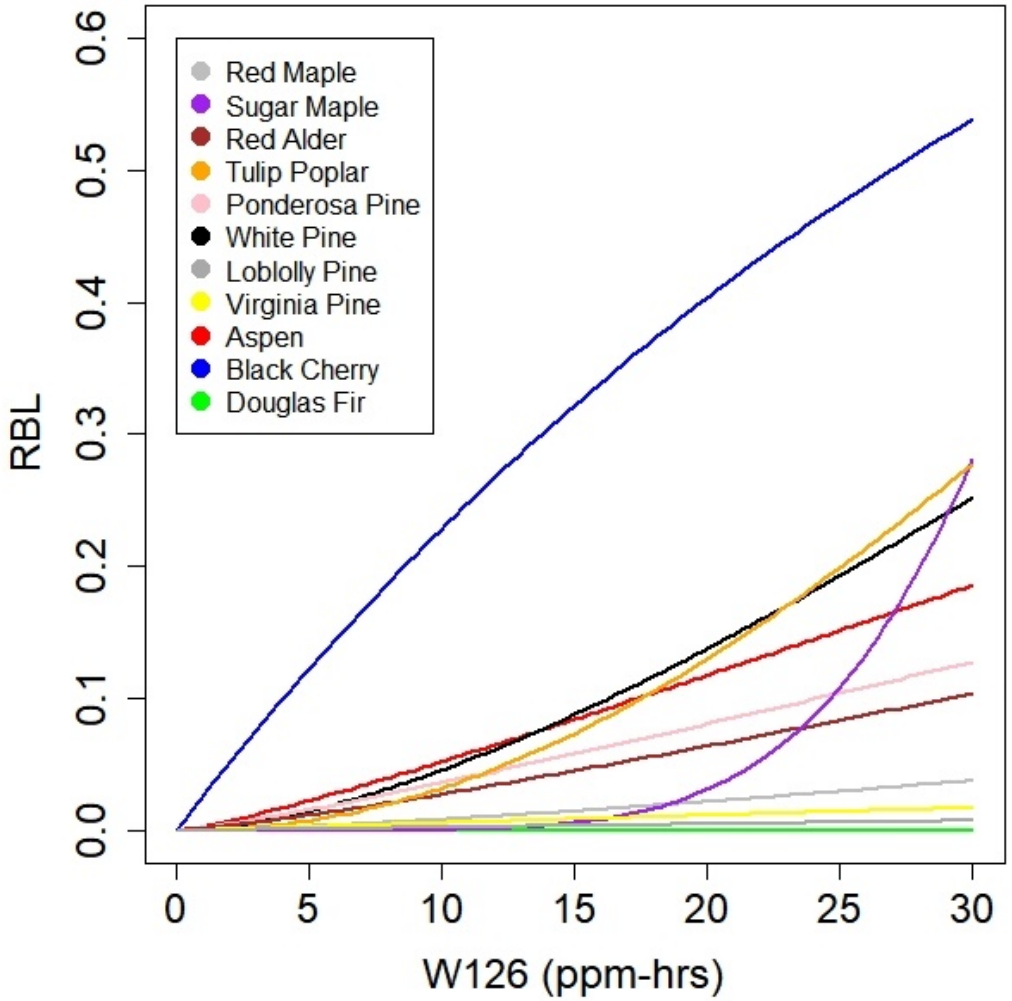
* Each hourly concentration is multiplied by a "weight" which is greater at higher concentrations



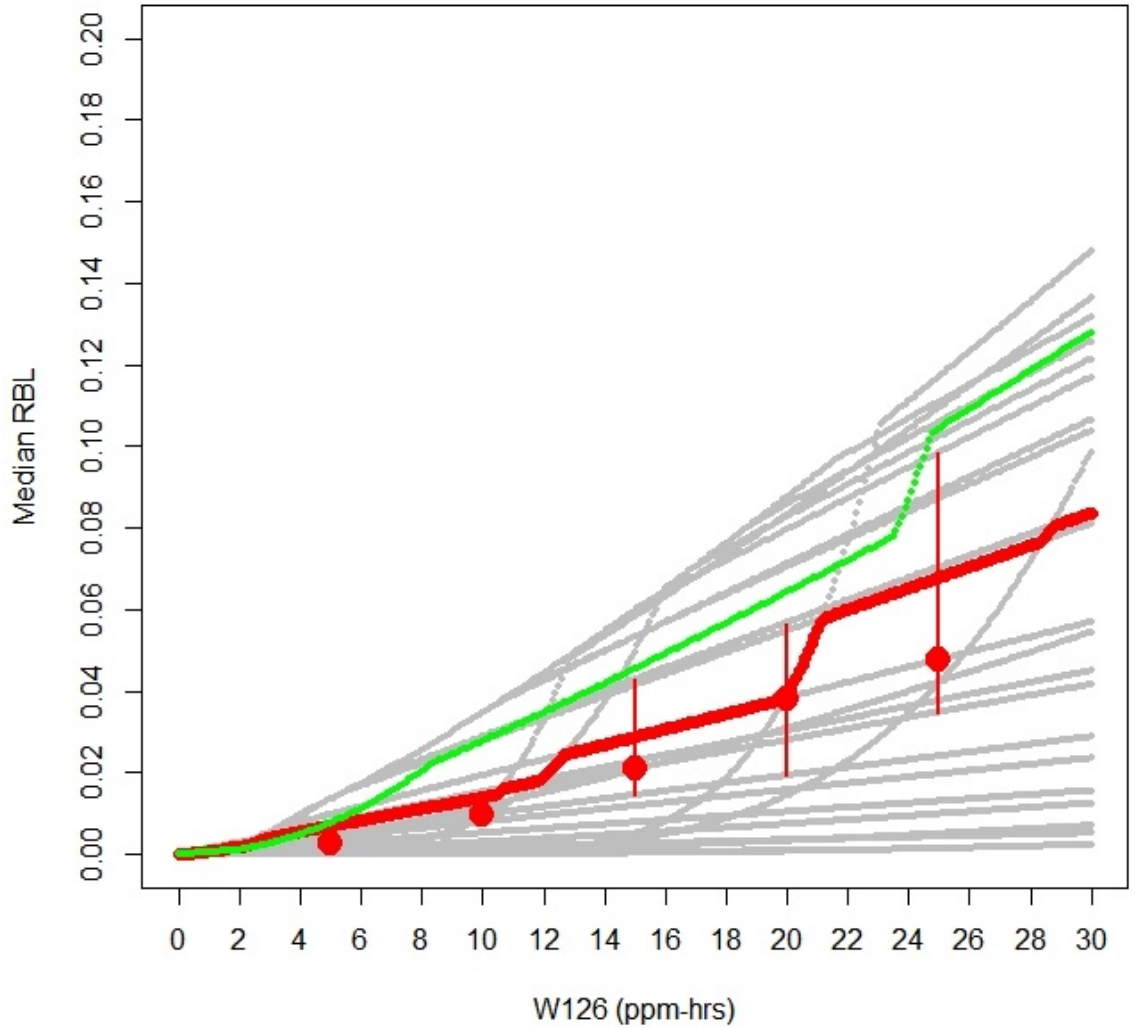
Tree seedling RBL estimated for a seasonal W126 O_3 exposure (from PA, Table 4A-5)

W126 index	Estimated tree seedling relative biomass loss
	(median across 11 species-specific E-R functions)
23 ppm-hrs	7.6%
22 ppm-hrs	7.2%
21 ppm-hrs	6.8%
20 ppm-hrs	6.4%
19 ppm-hrs	6.0%
18 ppm-hrs	5.7%
17 ppm-hrs	5.3%
16 ppm-hrs	4.9%
15 ppm-hrs	4.5%
14 ppm-hrs	4.2%

RBL functions for seedlings of 11 tree species (PA, Figure 4A-1)



Sensitivity analyses of median E-R function across 11 species. (PA, Figure 4A-13)



KEY: Grey indicates medians across 11 species-specific functions where the species-specific functions are represented by a random draw from the available experiment-specific functions. Red points are the median across the random draws at that W126 value and the whiskers extend to the 75th and 25th percentiles of those draws. Green line is the median across the 11 species-specific functions, and the red line is the median across the 51 experiments (regardless of species).

Other O_3 Exposure Metrics or Indices

- Exposure indices have been derived primarily for quantitative relationships of O_3 with growth effects (RBL, RYL)
  - 2013 ISA and current draft ISA state that quantifying exposure with indices that accumulate the hourly concentrations with preferential weight to the higher concentrations improves explanatory power of exposure-response models for growth and yield (over indices based on mean and peak concentrations), e.g., W126 and others
    - SUM06 (sum of hourly concentrations that exceed 0.06 ppm),
    - SUM00 (sum of all hourly concentrations)
    - AOTx (sum of the difference between hourly concentrations greater than a specified threshold, x)
- Peak concentrations (and the pattern/duration of their occurrence) also have an important role for occurrence of visible foliar injury (2013 and 2006 ISAs), e.g.,
  - N100 (number of hours with O_3 at/above 100 ppb) has been considered in several studies of USFS biosite scores