Responses to Additional Significant Comments on the 2020 Proposed Action on the Ozone National Ambient Air Quality Standards

(August 14, 2020; 85 FR 49830)

Docket Number EPA-HQ-OAR-2020-0279

U.S. Environmental Protection Agency
December 2020

[This page intentionally left blank.]

Table of Contents

Frequently Cited Documents ii
I. Introduction 1
II. Comments on the Health and Welfare Effects Evidence..
III. Comments on Quantitative Air Quality, Exposure and Risk Analyses ....
IV. Legal, Administrative, and Procedural Issues and Misplaced Comments............................
V. References...
Appendix A. List of Abbreviations and Acronyms

Frequently Cited Documents

The following documents are frequently cited throughout the EPA's response to comments, often by means of the short names listed below:

Integrated Science Assessment (ISA)
U.S. EPA (2020a). Integrated Science Assessment of Ozone and Related Photochemical Oxidants (Final). U.S. Environmental Protection Agency, Washington, DC. EPA/600/R-20/012. *https://cfpub.epa.gov/ncea/isa/recordisplay.cfm?deid=348522*

Policy Assessment (PA)
U.S. EPA (2020b). Policy Assessment for the Review of the Ozone National Ambient Air Quality Standards. U.S. Environmental Protection Agency, Office of Air Quality Planning and Standards, EPA-452/R-20-001. *https://www.epa.gov/sites/production/files/2020-05/documents/o3-final_pa-05-29-20compressed.pdf*

Proposed Action (Proposal)
Review of the Ozone National Ambient Air Quality Standards: Proposed Action. 85 FR 49830, August 14, 2020.

Final Action (NFA)
Review of the Ozone National Ambient Air Quality Standards: Final Action. To be published in the *Federal Register*.

Responses to Significant Comments on the 2020 Proposed Decision on the Review of the Ozone National Ambient Air Quality Standards

I. Introduction

This document, together with the *Federal Register* notice of final decision on the review of the ozone (O_3) national ambient air quality standards (NAAQS), presents the responses of the Environmental Protection Agency (EPA) to some of the public comments received on the 2020 O_3 NAAQS proposal notice (85 FR 49830, August 14, 2020). All significant issues raised in timely public comments have been addressed. Where comments were submitted after the close of the public comment period, the EPA has responded to the extent practicable. The responses presented in this document are intended to address comments not discussed in the final decision notice. Although portions of the final decision may be paraphrased in this RTC document, to the extent such paraphrasing introduces any confusion or apparent inconsistency, the preamble itself remains the definitive statement of the rationale for the decisions in the final action. This document, together with the preamble to the O_3 NAAQS final decision notice and the information contained in the Integrated Science Assessment (ISA, U.S. EPA, 2020a), the Policy Assessment (PA, U.S. EPA, 2020b), and related technical support documents, should be considered collectively as the EPA's response to all of the significant comments submitted on the EPA's 2020 O_3 NAAQS proposal.[1]

Sections II and III address public comments related to the air quality criteria (and ISA) and the quantitative analyses (of air quality, exposure and risk), respectively. Section IV includes responses to legal, administrative, procedural, or misplaced comments.

[1] The docket for this review is EPA-HQ-OAR-2018-0279.

II. Comments on the Health and Welfare Effects Evidence

This section addresses public comments related to the EPA's *Integrated Science Assessment for Ozone and Related Photochemical Oxidants* that are not addressed in the final decision notice.

A. Health Effects Evidence

This section addresses significant comments on the EPA's interpretation of the health effects evidence.

<u>(1)</u> <u>Comment:</u> Some commenters disagree with the EPA's causality determinations for O_3 exposure and cardiovascular effects and with total mortality, stating that the conclusions should be reevaluated. Some of these commenters express the view that the evidence is inadequate for these endpoints.[2] The commenters that express the view that the evidence is inadequate variously state that the term "suggestive" implies that a causal association is more likely than not, when they claim "this is clearly not the case."

<u>Response:</u> The EPA disagrees with these commenters that the causality determinations for short-term O_3 exposure and cardiovascular effects or total mortality should be "inadequate". The EPA has integrated the available evidence from animal toxicology, epidemiologic and controlled human exposure studies for each of these endpoints, and after applying the causality framework in a manner consistent with how it has applied it to other endpoints, has determined that the body of evidence is "suggestive of, but not sufficient to infer, a causal relationship" for each of these endpoints.

With regard to cardiovascular effects, the ISA notes that the evidence from both animal toxicological and epidemiologic studies is either "limited" or "consistent" depending on the endpoint evaluated and that the evidence from controlled human exposure studies is either "limited", "inconsistent" or provides evidence of no effect (ISA, Section 4.1.17, Table 4-1). Taken together, this evidence is consistent with the way that EPA applied the causality framework to all other endpoints, which states that "Evidence is suggestive of a causal relationship with relevant pollutant exposures but is limited, and chance, confounding and other biases cannot be ruled out" (U.S. EPA, 2015, Table II).

With regard to total mortality, the evidence base includes primarily epidemiologic studies, which, consistent with the 2006 AQCD and the 2013 ISA, continue to provide consistent, positive associations between short-term O_3 exposure and total mortality (U.S. EPA, 2006; U.S. EPA, 2013; ISA, Section 6.1.8). However, the evidence for biological plausibility for O_3 to result in mortality, especially cardiovascular mortality, which comprises a large percentage of total mortality, remains limited. In addition, while recent studies have further examined potential confounding by copollutants and other variables, confounding cannot be ruled out. Thus, the evidence base for short-term O_3 exposure and total mortality is limited, and chance, confounding, and other biases cannot be ruled out, making the "suggestive of, but not

[2] Comments expressing the view that the evidence supports a conclusion of likely causality are addressed in the NFA.

sufficient to infer, a causal relationship" determination appropriate under the causality framework.

Finally, the EPA disagrees with the commenters that the term "suggestive" implies that a causal association is more likely than not. The term "suggestive" is clearly defined in the presentation of the causality framework in the Preamble to the ISA as limited evidence for which chance, confounding, and other biases cannot be ruled out (U.S. EPA, 2015).

(2) *Comment:* One comment states that, in discussing the health research in the current review, the ISA dwells on exposure uncertainties (e.g., measurement error, activity patterns) and ignores "more certain" underestimation of health effects, especially with regard to respiratory health effects. The commenter seems to be claiming that an underestimation of respiratory effects is "more certain" than either an under- or over-estimation. The basis provided by the commenter is that epidemiologic studies focused on severe outcomes such as mortality, hospitalizations, and emergency department visits reflect just a fraction of relevant effects. The commenter states that ignoring the other effects may bias estimates of O_3 risk toward the null.

Response: The EPA disagrees with this comment that too much weight has been placed on the uncertainties related to exposure estimation in its assessment of epidemiologic studies. The implications of exposure measurement error on the results of epidemiologic studies and a characterization of the uncertainties due to such exposure measurement error are detailed in Section 2.6, as well as Tables 2.6 and 2.7 of the ISA. As stated in the ISA, "[t]he importance of exposure measurement error depends on the spatial and temporal aspects of the study design" (ISA, Section 2.6), which tend to vary based on whether short- or long-term exposures are being examined. When evaluating both short- and long-term exposure studies, the evidence demonstrates that "[f]or epidemiologic studies of short-term exposure to ozone, the effect estimates potentially have decreased precision and negative bias" (ISA, p. 2-55) and that "[f]or epidemiologic studies of long-term exposure to ozone, when concentrations measured at fixed-site monitors are used as exposure surrogates, effect estimates have the potential to be biased in either direction" (ISA, p. 2-56). We additionally note that there is greater uncertainty for the results of long-term O_3 exposure studies, for which effect estimates may be biased in either direction, than for the results of short-term O_3 exposure studies, for which effect estimates are bias toward the null. Recognition of this greater uncertainty is reflected in the different causality determinations for short- and long-term respiratory effects, which are causal and likely to be causal, respectively (ISA, Appendix 3). The potential for underestimating the risk of respiratory health effects is greater for epidemiologic studies of short-term O_3 exposure compared to long-term O_3 exposure and is not dependent on the severity of the respiratory effect, but instead on the study design, as reflected in Tables 2.6 and 2.7 of the ISA.

Further, we disagree that the ISA ignores the evidence for effects other than the more severe effects, such as those emphasized by the commenter. The EPA considers the weight of evidence across all respiratory endpoints, from sub-clinical effects measured in animal toxicological, controlled human exposure and epidemiologic studies, to more severe endpoints, such as ED visits, hospital admissions or mortality evaluated in epidemiologic studies, and considers the strengths and limitations of the evidence from different scientific disciplines and study designs. Bias due to exposure measurement error is a single limitation that is considered when evaluating epidemiologic evidence.

(3) Comment: A comment stated that ISA presentation of recent studies should, and does not, facilitate evaluation with regard to informing level and averaging time of standard. Commenters suggest that the final ISA should include additional tables that facilitate evaluation of studies with respect to informing the level and averaging time that would protect public health.

Response: The EPA disagrees with the premise of the comment that the ISA does not present information useful to considering the adequacy of the standard in all its elements, while noting that the PA with its policy-relevant evaluations builds on the evidence in the ISA with quantitative exposure and risk analyses and identification of policy-relevant considerations. As described in the PA and summarized in the Notice of Final Action (NFA), the exposure and risk analyses builds on information from controlled human exposure studies assessed in the ISA to characterize exposure and risk under air quality conditions that just meet the current standard, in all its elements (and two alternative standards). By their very designs, these analyses consider the effectiveness of the current form and averaging time in providing protection for effects documented in the controlled human exposure studies. The evidence from these studies is considered the "strongest evidence" that O_3 causes respiratory effects (ISA, p. IS-1).

To the extent that this comment is asserting that the ISA should include additional tables that facilitate evaluation of epidemiologic studies with respect to considering the level and averaging time of the standard, the EPA disagrees. While epidemiologic studies evaluate the relationship between health effects and specific ambient air O_3 concentrations during a defined study period and the generally consistent and coherent associations observed in these epidemiologic studies contribute to the causality determinations and the conclusions regarding the causal nature of the effect of O_3 exposure on health effects, "they do not provide information about which averaging times or exposure metrics may be eliciting the health effects under study" (ISA, section IS.6.1, p. IS-87). In general, the epidemiologic studies using ambient air quality measurements provide less information on details of the specific O_3 exposure circumstances that may be eliciting health effects, and whether these occur under air quality conditions that meet the current standard. For example, when considering short- or long-term O_3 concentrations with respiratory effects, there are no single-city studies conducted in the U.S. in locations with ambient air O_3 concentrations that would have met the current standard for the entire duration of the study (ISA, Appendix 3, Tables 3-13, 3-14, 3-39, 3-41, 3-42 and Appendix 6, Tables 6-5 and 6-8; PA, Appendix 3B, Table 3B-1). When considering other lines of health evidence, such as that from controlled human exposure studies, the EPA has compiled the evidence from relevant studies into figures which can be used to inform the level and averaging time of the standard that would protect public health (e.g., see ISA, Figure 3-3).

(4) Comment: The ISA failed to include a relevant study (Bell et al., 2014) which describes increased risk of emergency department visits, hospital admissions, and mortality to older adults.

Response: The study by Bell et al. (2014) is a systematic review and meta-analysis, which does not include any original results. As such, it was purposely excluded from the ISA consistent with the Population, Exposure, Comparator, Outcome, Study Design (PECOS) statement, which does not include reviews or meta-analyses as study designs to be considered (ISA, p. 3-4, p. 6-4).

(5) *Comment:* The EPA did not and should have identified people with any lung impairment (other than asthma) as at risk.

Response: The EPA can only make determinations about groups at increased risk when there is evidence available to evaluate and support such a determination. In the evaluation in the ISA of the available evidence, the EPA evaluated populations potentially at increased risk of health effects due to O_3 exposure for which evidence was available. With regard to pre-existing respiratory disease, this included those with asthma or COPD. In fact, the evidence supported a conclusion that populations with asthma are at increased risk, though there was inadequate evidence to make any determination for populations with COPD (ISA, Table IS-10). As no evidence was identified comparing the health effects associated with O_3 among those with other lung impairments (other than asthma or COPD) to those without such impairments, no determinations could be made for people with any other lung impairment.

(6) *Comment:* One comment stated that the ISA does not recognize how anthropogenic O_3 has been controlled.

Response: Section 108 of the Clean Air Act requires the EPA to issue air quality criteria, which accurately reflect the latest scientific knowledge useful in indicating the kind and extent of all identifiable effects on public health or welfare which may be expected from such pollutant in the ambient air. Consistent with Section 108, the ISA describes precursor emissions, precursor chemistry, and meteorological effects and related scientific information, but does not describe how this information has been used to date for air quality management decisions. Rather, the discussion in the ISA of the atmospheric sciences of the subject criteria air pollutant provides a succinct description of general context for the discussion of human and ecosystems exposure, human dosimetry, and epidemiology.

The general photochemistry of urban-scale O_3 is understood and well-documented in the previous O_3 ISA and preceding assessments. These sources were cited in the Appendix 1 of the ISA as providing the details to support the overview discussions of precursor emissions and their trends, atmospheric chemistry and observed ambient air concentrations and their trends provided as necessary context for the discussion of U.S. background (USB) O_3,[3] and in support of the central discussion of the ISA, i.e. the health and welfare impacts of O_3 in ambient air. Beyond that, the ISA atmospheric sciences discussion was focused on new developments in scientific understanding of the sources and formation of USB O_3.

The commenters misrepresented a relatively minor group of sources as total anthropogenic volatile organic compounds (VOCs). What is stated in the ISA is: "U.S. industrial and related

[3] Concentrations of O_3 in ambient air that result from natural and non-U.S. anthropogenic sources are collectively referred to as USB.

VOC emissions have increased by approximately 20% since 2012, while other anthropogenic emissions have declined over the same period" (ISA, Appendix 1, p. 1-14). This decline is described graphically in Figure 1-3, where it is clear that the dominant sources of VOC's, highway and non-highway vehicles, have steadily declined from 2011 to 2014 to 2017, and that the industrial sources that show increases are relatively minor in comparison.

The analysis provided by the commenters showing New York City biogenic VOC contributions are lower than the national average overlooks some important context and complexity for regional O_3 chemistry. The EPA-funded "Northeast Ozone and Particulate Study,"[4] now more than 15 years old, clearly showed with light detection and ranging (LIDAR) and balloon measurements that high O_3 episodes in the Northeast U.S. were largely due to downmixing of O_3 formed and transported aloft, rather than from local ground level precursors. This study was completed well before completion of the 2013 ISA. The overview presented in the current ISA as important reference material to provide context for the recent major advances in O_3 chemistry (i.e. winter O_3, halogen chemistry, and compression of the O_3 concentration distributions) provides citations to the 2013 ISA and earlier Air Quality Criteria documents in which results from these and other studies on regional Northeast O_3 studies are individually cited (ISA, section 1.4; 2013 ISA, section 3.2).

We agree with the comment that anthropogenic VOC sources are important to O_3 concentrations in urban areas and downwind of VOC sources. Excluding oil and gas, which is not quantified in the figure provided by the commenter, and making allowance for terminology differences, the three greatest anthropogenic VOC sources – highway vehicles (on-road mobile sources), non-highway vehicles (non-road mobile sources), and solvent use are shown to be the same in the ISA Figure 1-2 (trends plot), ISA Figure 1-3 (pie chart), and the commenter's figure. Since this pattern is usual for many urban areas, and we did not find there to be sufficient evidence to support a separate focus on the topic of anthropogenic VOC's as relevant precursors in urban areas, such as New York, with proportionally low biogenic contributions, such separate presentations were not included.

(7) *Comment:* One commenter stated that the ISA does not address all of the questions for the ISA in the Integrated Review Plan (IRP) including "what data are available to characterize precursor emissions of non-background O_3" and "how does recent evidence contribute to what is known about photochemical production of non-background O_3."

Response: The statement that the ISA does not address the question of what data are available to characterize precursor emissions of non-background O_3 is not correct. This is exactly what Section 1.3.1.1 "Ozone precursor emissions: anthropogenic sources and trends in the U.S." is intended to address (ISA, section 1.3.1.1). The U.S. National Emissions Inventory, the primary source of information used in this section to describe the sources and trends of ozone precursor emissions within the U.S., represents the synthesis of the best

[4] The results of this study appear in 20 peer-reviewed publications; citations for these publications can be found here: *https://cfpub.epa.gov/ncer_abstracts/index.cfm/fuseaction/display.publications/abstract/909#22732*

available data on emissions, emissions factors, and source activity factors. The statement that the ISA does not address recent evidence on what is known about photochemical production of non-background O_3 is incorrect. Section 1.4 of the ISA ("Ozone Photochemistry") addresses this topic. The section includes two extensive subsections on the major new research areas of winter O_3 formation and halogen chemistry (ISA, Appendix 1, section 1.4). Additionally, the commenter is correct in noting that the concentrations of O_3 coming near to or exceeding the NAAQS at urban scales is largely formed from precursors emitted at local scales. This point is emphasized in the ISA discussion of the importance of the USB O_3 contributions to total ground level O_3 in urban settings (ISA, Appendix 1, section 1.8.2).

(8) *Comment:* One commenter expresses the view that the finding of a 20% increase in industrial and related VOCs since 2012 should be studied. In addition, the commenter stated that the effects of VOC releases associated with natural gas extraction activities on ambient air O_3 in regions other than the Uinta Basin (i.e., Wyoming's Upper Green River Basin, the Colorado Front Range, and Pennsylvania) are also in need of examination.

Response: The ISA presents a graphical description of the national-scale trends in VOC emissions from industrial, petroleum, and related industries (ISA, Appendix 1, Figure 1-3C). Sector-based emissions at regional scales are readily available from the NEI as cited in the ISA. Studies of oil and gas-derived O_3 production in the Upper Green River Basin are discussed in the same section as those addressing the Uinta Basin (ISA, Appendix 1, section 1.4.1). Figure 1-10 of Appendix 1 of the ISA shows the average O_3 concentration trends for each region, including a decreasing trend for the Northeast. Figure 1-11 of Appendix 1 of the ISA, derived from the Air Quality Monitoring System database, provides detailed information concerning trends in the 4th highest daily maximum 8-hour average concentration O_3 trends at monitoring sites throughout the Northeast Corridor between 2008-2010 and 2015-2017. Given the objective of the air quality section of the ISA (see the response to the previous comment), the presentation of annual emissions, their trends, and examples of the influence of emissions from industrial, petroleum, and related industries on ambient air O_3 concentrations is considered sufficient.

B. Welfare Effects Evidence

This section addresses significant comments on the EPA's interpretation of the welfare effects evidence.

(1) *Comment:* In support of their views opposing the EPA's use of a 3-year average W126 index of 17 ppm-hrs as a target for assessing protection provided by the current standard, some commenters cite a meta-analysis by Wittig et al. (2009), also cited in comments addressed with the 2015 decision, stating that RBL estimates based on the established E-R functions for seedlings of 11 tree species "do not stand on their own" and are supported by studies such as Wittig et al., (2009). In making this statement, they quote a statement from the ISA ("A meta-analysis by Wittig et al. (2009) found that average O_3 exposure of 40 ppb significantly decreased annual total biomass by 7% across 263 studies.").

Response: We disagree with implication of the commenters' statement that the numbers in the ISA sentence cited by the commenters relate directly to the established E-R functions or their supporting data. Rather, the analysis by Wittig et al. (2009) provides support to the ISA determination of a causal relationship between O_3 exposure and reduced plant growth (ISA, section 8.3.4). But it does not provide information that can be directly compared to RBL estimates based on the established E-R functions or to their supporting data. This is because it is a very different and not directly applicable type of study. The study by Wittig et al. (2009) is not itself a carefully controlled experimental exposure study such as those on which the E-R functions are based. Rather, this study is a meta-analysis that groups together a broad array of controlled exposure studies of widely varying exposure circumstances and tested species.

The reference to a 7% decrease in annual total biomass refers to the central tendency (based on analysis of 263 publications[5] reporting on O_3 exposures of widely varying duration and magnitude) of the total biomass difference estimated between experiments involving tree exposure to charcoal-filtered air and exposure to untreated ambient air. The 40 ppb "average ozone exposure" refers to the overall average of the concentrations during all the hours across all study "ambient air" exposures. The exposures in these studies varied from four to 24 hours per day across seven to 365 days. The study authors characterize the value of 40 ppb average exposure (in comparison to negligible O_3 in charcoal filtered treatments) as "a measure of how the elevation of [O_3] that has occurred since the Industrial Revolution has reduced tree productivity" (Wittig et al., 2009). Not only is the 40 ppb estimate not directly comparable to values for commonly cited O_3 metrics, including metrics commonly used to represent cumulative exposures for assessing growth effects, the value is derived from studies of multiple species that involved differing numbers of hours exposure per day (e.g., potentially from four to 24 hours) and differing exposure durations (e.g., potentially from seven days to more than a year). Thus, we disagree with the commenters that the Wittig et al. (2009) study provides any quantitative support to the studies on which the E-R functions are based.

(2) *Comment:* In expressing their disagreement with EPA's conclusions regarding the potential impact of considering the W126 index as a 3-year average rather than each single year and with a description in the PA (Appendix 4A, pp. 4A-22, 4A-23) of the evaluation of the predicted growth impacts compared to observations from the multiyear study of O_3 impact on aspen by King et al. (2005), as presented in the 2013 and 2020 ISAs, one commenter objects to the observation made in the 2020 ISA (and repeated in the PA) that aspen growth observations (from a FACE multiyear O_3 exposure study) are "exceptionally close" to predictions based on single year W126 index (ISA, p. 8-192). The commenter states that, based on their analysis of information drawn from Figure 8-17 in the 2020 ISA, the correlation metric (r^2) for the percent difference (estimated vs observed biomass) and year of growth is approximately 0.7. This commenter additionally states that over the years of the study, the predictions (in the 2020 ISA) increasingly underestimate the observed biomass, describing the percent difference for the last year as approximately 40%, implying that that analysis is lacking in its ability to predict cumulative impacts of the multi-year exposure.

[5] Given the 99 degrees of freedom for the central tendency, less than or equal to 99 publications may be of greatest influence (Wittig et al., 2009).

This commenter suggests that the predictions are ignoring the cumulative growth effect of O_3.

Response: As an initial matter, we note that the aspect of the commenter's statements specific to the PA Appendix 4A, section 4A.3 (e.g., regarding cumulative growth effects and size of the tree) are addressed in section III.B(1) below.[6] Further, we note that the intention of the reference in the PA Appendix 4A to the ISA was in part to indicate that similar conclusions with regard to use of a function derived to describe growth response for a single season across multiple years have been reached by both ISAs based on slightly different analyses (2013 ISA, pp. 9-133 to 9-135; 2020 ISA, Appendix 8, pp. 8-192 to 8-193). The commenter describes the phrase, "exceptionally close," used in the 2020 ISA (ISA, p. 8-192) to describe its analysis, as inconsistent with specific quantitative estimates they provide based on their interpretation of the ISA's Figure 8-17 (in which the analysis utilized single-year W126 index). We note that the section of the PA Appendix 4A for which the commenter raises concerns also summarized the findings of the 2013 ISA analysis (on p. 4A-22 of the PA). In consideration of the calculations offered by the commenter with regard to Figure 8-17 in the ISA, we have used the values reported in Table 9-15 of the 2013 ISA (which are plotted in Figure 9-20), to derive correlation coefficients related to that analysis. The r^2 for predicted O_3 impact *versus* observed impact is 0.99 and for the percent difference *versus* year is approximately 0.85. We note that this indicates a much better correlation from the 2013 ISA analysis (compared to 2020 analysis, based on commenter's estimates) of the same observations with predictions based on a cumulative multiyear W126 index, suggesting a better fit for the exposure metric reflecting cumulative multiyear exposure.

III. Comments on Quantitative Air Quality, Exposure and Risk Analyses

A. Population Exposure and Health Risk Analyses

This section addresses significant comments on the EPA's quantitative exposure and risk analyses (presented in detail in the PA, Appendices 3C and 3D) that are not addressed in the final decision notice.

(1) Comment: One comment resubmitted a comment on the draft PA that expressed the view that the PA was constrained from conducting a comprehensive review of studies due to an accelerated timeline. In support of their claim the commenter cites a statement on p. 3D-146 of the Draft PA that "[g]iven the limited time schedule for review, we evaluated the contribution to risk from low [ozone]exposures using only three of the eight study areas, selected at random (i.e., Atlanta, Dallas, and St. Louis) and for a single year (2016)" and imply that for the main exposure and risk analysis, the EPA randomly selected three study cities that the commenter states were not representative of the various regions of the U.S. nor representative of hourly O_3 distributions.

[6] As noted in section III.B(1) below, the simple example presented in Appendix 4A of PA was not recognized as a consideration in the Administrator's decision in this review.

Response: As an initial matter, we note that the section of the draft PA cited by the commenter was describing a sensitivity analysis rather than the full risk analysis. As is common for sensitivity analyses, this analysis focuses on a specific aspect of the full analysis and explores the influence of certain parameters in a more limited context than the full analysis. That is what is described by the section of the draft PA quoted by the commenters. This analysis and the reasons for focusing on three study areas are also described in the final PA (PA, Appendix 3D, p. 3D-165). Thus, we disagree with the commenters' suggestion that the main risk and exposure analysis was incomplete or based on only three non-representative study areas. The main risk and exposure analysis provided comprehensive details on the data, tools, and methods employed, specific results based on those data, tools, and methods, and the sensitivity, uncertainty and variability analyses conducted. In making this comment the commenter referred to a sensitivity analysis that was not part of the results for the primary analysis. For the main risk exposure analysis, we analyzed eight study areas (PA, appendix 3D) which reflect the full range of air quality and exposure variation expected across major urban areas in the U.S and seven different NOAA climate regions (PA, section 3.4.1).

The sensitivity analysis cited by the commenter informed the characterization of uncertainty associated with the full analysis (PA, section 3.4, Appendix 3D, section 3D.3.4). This analysis was focused on evaluating the contribution to estimates of lung function risk (by both of the approaches used for such estimates) resulting from the lower exposure concentrations in light of the lesser data (between 50 ppb and 60 ppb) or lack of data (less than 40 ppb) for these low levels (PA, Appendix 3D, section 3D.3.4.2.3). To perform the analyses for the E-R function approach that were the basis for the main lung function risk, results reported in section 3D.3.3 of the PA were in a format useful for calculating the risk contribution from each 7-hr average exposure bin (0 to 160 ppb, in 10 ppb increments). Thus no new APEX simulations were needed for this evaluation. However, for the evaluations of the MSS model approach, new simulations were required. For purposes of efficiency and given the objectives for this evaluation, we focused on three of the eight study areas for this evaluation. These areas were selected at random (i.e., Atlanta, Dallas, and St. Louis), and simulations were performed for three air quality scenarios using a single year (2016) of data; the analysis focused on the risk contribution to lung function decrements occurring at least one and two days per year (PA, Appendix 3D, section 3D.3.4.2.3). These analyses were informative to the PA consideration of the lung function risk estimates by the two approaches employed. As discussed in the PA, these analyses indicated estimates via both approaches to have contributions from low exposures concentrations for which there are fewer data and the MSS model estimates to have appreciable such concentrations. These findings and other factors, as discussed in the PA and proposal contributed to the lesser weight placed on these estimates relative to estimates from the comparison-to-benchmarks analysis (PA, section 3.4.4; 85 FR 49857-49859, 49871-72, August 14, 2020).

(2) *Comment:* Some commenters express the view that the EPA failed to demonstrate that the APEX model provides "meaningful" estimates of population-level exposures or individual-level exposures. In so doing, they claim that APEX uses age, gender, race, and work status to establish user profiles and that the EPA does not provide analyses to establish that these variables alone or in combination reasonably and accurately explain the amount of time an individual spends outdoors at moderate exertion (e.g., "data [APEX] uses… have not been

shown to reflect" variables correlating with people's outdoor physical activity) or meaningful individual exposure estimates).

Response: As an initial matter, contrary to the implication or assertion of the commenters the EPA is not relying on age, gender, race, and work status as sole basis for estimation of population exposure in the study areas. As described in the PA, population exposures were estimated using the APEX, version 5 model, which probabilistically generates a large sample of hypothetical individuals from a population database and simulates each individual's movements through time and space to estimate their time-series of O_3 exposures occurring within indoor, outdoor, and in-vehicle microenvironments (PA, section 3.4.1 and Appendix 3D). The variables age, gender, race, and work status are used to identify a sample activity pattern to draw from the CHAD for simulation in APEX. In this way, the APEX creates, through stochastic sampling, a population with age, gender, race, and work status reflective of the specific study area. The APEX model generates each simulated person or profile by probabilistically selecting values for a set of profile variables, including demographic variables, health status and physical attributes (e.g., residence with air conditioning, height, weight, body surface area) and ventilation rate (PA, Appendix 3D, section 3D.2). For example, each modeled person is assigned anthropometric and physiological attributes by APEX, as described in detail in Appendix 3D of the PA, and associated attachments and cited references. All of these variables are treated probabilistically, accounting for interdependencies where possible, and reflecting variability in the population (PA, Appendix 3D, section 3D.2.2.3). Such variables include those that influence ventilation rate.

As explained in the sentences that the commenter only partially quotes conveys, "while a single profile does not, in isolation, provide information about the study population, a distribution of profiles represents a random sample drawn from the study area population. As such, the statistical properties of the distribution of simulated profiles are meant to reflect statistical properties of the population in the study area." (PA, Appendix 3D, p. 3D-20).

The APEX model accounts for the most important factors that contribute to human exposure to O_3 from ambient air, including the temporal and spatial distributions of people and ambient air O_3 concentrations throughout a study area, the variation of ambient air-related O_3 concentrations within various microenvironments in which people conduct their daily activities, and the effects of activities involving different levels of exertion on breathing rate (or ventilation rate) for the exposed individuals of different sex, age, and body mass in the study area (PA, Appendix 3D, section 3D.2). The analyses described in the PA, include a variety of updates from prior such assessments, including new statistical distributions for estimating body weight, equations for estimating resting metabolic rate, and equations for estimating activity-specific ventilation rate (PA, Appendix 3D).

Thus, the EPA disagrees with the commenter's implication that the APEX model does not provide "meaningful" estimates of population-level exposures or individual-level exposures with respect to time spent outdoors and physical activity data used in estimating exposures for the exposure and risk analyses. The APEX model is not focused on exposures for specific individuals. Rather it is intended to estimate distributions of population-level exposures. APEX probabilistically generates a large sample of hypothetical individuals from a population database and simulates each individual's movements through time and space to estimate their time-series of O_3 exposures occurring within indoor, outdoor, and in-vehicle microenvironments (PA, Appendix 3D, section 3D.2). The exposure and risk analyses inherently recognize that variability in human activity patterns (where people go and what they do) is key to understanding the magnitude, duration, pattern, and frequency of population exposures. By incorporating individual activity patterns from the CHAD,[7] the model estimates physical exertion associated with each exposure event. After the basic demographic variables are identified by APEX for a simulated individual in the study area, values for the other variables are selected as well as the development of the activity patterns that account for the places the simulated individual visits (such as indoors or outdoors) and the exertion level of activities they perform (PA, appendix 3D). For example, to account for the variability in activity patterns dependent on age, such as time spent outdoors and associated activities performed, the APEX model assigns age-specific diaries from CHAD to simulate age-specific individuals' locations visited and physical activities performed and thus accounts for when time expenditure varies due to influential individual attributes such as age. APEX is built upon accepted first principles and has high quality input data and therefore the results are meaningful. The "meaningfulness" of the results of the risk and exposure analysis is further supported by our consideration of the uncertainties associated with the quantitative estimates of exposure and risk, including those recognized by the characterization of uncertainty in Appendix 3D of the PA (PA, Appendix 3D, section 3D.3.4). This is further supported by an analysis of the uncertainty of APEX when used to model O_3 exposures (Langstaff, 2007) and an evaluation of APEX in microenvironments (Johnson et al., 2018).

_(3)_ _Comment:_ One commenter states that the APEX model (used in the exposure analysis) underestimates weather-dependent behavior changes (e.g., playing outside when the temperature is warm), which they argue results in the exposure analyses scenarios including too few children breathing at elevated respiratory rates.

Response: The EPA disagrees with the comment. In support of their view, the commenter provides descriptive statements about children's habits for playing outdoors in various locations every day, weather permitting, and does not also provide any evidence on which the statements are based. The exposure assessment, however, is based on extensive data and established methods. The APEX model used in the assessment accounts for the most important factors that contribute to human exposure to O_3 from ambient air, including the temporal and spatial distributions of people and ambient air O_3 concentrations throughout a study area, the variation of ambient air-related O_3 concentrations within various microenvironments in which people conduct their daily activities, and the effects of activities involving different levels of exertion on breathing rate for the exposed individuals of different sex, age, and body mass in the study area (PA, Appendix 3D, section 3D.2). To

[7] To represent personal time-location-activity patterns of simulated individuals, the APEX model draws from the consolidated human activity database (CHAD) developed and maintained by the EPA (McCurdy, 2000; U.S. EPA, 2019a). The CHAD provides data on human activities through a database system of human diaries or daily time series or daily time location activity logs collected in surveys at city, state, and national levels. Included are personal attributes of survey participants (e.g., age, sex), along with the locations they visited, activities performed throughout a day, time-of-day the activities occurred and activity duration (PA, Appendix 3D, section 3D.2.5.1).

represent personal time-location-activity patterns of simulated individuals, the APEX model draws from CHAD, which provides time series data on human activities through a database system of collected human diaries, or daily time location activity logs. This information indicates that children spend more time outdoors than all other age groups while at elevated exertion, and consistently do so when considering the most important influential factors such as day-of-week and outdoor temperature, all of which APEX takes into account. The APEX model stochastically generates a user-specified number of simulated people to represent the population in the study area. The number of simulated individuals can vary and is dependent on the size of the population to be represented. For the current analysis, the number of simulated individuals was set at 60,000 for each of the children and adult study groups (which includes people with asthma for both of these study groups) to represent population residing within each study area (i.e., between 2 and 10 million). While precisely 60,000 children and 60,000 adults were simulated as part of each APEX model run, the number of individuals estimated to be exposed are appropriately weighted to reflect the actual population residing within the census tracts that comprise each respective study area. In considering the available information regarding prevalence of behavior (time outdoors and exertion levels) and daily temporal pattern of O_3 concentrations, we take note of the findings of evaluations of the data in the CHAD. Based on these evaluations of human activity pattern data, children spend about 2 hours of afternoon time outdoors per day and 80% of which is at elevated exertion levels (PA, section 3.3.2 and Appendix 3D, section 3D.2.5.3 and Figure 3D9, p. 3D-56).

(4) *Comment:* Some commenters expressed the view that the exposure assessment "irrationally and arbitrarily" presumes that people with asthma will experience identical lung function decrements as healthy individuals at a given exposures of concern.

Response: As an initial matter, we note that the exposure assessment does not make any presumptions with regard to lung function decrements; it simply estimates exposure. Accordingly, we assume that the commenter is referring to the lung function risk assessment. As described in the PA, that assessment uses the APEX model estimates of population exposures for simulated individuals with information for O_3 exposures and FEV_1 decrements to estimate the portion of the simulated at-risk population expected to experience one or more days with an O_3-related FEV_1 decrement of at least 10%, 15% and 20% (PA, section 3.4). These estimates are derived by two different approaches, one using E-R functions and the other based on a more mechanistic model (the MSS model). In both cases, the underlying data are from controlled human exposure studies comprised of largely healthy subjects. As recognized in the PA, the evidence is quite limited with regard to such studies conducted with subjects with asthma. Further, as described in the ISA, the evidence that does exist indicates generally similar responses for the two populations (ISA, Appendix 3, section 3.1.5.4.4).

(5) *Comment:* Some commenters claim that the exposure and risk analysis use of the National Health Interview Survey (NIHS) responses biased the size of vulnerable populations downward by asserting that the EPA only considered adults who responded that they "still have asthma" versus including respondents who had "ever" had an asthma diagnosis.

Response: We disagree that our approach significantly biased the size of sensitive populations with asthma in the exposure and risk analysis. We note that focusing on adults and children who "still have asthma," is consistent with the characterization of asthma prevalence in the ISA (ISA, Table IS-11), and as such, this approach provides us with the most appropriate estimate of the population of individuals that have asthma (PA, appendix 3D, p. 3D-150). As discussed in the uncertainty characterization documented in the PA, based on analyses also documented there, we conclude that using the response for the "Still" question may underestimate asthma prevalence for those not having a physician determined diagnosis. Those analyses indicate such an underestimation to be at most about 0.6 percentage points (i.e., with an "ever had" variable, the overall 'current' asthma prevalence for children would be about 9.0% rather than the 8.4% used in the simulations), as discussed in detail in the PA (PA, appendix 3D, Attachment 1). Thus, while it is likely that using the response for the "Still" question underestimates asthma prevalence for those not having a physician determined diagnosis, the magnitude of underestimation is likely quite small. We note that with regard to asthma prevalence, the data are used to identify if a simulated individual residing within a modeled census geographic area has asthma. The data are not used for selection of any other personal attribute nor in the selection of activity pattern data (PA, Appendix 3D, section 3D.2.2.1).

(6) *Comment:* One commenter claimed that the EPA failed to consider several issues in exposure assessment and as such, they imply that reliance on this analysis is unlawful. In particular, the commenter asserts that the EPA did not adequately consider averting behavior, the correlation between asthma and race, and that the EPA failed to perform the quantitative uncertainty analysis recommended by CASAC on the draft PA. As a basis for their claim on averting behavior, they state that in contrast to the 2014 HREA, the EPA arbitrarily failed to discuss how averting behavior influences the activity diaries in the APEX modeling in the current review and as such the exposure estimates may be inaccurate. With regard to the issue on asthma and race, the commenter holds that the EPA failed to address the correlations between asthma and race in attributing asthma prevalence to simulated study populations. With respect to the comment on CASAC and the uncertainty analysis, they express the view that the EPA failed to provide uncertainty bounds on its exposure and risk estimates, noting that the CASAC observed that the ranges of estimates "represent variability between cities, not uncertainty."

Response: The EPA disagrees that the exposure assessment does not adequately consider the issues raised by the commenter and consequently disagree with the view that reliance on results of the assessment is unlawful. As an initial matter, we note that the NAAQS must "be established at a level necessary to protect the health of persons," not the health of persons refraining from normal activity or resorting to medical interventions to ward off adverse effects of poor air quality (S. Rep. No. 91-1196, 91st Cong. 2d Sess. at 10). We additionally note that the issue of averting behavior and potential modifying effect on O_3 exposure estimates was investigated in the 2014 HREA through a very limited sensitivity analysis.[8]

[8] This analysis was limited to a single urban study area, a 2-day period, and a single air quality adjustment scenario (2014 HREA, section 5.4.3.3 and Appendix 5G). The analyses include a number of limitations to and uncertainties in the analyses with regard to simulating the averting behavior (e.g., prevalence and duration of the behavior), given the lack of actual activity pattern data that explicitly incorporated this

Based on the available information, including the limited analyses in the 2014 HREA, we find it reasonable to conclude that overall averting behavior will likely have little effect on the range of exposures generated from the APEX simulations.

With regard to the commenter's statement regarding correlations of asthma prevalence and race, the PA provides appreciable discussion (e.g., PA, Appendix 3D, sections 3D.2.2.2 and 3D.3.4). As explained in the PA, there are personal attributes other than those used to stratify asthma prevalence for use in the exposure and risk analysis that have been shown to influence asthma prevalence, such as race, ethnicity, obesity, smoking, health insurance, and activity level (e.g. Zahran & Bailey, 2013). The set of variables chosen to stratify asthma prevalence for use in the exposure and risk analysis (i.e., age, sex, and family income level) was based on maximizing the potential range in asthma prevalence variability, maximizing the number of survey respondents comprising a representative subset study group, and having the ability to link the set of attributes to variables within the U.S. Census population demographic data sets. Of the additional influential factors identified here, race is perhaps the only attribute common to both the prevalence and population data sets that could be an important influential factor and was not directly used to calculate asthma prevalence. However, the use of race in calculating asthma prevalence, either alone or in combination with family income level, would further stratify the NHIS analytical data set and appreciably reduce the number of individuals of specific age, sex, race, and family income level, potentially reducing the confidence in calculated asthma prevalence based on having so few data in a given stratification. Because family income level already strongly influences asthma prevalence across all races and stratifies the NHIS data into only two subgroups (i.e., above or below the poverty threshold) in comparison to the larger number of subgroups a race variable might yield, family income was chosen as the next most important variable beyond age and sex to rely on for weighting the spatial distribution of asthma prevalence.

With regard to the comment regarding the CASAC recommendation concerning quantitative uncertainty analyses, as an initial matter, we agree that the PA presents estimates for each study area (by simulated at-risk population) and note that those estimates are described in the PA as simply that (i.e., they are not implied to represent uncertainty). With regard to the uncertainty characterization provided in the PA, it does not include a completely quantitative uncertainty analysis. We did not have the data necessary to complete a full probabilistic uncertainty analysis (that would have required, for example, use of expert elicitation to derive confidence levels for all key inputs). Rather, the PA includes a full and rigorous analysis of key sources of uncertainty including discussion of the potential nature and magnitude of the impact of individual sources of uncertainty on the estimates generated, following an approach that is employed in exposure/risk analyses conducted for NAAQS reviews. The mainly qualitative approach used in this and other REAs, also informed by quantitative sensitivity analyses, is described by WHO (2008). This approach identifies key

type of behavioral response (2014 HREA, p. 5-33). As noted in the 2014 HREA, "because most activity diaries are limited to a single day and the survey participants were not directly asked if they altered their daily activities in response to a high air pollution event, we do not know if any diary day represents the activities of an individual who averted. Thus it is entirely possible that the 'no averting' simulation includes, to an unknown extent, individuals who spent less time outdoors than would have occurred if absolutely no individuals averted." (2014 HREA, p. 5-33).

aspects of the assessment approach that may contribute to uncertainty in the exposure and risk estimates and provided the rationale for the inclusion of such aspects (PA, Appendix 3D, sections 3D.2.9.2 and 3D.3.4). The output of the uncertainty characterization is a summary that describes, for each identified source of uncertainty, the magnitude of the impact and the direction of influence the uncertainty may have on the exposure and risk results. The uncertainty characterization in the PA additionally draws on uncertainties associated with APEX exposure modeling that have been previously characterized in the REAs for nitrogen dioxide (NO_2), carbon monoxide (CO), and sulfur dioxide (SO_2) conducted for recent primary NAAQS reviews, along with other pollutant-specific issues (U.S. EPA, 2010, 2017b, 2018a), all complementary to quantitative uncertainty characterizations conducted for the 2007 O_3 exposure assessment by Langstaff (2007). Conclusions drawn from each of these characterizations have been considered in the current analyses in light of new information, data, tools, and approaches used in this exposure and risk analysis. Thus, the PA includes full discussion of uncertainties and an extensive table describing key uncertainties (PA pages 3D-144 to 3D-158). Further, the characterization in the PA is also informed by an array of quantitative sensitivity analyses. As described in the PA, a number of additional quantitative analyses aimed at informing our characterization of uncertainty were added in consideration of the CASAC advice. For example, in consideration of CASAC recommendations and public comments, the PA exposure/risk analysis includes presentations reflecting further analyses, investigations, and/or clarifications of the available data with regard to a number of areas (listed below).

- Analyses of data on outdoor activity by different population groups including those identified as at risk in this review (e.g., children with asthma and older adults) during times of day when O_3 may be elevated (PA, section 3D.2.5.3);
- Estimates for the comparison-to-benchmarks analysis additionally summarized in light of the estimates from the last review (PA, section 3D.3.2.4);
- Evaluation of risk characterization uncertainty related to its representation of population groups having health conditions other than asthma, of older adults, and of outdoor workers (PA, section 3D.3.4.1);
- Evaluation of uncertainty in estimates for people with asthma that may be associated with method for identifying individuals with asthma (PA, section 3D.3.4.1);
- Evaluation of uncertainty with the E-R function and risk estimates (PA, section 3D.3.4.1);
- Analyses investigating the sensitivity of the MSS model outputs to the value assigned the individual variability parameter, and to low-level ventilation rates, as well as overall model uncertainty in the MSS model (PA, section 3D.3.4.1).

(7) *Comment:* In claiming there to be problems with the EPA's exposure assessment, some commenters state that the EPA did not adequately address a CASAC comment regarding performance evaluations conducted for the air quality modeling in each of the study areas. The CASAC letter on the draft PA stated that "it would be useful" for the EPA to conduct additional model performance evaluations for the O_3 precursors, NO_X and VOC, suggesting that if the precursor concentrations did not match the observations, the HDDM sensitivities "may not be" accurate (Cox, 2020, Consensus Responses to Charge Questions p. 11).

Response: Model evaluations presented in the PA focused on the O_3 concentrations predicted for the three air quality scenarios assessed primarily because the population exposure assessment focuses on O_3 concentrations (and does not utilize NO_X and VOC concentrations). In the model-based rollback, predicted model concentrations were not used at all,[9] and so an evaluation of predicted NO_X or VOC concentrations individually would have limited relevance to judgements related to confidence in the rollback outcomes. Since the HDDM sensitivities reflect the model characterization of O_3 production chemistry derived from first principles, the relationship between NO_X and VOC in the atmosphere along with the representation of local meteorological conditions is what matters for the predicted chemistry, rather than absolute concentrations of either species. Additionally, ambient air monitoring data for VOC concentrations are not uniformly available, with very few locations that include measurements are available for both NO_X and VOC compounds. A performance evaluation for both precursors would therefore only be possible for a very small number of sites, thus making it also less useful or relevant for consideration across the set of study areas assessed.

(8) Comment: In support of their disagreement with the exposure and risk analysis conclusions related to the 70 ppb benchmark, one commenter claims that the "sample size" of the exposure and risk analysis is limited ("extremely small") due to the focus on children in the study areas breathing at an elevated rate. In so doing, they state that of the full simulated populations for the eight study areas, about 2.3% are children with asthma (pointing to Table 3D-25 of the PA), and claim, based on an assumption that 79% of those children spend seven hours outdoors at moderate or greater exertion, that 1.82% of the full simulated populations would be children with asthma that are outdoors at exertion for seven hours a day.

Response: To the extent that the commenter intends to disagree with the premise of the comparison to benchmarks analysis that the pertinent exposures for comparison are those while at elevated exertion, we disagree. As discussed in the PA and the ISA, the controlled human exposure studies on which the benchmarks are based evaluate effects of exposures experienced while subjects are engaged in quasi-continuous exercise (6.6 hours including six 50-minute periods of moderate or greater exertion) (ISA, Appendix 3, section 3.1.4.1; PA, sections 3.3.3 and 3.4). Further, to the extent that the commenter is claiming that the exposure assessment only estimates exposure for a subset of the identified population in a study area, we also disagree. In fact, the exposure assessment estimates population exposures for simulated individuals in eight study areas. The "sample size" consists of 60,000 simulated children in each of the eight study areas with the number of individuals estimated to be exposed weighted to reflect the actual population residing within the census tracts that comprise each respective study area. Thus, of the over 8.2 million children simulated, 10.8% were children asthma which is somewhat higher than the actual national prevalence of 7.9% children with asthma (PA, Table 3-1, appendix 3D, Table 3D-25). Lastly, the commenter implies that the exposure assessment only considers exposures occurring outdoors. This is

[9] The model-based adjustment approach employed to develop the air quality scenarios for the exposure and risk analyses is described in detail in Appendix 3C of the PA (e.g., see PA, Appendix 3C, section 3C.5). As part of the methodology used, photochemical modeling results are not used in an absolute sense but instead are applied to modulate ambient air measurements, thus tying estimated O_3 distributions to measured values (PA, Appendix 3C, section 3C.5.2).

incorrect. As described in the PA, the exposure assessment focuses on exposures to O_3 that originated in ambient air, and such exposures include microenvironments that are both indoor and outdoor locations (PA, section 3.4.1 and Appendix 3D, section 3D.2.6).

B. Environmental Exposure Analyses

This section addresses significant comments on quantitative environmental exposure related analyses that are not addressed in the final decision notice.

(1) *Comment:* One commenter identifies what they describe as flaws in example analyses included in the PA that use biomass measurements from the multiyear study by King et al. (2005) to estimate above-ground aspen biomass over a multiyear period using the established E-R function for aspen with a constant single-year W126 index, e.g., of 17 ppm-hrs, or with varying annual W126 index values (10, 17 and 24 ppm-hrs) for which the 3-year average is 17 ppm-hrs (PA, Appendix 4A, section 4A.3). The first of the two criticisms concerning the example analyses concerns application of the RBL (for each W126 index value) to an annual growth increment derived from the "control" trees (represented in the analysis by the trees in King et al (2005) exposed to unadjusted ambient air). The commenter states that this assumes the effect of O_3 in one year to have no effect on tree growth in a subsequent one, yet this ignores that smaller trees (presumably including an O_3 exposed tree compared to a control) grow less than larger trees (Binkley et al., 2013) and ignores that this can explain long-term negative cumulative effects of O_3 on tree growth (Talhelm et al., 2014). The second criticism of the analysis was the EPA's use of aspen, for which the E-R relationship is relatively linear. The commenter claims that it does not reflect species with a more pronounced curve, such as sugar maple. Lastly, the commenter claims that a statement regarding multiyear studies in the PA summary of limitations for this analysis was "boldly incorrect."

<u>Response:</u> While the example analysis in the PA critiqued by the commenter was not, itself, recognized as a consideration in the Administrator proposed decision on the secondary standard (85 FR 49907-49913, August 14, 2020), or in his final decision (NFA, section III.B.4), the EPA has considered the points raised by this commenter.

With regard to the first point, the EPA agrees with the general concept explained by the commenter, essentially that an O_3-exposed tree would have a smaller annual incremental growth than a control tree due to its being of smaller size as a result of the O_3 exposure in prior year.[10] We note, however, that the comparison in this analysis was between two O_3-exposed scenarios, and the point raised by the commenter has little impact on that comparison in the PA example. This is illustrated in a revised version of the PA example, provided in Appendix B of this document, in which the annual biomass increment is estimated using a function of prior year biomass (derived from the measurements for the control aspen in King et al. [2005]). As the commenter suggested, the difference of the O_3-

[10] As recognized in the ISA, "[i]t is well established that exposure duration influences the degree of plant response and that ozone effects on plants are cumulative," "effects are clearly demonstrated to be related to the cumulative exposure over the growing season for crops and herbaceous plant species," and "[f]or long-lived plants, such as trees, exposures occur over multiple seasons and years" (ISA, p. ES-19). These are reasons identified for the focus on using cumulative indices of exposure to assess vegetation exposure (ISA, p. ES-19).

exposed scenario from the control scenario is larger (than in the PA Appendix 4A example). The difference between estimates for the different patterns of O_3 exposure (the focus of the example analysis), however, is still relatively small (a fraction of a percent). Further, we note that the varying W126 values in the simple example include a W126 index value of 24 ppm-hrs every third year. Yet the frequency of such a value for air quality meeting the current standard is quite rare, as can be seen from the air quality analyses in the PA, which show that across the period from 2000 through 2018 for even just a subset of sites meeting the current standard, i.e., those with design value closest to 70 ppb (66-70), the 99th percentile is below 20 ppm-hrs (PA, Appendix 4D, Figure 4D-8). Focusing just on Class I areas (sites meeting the current standard), there are no more than 15 occurrences of a single-year W126 index value above 19 ppm-hrs in the entire time period (2000-2018) and all of those occurrences date prior to 2013 (FR 85 49904, August 14, 2020). Thus, the varying scenario in the example analyses generally represents much higher cumulative exposures that those occurring across the U.S. at sites that meet the current standard, with a much greater frequency of higher W126 index values. Specifically, they include as one of the three years of air quality, a magnitude of W126 index that has been quite rarely observed in areas that meet the current standard since 2000.

With regard to the second point, the EPA recognizes that the shape of the E-R relationship may have the potential to influence the difference in the comparison analyzed. We note, however, that the large change in slope of the relationship for sugar maple (the only species for which such a pattern is seen in the 11 E-R functions) occurs at or above the highest W126 index values observed at U.S. ambient air monitoring sites (as well as the highest value used in the PA example analysis, 24 ppm-hrs), as summarized above (PA, Appendix 4A, Figure 4A-1). For W126 index values at or below 19 ppm-hrs, the slope for sugar maple is much smaller and RBL estimates associated with its E-R function are appreciably lower than those for the aspen (PA, Appendix 4A, Figure 4A-1).[11] Thus, while the shape of the sugar maple differs substantially from the aspen at higher exposure conditions, there are much more limited differences at exposures more common in U.S. areas where the current standard is met. Accordingly, any difference that a sugar maple example might indicate from the aspen example would not be significant. Further, sugar maple occurs in the northeast and upper midwest of the U.S., areas with among the relatively lower W126 index levels across the U.S. (PA, Appendix 4D, Figure 4D-2). Across the other 10 species for which there are established E-R functions, nine of them have generally linear E-R relationships. The tenth, black cherry, has a slope for the E-R function that presents the opposite pattern to that of red maple (the slope of the curve slowly declines with increasing W126 index).

[11] At sites and time periods during 2000 through 2018 in which the current standard was met, even focusing on just the design values closest to the current standard (e.g., 66 -70 ppb), the sugar maple RBL estimated for the 75th percentile is less than 1% (PA, Appendix 4A, Table 4A-4 and Appendix 4D, Figure 4D-8). It is also of note that the lowest nonzero O_3 exposure represented in the dataset from which the sugar maple E-R function is derived has been reported as a SUM06 of 25.2 ppm-hrs (a value that the 2007 Staff Paper indicated may be similar to a W126 index of 21 ppm-hrs (PA, Appendix 4A, Table 4A-6; U.S. EPA 2007). This lack of an exposure representative of exposure levels more commonly occurring in U.S. areas that meet the current standard contributes appreciable uncertainty to interpretations of sugar maple RBL for exposure for air quality meeting the current standard.

Lastly, in characterizing the EPA's statement regarding multiyear studies "boldly incorrect," the commenter has taken the statement out of the context intended by the EPA. The sentence referenced by the commenter is as follows: "However, datasets of tree growth across multiple-year periods such as that available for aspen in the study by King et al. (2005) are not prevalent" (PA, p. 4A-23). The commenter apparently assumes the statement concerned any multi-year tree growth study, of which the EPA agrees there are many. In the statement cited, however, the EPA was referring to multiyear studies of growth that investigated the impact of O_3 as in the case of the study by King et al (2005) that the EPA's sentence cites.

IV. Legal, Administrative, and Procedural Issues and Misplaced Comments

A number of comments were received that addressed a wide range of issues including legal, administrative, and procedural issues, as well as issues that are not germane to the review of the NAAQS. Many legal issues are addressed generally throughout the notice of final action. Specific responses to other comments are presented below

(1) *Comment:* Some commenters conveyed the view that the process followed by the EPA in this review of the O_3 NAAQS has been conducted in compliance with the applicable substantive and procedural requirements under the Act and relevant case law. In support of this view, these commenters state that the CASAC fulfills the CAA criteria for the committee, that the CAA-required air quality criteria are provided in the ISA, which they note was reviewed by the CASAC (which provided the Administrator with written advice on the draft document), and that the CASAC provided its advice to the Administrator on the NAAQS. These commenters additionally cite the EPA actions that fulfilled requirements for a public docket, a published proposed decision that explains the basis for associated judgments and consideration of CASAC advice, and a public comment period of 48 days (that also included two days of public hearings with oral testimony from the public). The commenters also recognize the expedited nature of the current review which they find appropriate, stating that the EPA has acted appropriately and lawfully to ensure timely completion of the review. In response to questions raised during the review, these commenters note that the Act does not require that the EPA issue a final ISA prior to a draft PA, further noting that the CASAC written comments on the draft ISA and PA were available to the EPA, as well as the final ISA, prior to its completion of the final PA. The commenters also note that the Act does not require the EPA to release multiple review drafts of a document, or of a separate exposure/risk document (noting that this was also not done in the NO_2 primary NAAQS review).

Response: We agree with this comment that this review of the O_3 NAAQS complied with the applicable legal requirements, including for reasons identified in the comment, as well as for reasons described elsewhere in this Response to Comments document and in the Federal Register notice describing the final decision in this review. We further note that, as described in Administrator Pruitt's memo (Pruitt, 2018), the EPA recognizes the importance of completing NAAQS reviews in a timely, efficient, and transparent manner in order to ensure a full evaluation of whether any revisions to the standards are necessary to provide requisite protection of public health and welfare, while remaining cognizant of the statutory time frames for completion such reviews.

(2) *Comment:* Some commenters criticized the process that the EPA followed in this NAAQS review, stating that the EPA had failed to provide any explanation (reasoned or not) for process changes and state that when the EPA made changes to the process in 2006, it provided an opportunity for CASAC and others to provide input on the changes. Some commenters claim that the EPA has failed to conduct the necessary scientific review to reflect the latest scientific knowledge that Congress intended (or that it was impossible to ascertain based on a lack of explanation for the selection of the CASAC and the consultant pool). Some commenters emphasize that particularly given the CAA specified role filled by the CASAC, and the concerns they raise with regard to CASAC, the process followed in the current review was flawed, arbitrary and capricious, and unlawful and that accordingly the proposed decision suffers from fatal procedural errors and is contrary to law. Some commenters assert that these flaws mean that the Administrator should not defer to CASAC advice and that they call into question any decision that relies on CASAC review.

With regard to the CASAC and its role in the review, some commenters claim that CASAC was not lawfully constituted. Such commenters assert that the CASAC is unqualified for scientific advice on NAAQS or the expertise contemplated by its charter, that it lacked or did not have appropriate access to relevant scientific expertise (e.g., epidemiology, toxicology, clinical experience, exposure assessment, plant and climate impacts); and that it did not provide "valid expert advice." Such commenters additionally claim that CASAC members were appointed based on geographic location and government affiliation *versus* scientific expertise, and that the chair appears to lack impartiality. Some commenters claimed that the CASAC is at odds with the CAA-specified role that the EPA describes the CASAC as filling and that it lacked critical expertise because the EPA failed to form an expert O_3 review panel, such that the EPA could not ensure that the NAAQS accurately reflects the latest scientific knowledge, as required under the CAA. Some commenters state that the process of allowing CASAC to seek written input from a pool of consultants did not provide an adequate substitute for the O_3 review panel, citing similar concerns about lack of expertise in the group of consultants, as well as concerns that the process of exchanging information through writing does not replace the process that CASAC and expert review panels have used in past reviews. Some commenters further claim that the process followed in the current NAAQS review fails to meet requirements for federal advisory committees and federal peer review guidance, citing the EPA's *Peer Review Handbook* and the Office of Management and Budget's 2004 Peer Review Bulletin, and asserting CASAC to lack appropriate expertise and balance contemplated by these documents. These commenters also assert that the EPA barred from CASAC nongovernment recipients of the EPA funding (a requirement they state was later overruled by court decisions and for which the EPA provided no rationale), which they further state resulted in a lack of balance of scientific perspectives on the panel. Further, some commenters suggested that the change in membership in the chartered CASAC conflicts with established Science Advisory Board (SAB) criteria for advisory panels, which call for "continuity of knowledge." Some commenters also stated that CASAC overlooked or was not informed of important aspects of the review, such as thorough review of the form of the standard, consideration of lower primary standard levels with regard to margin of safety, and potential conflict between draft PA and *Murray* decision.

Some commenters also criticize the approach the EPA followed for preparing the ISA, PA, and exposure and risk analyses. These commenters variously state that what they describe as simultaneous preparation of draft the ISA and PA, and presentation of the exposure/risk analyses within the PA (versus in a separate document) results in insufficient time for CASAC and public review, as well as a "commingling" of science and policy. The commenters claim that presenting the exposure/risk analyses in the PA document "eliminates" CASAC and public review of these analyses, and that development of the PA prior to CASAC review of the ISA or risk and exposure analyses contributes to CASAC and the EPA reviewing policy considerations in the PA based on unreviewed scientific analyses, stating the view that this results in severe limitations on CASAC's ability to advise on the NAAQS. Additionally, some commenters state that the lack of second draft documents handicaps accuracy and contributes to the PA not reflecting the best science. Some commenters point out that CASAC requested a second draft of the PA, but the EPA did not provide one.

Some commenters also raise concerns regarding public participation and review of documents prepared during the course of the review, claiming among other things that it did not meet CAA requirements for public participation. In support of this view, commenters variously cite the overlapping public review periods for the draft ISA and PA, a lack of second drafts of these documents, and the brevity of the public comment period for the proposal, claiming that these placed burdens on public review (especially for respiratory health professionals who may have less time for review during the current pandemic).

Response: We disagree with these commenters that the current review process, including aspects involving the CASAC review, public participation, and development of scientifically sound documents in support of the decision, is flawed, inadequate, arbitrary, capricious, or contrary to law.

The process by which the CASAC was established was proper and met all applicable CAA and Federal Advisory Committee Act (FACA) requirements, and was consistent with the EPA policy and procedure as outlined in the CASAC Charter. Section 109(d)(2)(A) of the CAA addresses the appointment and advisory functions of an independent scientific review committee. Section 109(d)(2)(A) requires the Administrator to appoint this committee, which is to be composed of "seven members" including "at least one member of the National Academy of Sciences, one physician, and one person representing State air pollution control agencies." Section 109(d)(2)(B) provides that the independent scientific review committee "shall complete a review of the criteria…and the national primary and secondary ambient air quality standards…and shall recommend to the Administrator any new…standards and revisions of existing criteria and standards as may be appropriate…" Since the early 1980s, this independent review function has been performed by the CASAC. The seven-member chartered CASAC meets these statutory requirements. [12]

[12] The list of chartered CASAC members, along with their bio sketches, is available at: https://yosemite.epa.gov/sab/sabpeople.nsf/WebExternalCommitteeRosters?OpenView&committee=CASAC&secondname=Clean%20Air%20Scientific%20Advisory%20Committee%20

With regard to commenters' claims that the CASAC lacks necessary scientific expertise, thus jeopardizing its ability to provide the EPA with the required scientific advice or the EPA's ability to rely on CASAC's advice, we first note the CAA requirements for the independent scientific review committee whose role is currently filled by the CASAC. Section 108(a)(2) of the CAA directs the EPA to prepare "air quality criteria" that accurately reflect the latest scientific knowledge regarding all identifiable effects on public health and welfare that may result from the presence of the criteria pollutant in the atmosphere. Section 109(d)(2) of the CAA directs the EPA to appoint an independent scientific review committee that shall conduct a review of the air quality criteria and the national primary and secondary ambient air quality standards and shall recommend to the Administrator any new standards and revisions of existing criteria and standards as may be appropriate. Section 109(d)(2)(A) provides that the review committee is to be "composed of seven members including at least one member of the National Academy of Sciences, one physician, and one person representing State air pollution control agencies." The CAA does not further identify specific areas of experience or scientific expertise to be represented on the review committee, and it would be unreasonable to expect all the individual disciplines from the wide array of atmospheric, health, and welfare sciences to be explicitly represented on the committee itself. To address this expertise concern as expressed by the CASAC, in this review the EPA made available a pool of consultants with expertise in a number of scientific fields germane to the O_3 NAAQS (84 FR 38625, August 7, 2019). The approach employed for the CASAC to utilize outside technical expertise represents a modification of the process used in past reviews. Rather than join with some or all of the CASAC members in a pollutant-specific review panel as has been common in other NAAQS reviews in the past, in this review, the consultants comprised a pool of expertise that CASAC members drew on through the use of specific questions, posed in writing prior to their public meeting on the review, regarding aspects of the documents being reviewed. This allowed the CASAC to obtain subject matter expertise for its document review in a focused, efficient, and transparent manner.

The pool of expert consultants utilized by the CASAC was assembled using a public process beginning with a Federal Register notice requesting the nomination of scientists from a broad range of 15 disciplines, with demonstrated expertise and research in the field of air pollution related to PM and O_3, including epidemiology (84 FR 38625, August 7, 2019). From among the nominees, the Administrator selected scientists, all with advanced scientific degrees (PhDs), many active in academia, and reflecting a broad range of areas of expertise, including aerosol science and atmospheric chemistry, predictive and causal modeling method development and application, human health risk assessment, quantitative risk analyses, environmental exposures, toxicology, statistics, environmental and genetic epidemiology, and human clinical studies in respiratory effects. Therefore, the Agency does not agree with commenters who contend that the current CASAC review process lacked the appropriate breadth or balance of expertise. Further, the EPA notes that the decision to provide supplemental expertise to the chartered CASAC, whether with an additional panel of experts as in previous NAAQS reviews or via a publicly nominated pool of experts as in this review, goes beyond the requirements of the Act.

As outlined in the EPA's call for nominees to the consultant pool, the EPA was resolved to provide complete public transparency with respect to the consultant pool's input to the independent scientific review and established a process whereby all communications between the chartered CASAC and the individual consultants was accomplished via written requests and responses. Contrary to claims of these commenters, which include a concern that having the process involve CASAC raising an issue before the consultant pool could address it could have led to deficiencies in the review documents being overlooked (a concern for which the commenters provided no evidence), the EPA believes that this process allowed for focused and transparent information exchange on the subjects where CASAC members most needed additional expertise. Certainly, there is ample evidence of robust information exchange between the chartered CASAC and individual consultants in which CASAC members pose questions and, in addition to responding to the questions, consultants provide comments on a wide range of issues regarding the EPA documents. For example, Appendix D of the CASAC February 19, 2020 letter providing its review of the draft ISA, and Appendix C of the CASAC February 19, 2020 letter providing its review of the draft PA, contain 126 and 53 pages, respectively, of CASAC questions and consultant answers that document substantive technical and scientific interpretations. The CASAC questions and consultant feedback were presented on the EPA webpage prior to the public meeting of the CASAC. In sum, while not explicitly required by the CAA, the EPA believes that the pool of consultants established for this review provided CASAC access to additional expertise beyond that of the seven chartered members and helped contribute to a rigorous and thorough scientific review that satisfied the CAA requirements.

While some commenters referred to an EPA directive concerning membership of the EPA advisory committees, claiming that it prohibited leading research scientists from CASAC membership which resulted in a lack of balance on the Committee, we note that the grants portion of the directive was never applied to exclude any person from membership on the CASAC. With respect to the recent court decisions that address the EPA's directive concerning membership of advisory committees, those decisions were issued after the CASAC membership was finalized. Further, although the CASAC membership was finalized prior to the court decisions, the only court decision to vacate the section of the directive pertaining to EPA grants does not require the EPA to reopen the composition of any advisory committees. See *Nat. Res. Def. Council, Inc. v. U.S. Envtl. Prot. Agency*, No. 19CV5174 (DLC), 2020 WL 2769491, at *1 (S.D.N.Y. Apr. 15, 2020).

Further, in light of the above discussion, we disagree with these commenters that the CASAC composition and the expertise brought to bear in the CASAC reviews of the draft ISA and PA were contrary to federal peer review guidance. While the two documents cited by the commenters do not constitute statutory requirements, we note that, as described in the paragraphs above, the factors with which commenters expressed concern -- expertise and balance -- were of major importance in selection of committee members (in addition to the CAA specific representation requirements). The CASAC review process addressed these factors in its provision of external scientific review while additionally providing the Agency with a streamlined review process that facilitated Agency attention to statutory deadlines. Regarding the Administrator's decision to increase state, tribal, and local government participation and enhance geographic diversity, the Administrator has discretion to consider such criteria in staffing the EPA's advisory committees, and doing so is not inconsistent with any requirement of the CAA or FACA. Further, the EPA does not agree with commenters' claim that the EPA considered such criteria instead of scientific expertise. Rather, the EPA considered expertise and geographic diversity and governmental affiliation in addition to scientific expertise. With respect to the comment concerning continuity of knowledge, one CASAC member has prior experience with a NAAQS review thus providing a degree of continuity of knowledge. Further, the "continuity of knowledge" criteria referred to by commenters is contained in a report issued by the Science Advisory Board Staff Office and describes non-binding criteria used to develop a list of potential candidates.

We also disagree with the comments suggesting that the EPA has not provided a rationale for the changes in process in this review. Changes can be made to these procedures without public comment. The EPA has made changes to the NAAQS review process on multiple occasions such that it has evolved in multiple ways since the Agency began conducting reviews back in the 1970's while continuing to meet the CAA requirements for such reviews. In addition to these changes in the larger framework for NAAQS reviews, each review has also had its own unique characteristics, related to considerations such as the specific nature of the pollutant and the standard(s) being evaluated. While the scientific review process here may have differed in format from previous O_3 NAAQS reviews, it still fully comported with all relevant CAA requirements, including in sections 108 and 109 of the Act, and reflected a thorough review of the latest scientific knowledge relevant in reviewing the air quality criteria for O_3 and related photochemical oxidants and the adequacy of the existing standards.

Prior to initiating this review, the EPA released to the public and posted on its website Administrator Pruitt's memo (Pruitt, 2018), which explains the rationale for the process changes the EPA incorporated into this particular NAAQS review. Two of the key reform principles specifically centered on the CAA statutory requirements in Section 109(d) for both meeting the five-year review deadlines and properly establishing the functions of the independent scientific review committee. Emphasizing these goals is well within the Administrator's discretion. The memo announced publicly that the EPA would be identifying ways in which the review process could be streamlined, including development of robust initial draft versions of the ISA and PA that could allow the CASAC and the public to comment significantly on the review documents. While some of these aspects differed from how prior reviews had been structured, the specific processes used in those reviews were not binding or required by the statute. The comments fail to establish that the process changes made for this review, or the manner in which they were made, were inconsistent with any statutory requirement or that the process changes invalidate the final decision or limit the EPA's ability to rely on the advice that the duly constituted CASAC has provided in this review.

The EPA disagrees that the current review process did not provide sufficient time for public and CASAC review documents prepared in the review. As summarized in section I.D of the Federal Register notice describing the final decision in this review, the draft ISA and draft PA were made available to the public and the CASAC 69 days and 34 days, respectively, prior to being discussed by the CASAC at a public meeting on December 4, 5 and 6, 2019 (84 FR 50836, September 26, 2019; 84 FR 58713, November 1, 2019). They were subsequently discussed by the CASAC at a public teleconference on February 11 and 12, 2020 (85 FR 4656, January 27, 2020). As described in the public notice announcing the meeting and teleconference, members of the public had the opportunity to provide written comments in advance of, and oral comments during, the meeting and teleconference. Further, the Agency publicly announced the availability of the draft ISA and draft PA for public review over periods of 68 days (9/26/2019 to 12/2/2019) and 46 days (11/01/2019 to 12/16/2019), respectively, specifying the submission of comments to the respective dockets (84 FR 50836, September 26, 2019; 84 FR 58711, November 1, 2019). Comments from the public and the advice of the CASAC were considered by the EPA in preparing the final ISA, and also in the development of the draft PA. Further, the public comment period for the proposal provided 48 days for the submission of written comments and two days of public hearings for the provision of oral comments. This process met the legal requirements for CASAC review and public participation on NAAQS decisions. Comments received on the proposal have been considered in reaching the final decisions. Thus, we disagree with these commenters that the process adopted in the current O_3 NAAQS review has not allowed sufficient opportunity for public input and CASAC advice.

Lastly, with regard to concerns raised on the development of support documents in the review, as directed by Administrator Pruitt's memo, the EPA determined to streamline the NAAQS review process to expedite its completion in an efficient and transparent manner (Pruitt, 2018). The CAA leaves the Administrator considerable discretion as to what documents and analyses are useful in informing a particular review of the air quality criteria and existing standards and how to structure the review; it does not establish a particular sequential order for the documents prepared during a review, nor does it require completion of multiple drafts of any review document. Several recent NAAQS reviews have established precedent for single drafts of the PA (e.g., the lead and sulfur dioxide NAAQS reviews completed in 2016 and 2018, respectively). Additionally, it is not uncommon, as implied by commenters, for past reviews to have included CASAC review of draft PAs before a final ISA had been released, nor to have the same public meeting include CASAC's review of a draft ISA, a draft REA, and a draft PA, as occurred in the 2015 O_3 review (77 FR 46755, August 6, 2012). Further, regarding the inclusion of the exposure and risk analyses in the PA rather than being presented in a separate document, we disagree with commenters that that the current NAAQS review process necessitates a separate REA. Consistent with the recently completed particulate matter NAAQS review, detailed and complete quantitative analyses, including those focused on human exposure and health risk, environmental exposure, and various welfare effects are included in the PA. In this O_3 NAAQS review, the health-related analyses and associated policy-relevant considerations are described in Chapter 3 of the final PA, while appendices 3C and 3D provide comprehensive details on the data, tools, and methods employed, specific results and sensitivity, uncertainty, and variability analyses. The welfare-related analyses and associated policy-relevant considerations are described in Chapter 4 of the final PA, while appendices 4C and 4D provide comprehensive details on data, tools, and methods employed, specific results and summaries of limitations and uncertainties. The CASAC provided advice on all of these quantitative analyses, as did several public commenters, when reviewing the draft PA. In some past NAAQS reviews, the risk and exposure analyses have been included in the PA (most recently in the nitrogen dioxide NAAQS review completed in 2017),[13] and as noted above, there have been reviews

[13] Prior to embarking on these steps in the review, that were described in the draft IRP, we noted comments received from individual CASAC members during consultation on the draft IRP, which did not generate consensus CASAC advice. Such comments did not take consider the Agency's past experiences with such an approach in prior reviews or raise issues that had not been accounted for in those prior reviews. Thus, after consideration of past experience, the efficiency objectives for the process objectives

in which the CASAC and public review of a draft REA were coincident with review of a draft PA. Therefore, we disagree with the commenter that a separate REA is required to allow for a technically rigorous analysis of risk, or that inclusion of the risk and exposure analyses in the PA improperly commingles policy and scientific considerations or prevents transparent and informed review by the CASAC and the public. Similarly, we disagree with the comments that review of the draft PA before the ISA had been finalized limited the CASAC's ability to provide advice on the NAAQS. CASAC considered the draft ISA and draft PA each in turn and provided separate advice on each document. In addition, the EPA completed the ISA before it completed the PA, so it was able to consider the final scientific assessment, which reflected consideration of the CASAC's advice, in finalizing the PA.

With regard to claims by some commenters stated that the CASAC overlooked or was not informed of important aspects of the review, such as thorough review of the form of the standard, consideration of lower primary standard levels with regard to margin of safety, and potential conflict between draft PA and *Murray Energy* decision, we note that, as in past reviews, the PA discuss these topics. Although this might be implied by these comments, PAs do not always discuss specific alternative standards, as illustrated by the PAs for the recent Pb, NO_2, and SO_2 NAAQS reviews (U.S. EPA, 2014b, 2017b, 2018a). As in those cases, the O_3 PA discussed policy-relevant aspects of the current evidence and quantitative analyses in discussing key considerations for the Agency's consideration in its review of the existing standards, in addition to describing the CAA requirements for NAAQS reviews and the approaches employed in past reviews. Further, the Agency solicited input from the public for consideration by the CASAC in its review of the PA and such concerns could have been raised at that time (84 FR 58713, November 1, 2019).

(2) <u>*Comment:*</u> One commenter states that the EPA was required to and failed to conduct a consultation with the U.S. Fish and Wildlife Service and the National Marine Fisheries Service under Section 7(a)(2) of the Endangered Species Act, stating that without such consultation the EPA cannot assure that any final standard is not likely to jeopardize continued existence of endangered or threatened species or result in the destruction or adverse modification of critical habitat. The commenter further states that Section 7 "consultation" is required under the ESA for "any action [that] may affect listed species or critical habitat" to "insure that any action authorized, funded, or carried out by such agency… is not likely to jeopardize the continued existence of any endangered species or threatened species or result in the adverse modification of habitat of such species… determined…to be critical…." The commenter asserts that agency "action" is broadly defined in the ESA's implementing regulations at 50 CFR 402.02 to include: "(b) the promulgation of regulations; … or (d) actions directly or indirectly causing modifications to the land, water, or air." The comment states that the EPA's review of the NAAQS is "an activity carried out by a federal agency in the United States which directly and indirectly causes modifications" to the land, water or air.

The commenter also notes that ESA regulations at 50 CFR 402.03 provide that Section 7 of the ESA applies to all actions in which there is discretionary Federal involvement or control

described in the Pruitt (2018) memo, as well as any public or CASAC member comments on the issue, we implemented the approach.

and asserts that the EPA has discretion to consider impacts to listed species in its review of both the primary and secondary NAAQS. With respect to the secondary NAAQS, the commenter states that the CAA both empowers and mandates the EPA to exercise its discretion to consider impacts to listed species and critical habitat in reviewing the secondary NAAQS because the secondary NAAQS is designed to protect the "public welfare," which is defined to include effects on soil, water, crops, vegetation, animals, wildlife, weather, visibility, and climate. The commenter further claims that review of the primary standard allows for consideration of impacts to listed species and critical habitat because the primary NAAQS is designed to protect the public health because the health and vigor of human societies and the integrity and wildness of the natural environment are closely linked, and many people suffer significant long-term stress from species going extinct and their critical habitat being adversely modified. The comment further asserts that biodiversity is a foundation of human health because it allows humans to secure life-sustaining goods and services, while the loss of biodiversity is a threat to public health, for example through threats to food security, increased prevalence of infectious disease, and because biodiversity can provide important resources for traditional practices, medical research, and drug development, as well as reducing risks from climate disasters and supporting recovery and adaptation efforts.

The commenter additionally cites the ISA's description of O_3 impacts on a variety of plant and animal species, asserting that O_3 can directly harm several listed species and critical habitat for several listed species, as well as claiming that O_3 can harm listed species through its effects on plant-insect signaling, herbivore growth and reproduction, and climate change. The commenter also cites additional studies that it claims shows that O_3 can adversely affect the growth and flowering of plants, alter species composition and richness, change water flux regulation, pollination efficiency, plant pathogen development, and functioning belowground, including nutrient cycling and carbon pools. As further support for their view, the commenter further claims that the EPA must consider co-benefits of a more stringent O_3 NAAQS for listed species and habitats, as a more stringent O_3 NAAQS would lead to reductions in emissions of NOx, mercury, fine particulate matter, VOCs, and greenhouse gases. The comment further states that such consideration of co-benefits is consistent with OMB Circular A-4.

Response: The EPA disagrees with the commenter's assertion that this review is "an activity carried out by a federal agency in the United States which directly and indirectly causes modifications" to the land, water or air, and therefore the EPA was required to consult under Section 7(a)(2) of the ESA. Even assuming that the ESA consultation requirement could apply to a decision to revise the NAAQS, the EPA does not agree that leaving the NAAQS unaltered triggers the requirement to consult under the ESA. Leaving the NAAQS unchanged does not authorize or carry out any "action" under the statutory terms of the ESA.[14] Both the Code of Federal Regulations and the status quo regarding the NAAQS are entirely undisturbed. The EPA is not taking any affirmative action. Moreover, leaving the NAAQS unaltered will not require the EPA to make new air quality designations, nor will it require

[14] Section 7(a)(2) of the ESA only applies to "action authorized, funded, or carried out" by a federal agency.

States or authorized tribes to undertake new planning or control efforts or to change air quality.

Similarly, even if the EPA's review decision on the O_3 NAAQS were found to be an "action" for ESA purposes, the EPA's decision to leave the O_3 NAAQS unaltered causes no change to the status quo for air quality and regulatory requirements, and thus has no effect on species or their habitat.

Additionally, the EPA does not believe it is necessary or appropriate to consider O_3 impacts on species and habitats as part of the review of the primary O_3 NAAQS. To the extent the commenter is suggesting the primary standard should be set to protect species and habitats, the EPA believes that would be inconsistent with the text and structure of the Clean Air Act. Section 109 of the CAA requires the EPA to establish primary standards to protect public health (see section 109(b)(1)) and secondary standards to protect public welfare (see section 109(b)(2)). Under Section 109(b)(1) and *Whitman v. Am. Trucking Associations*, 531 U.S. 457 (2001), the EPA sets primary standards that are requisite to protect public health, allowing an adequate margin of safety. The EPA does not have discretion to set a different primary standard than the one the Administrator judges is required under Section 109(b)(1) to protect public health in order to protect species and habitats.

Moreover, even if the EPA's review of the NAAQS were an "action" that was anticipated to have some effect on a listed species or habitats, consultation under Section 7(a)(2) of the ESA would not be required, because the statute leaves the EPA no discretion to set a NAAQS more stringent than is "requisite" to protect public health and welfare. See 50 CFR 402.03. The Supreme Court adopted the Solicitor General's definition of "requisite" to mean "sufficient, but not more than necessary." *Whitman v. Am. Trucking Associations*, 531 U.S. 457, 473 (2001). In other words, the Administrator must select a standard that is "not lower or higher than necessary" to achieve the CAA's statutory objectives. *Id.* at 476. This leaves the Administrator no discretion to weigh factors that do not bear on public health and welfare.

As to the primary standard, the EPA must set a standard that is "requisite to protect the public health" with "an adequate margin of safety." CAA § 109(b)(1). The EPA would have no discretion to modify the requisite standard based on consideration of factors that are not related to health. To the extent the commenter is arguing that effects on species also have effects on people, e.g., because the commenter knows of people who place great value on the continued existence of species, the commenter is describing an effect that cannot be considered without assessing the effects on species, which is done in the review of the secondary standard, not the primary review. Thus, any such effects on people are beyond the scope of this review of the primary standard. Even as to the secondary standard, the Administrator has no discretion to adapt the welfare standard to be more protective of listed species and habitats than is necessary "to protect the public welfare from any known or anticipated adverse effects associated with the presence of such air pollutant in the ambient air." CAA §109(b)(2). To be sure, the Clean Air Act says that "[a]ll language referring to effects on welfare includes, but is not limited to, effects on . . . vegetation [and] animals" among other factors. CAA §302(h). The Administrator must therefore set a secondary standard which protects against known or anticipated effects on plants and animals to the extent they constitute adverse effects on public welfare. But the NAAQS are not zero risk standards, *see, e.g., Murray Energy Corp. v. EPA*, 936 F.3d 597, 610 (D.C. Cir. 2019), and not every adverse effect on welfare constitutes an adverse effect on public welfare.

The EPA may only set a standard that is requisite (neither more nor less stringent than necessary) to protect against adverse effects on public welfare. The universe of "effects" which are to be addressed under the ESA can be considerably broader than the "adverse effects on public welfare" which are the proper subject of a secondary NAAQS. In particular, consultation under ESA § 7(a)(2), when applicable, requires the agency to "insure" that the agency's action "is not likely to jeopardize the continued existence of any endangered species or threatened species or result in the destruction or adverse modification of [critical] habitat of such species." ESA § 7(a)(2). The EPA lacks the discretion to set a secondary NAAQS that goes beyond the proper scope and stringency required by the Clean Air Act.

Furthermore, the EPA disagrees that it is necessary or appropriate to consider in this review the co-benefits of reductions in pollutants other than O_3, such as mercury, that might result from establishing a more stringent O_3 NAAQS. To the extent the commenter is suggesting that either the primary or secondary standard should be set to protect against effects from pollutants other than O_3 or related photochemical oxidants, the EPA believes that would be inconsistent with the text and structure of the Clean Air Act. Under section 109(a)(1) and (2) of the CAA, NAAQS are to be promulgated for air pollutants for which air quality criteria have been issued. Section 109(b) of the CAA requires the EPA to establish primary standards to protect public health (see section 109(b)(1)) and secondary standards to protect public welfare (see section 109(b)(2)), and provides that both the primary and secondary standards are to be based on the air quality criteria. Section 108(a)(2) of the CAA requires that the air quality criteria for an air pollutant "shall accurately reflect the latest scientific knowledge useful in indicating the kind and extent of all identifiable effects on public health or welfare *which may be expected from the presence of such pollutant in the ambient air*" (emphasis added). Under section 109(d), the EPA is required to periodically review the air quality criteria and standards, consistent with sections 108 and 109(b). As described in the Integrated Review Plan, in this review the EPA is revising the air quality criteria and NAAQS for photochemical oxidants including O_3 (U.S. EPA, 2019a). Accordingly, the 2020 ISA "review[ed] and synthesize[d] the air quality criteria for the health and welfare effects of ozone and related photochemical oxidants in ambient air" (ISA, IS-2). Accordingly, this review is appropriately focused on the health and welfare effects of O_3, and whether any revisions to the existing standards would be appropriate under section 109 to provide additional protection from O_3 effects. *Cf. WildEarth Guardians v. EPA*, 759 F.3d 1196, 1209 (10th Cir. 2014) ("Just as the ESA consultation requirement cannot be invoked by characterizing agency nonaction as action, it cannot be invoked by trying to piggyback nonaction on an agency action by claiming that the nonaction is really part of some broader action. When an agency action has clearly defined boundaries, we must respect those boundaries and not describe inaction outside those boundaries as merely a component of the agency action."). The EPA does not have discretion to set a different primary or secondary standard than the one the Administrator judges is required under section 109(b)(1) or (2), to protect public health or welfare from effects associated with other pollutants, for which air quality criteria have not been issued.

(3) *Comment:* Some commenters state that the proposed decision had not adequately considered environmental justice and equity concerns. More specifically, some commenters variously state that the EPA's consideration of at-risk groups in NAAQS decisions does not fulfill its obligations under EO 12898; that the EPA's finding that the action does not have disproportionately high and adverse human health or environmental impacts on minority, low-income, or indigenous populations is unfounded; and, that the EPA must undertake a review of cumulative impacts and set the O_3 standard using a precautionary approach. Some of these commenters assert that given disproportionate distribution of some diseases and health outcomes (e.g., asthma, associated emergency department visits, cardiovascular disease, and associated deaths), that the commenters consider to also be related to O_3, the EPA should and has not considered how a lower standard level would benefit these Black and Native American communities. Other commenters state that "fact that the status quo is inequitable is not a rational reason to forego meaningful analysis of the inequity of the status quo or to avoid redressing these inequities." In support of their view that EJ concerns were not adequately considered, some commenters state that tribal populations are more vulnerable than the general population to O_3 and socioeconomic-related impacts.

Response: As described in section I.A of the NFA, the NAAQS must protect public health with an adequate margin of safety, including for sensitive groups (or populations) as well as the general populace. Minority populations, low-income populations, and/or indigenous peoples are often such sensitive populations. The EPA agrees that the NAAQS should be set in a precautionary fashion because the margin of safety is intended to provide a reasonable degree of protection against hazards that research has not yet identified, and does not assume that the status quo is adequate, but disagrees that the EPA is required to undertake a review of cumulative impacts of other pollutants. The primary O_3 standard is a nationally uniform standard which in the Administrator's judgment is requisite to protect public health, including the health of sensitive groups (also termed at-risk populations), with an adequate margin of safety, from the effects which may be expected from the presence of O_3 in the ambient air, consistent with CAA requirements. Thus, the CAA requires the NAAQS to be "requisite," i.e., neither more nor less stringent than necessary, to provide protection, with an adequate margin of safety, for sensitive groups.

In making its determination regarding the requisite protection of at-risk populations, as discussed in section II.A.2.b of the final action, in other comment responses, and as summarized in section IX.K of final action, the EPA expressly considered the available information regarding O_3 exposure and health effects among sensitive populations, including low income and minority populations. The ISA and PA for this review, which include identification of populations at risk from O_3-related health effects, are available in the docket, EPA–HQ–OAR–2018–0279. In accordance with E.O. 12898, the EPA has considered whether the decision may have disproportionate negative impacts on minority populations, low-income populations, or indigenous peoples. This decision retaining the existing primary O_3 standard, without revision, is not expected to have disproportionate negative impacts on minority or low-income populations. Rather, the EPA expects that actions taken to bring all areas of the U.S. into compliance with this standard will reduce health risks in the areas subject to the highest ambient air concentrations of O_3. We further note that to the extent that areas currently not complying with the current standard are disproportionately populated by Black or low-income populations, as implied by commenters, improvements in air quality to come into compliance with the current standard will reduce O_3-related health risks in these populations.

To the extent any of the commenters is suggesting E.O. 12898 requires additional quantitative analysis or assessment of environmental justice issues, or that the standard should be revised to be more stringent than necessary to protect the health of sensitive and other groups with an adequate margin of safety, the EPA disagrees. This action retains the existing O_3 NAAQS. States have primary response for implementing the NAAQS and implementation plans are beyond the scope of this action. However, the EPA notes that recipients of EPA financial assistance must comply with all federal nondiscrimination statutes that together prohibit discrimination on the bases of race, color, national origin (including limited-English proficiency), disability, sex, and age. These laws include: Title VI of the Civil Rights Act of 1964; Section 504 of the Rehabilitation Act of 1973; Section 13 of the Federal Water Pollution Control Act Amendments of 1972; Title IX of the Education Act Amendments of 1972; and the Age Discrimination Act of 1975. The EPA's Office of Civil Rights (OCR) is responsible for carrying out compliance with these federal nondiscrimination statutes and does so through a variety of means, including: complaint investigation; agency-initiated compliance reviews; pre-grant award assurances and audits; and technical assistance and outreach activities. Anyone who believes that any of the federal nondiscrimination laws enforced by OCR have been violated by a recipient of EPA financial assistance may file an administrative complaint with the EPA's OCR.

The commenter has provided no evidence that the current O_3 standards result in a disproportionate impact on Native Americans and Alaska natives with asthma or that revision would not, and the EPA is not aware of such evidence. Further, contrary to the comments, and consistent with the assessment conducted in each NAAQS review, the EPA has evaluated the available evidence with regard to populations that may be at greater risk of O_3 health effects than the general population. That assessment, described in the ISA, identified people with asthma as an at-risk population but did not identify native Americans as an at-risk population. Likewise, the ISA concluded that available evidence is not adequate to conclude an increased risk status based solely on racial, ethnic, or income variables, or pre-existing cardiovascular disease or diabetes, alone (ISA, section IS.4.4). The term "at-risk populations" is used to recognize populations that have a greater likelihood of experiencing O_3-related health effects (sometimes referred to as sensitive groups). Thus, the EPA expects that a standard providing protection for populations identified as at risk also provides protection for other groups. Finally, to the extent that these comments are premised on the commenters' view that the current O_3 standards do not provide adequate public health or public welfare protection, the EPA disagrees for the reasons described elsewhere in this Response to Comments document and the NFA describing the EPA's final decision in this review.

(4) *Comment:* Some commenters express the view that the EPA should have engaged in consultation with Tribes and should not have claimed there are no tribal implications of the proposed action. In support of this view, the commenters state that American Indian or American Native (AI/AN) populations in America suffer disproportionately from health discrepancies that leave them more vulnerable to impacts from pollution than the general public. The commenters state that the EPA ignored these implications and has not offered

Tribal consultation on the proposal, directly disregarding EO 13175. The commenters further state that only Tribes (not the EPA) can determine whether Tribes are impacted by this action, claiming immeasurable cost to Tribes from the loss or diminishment of culturally significant species due to the impacts of O_3 or other pollutants and noting the benefits to an entire Tribe and individuals from being able to exercise hunting, fishing, and gathering rights as guaranteed by treaties with the United States.

Response: Executive Order 13175, entitled ‘‘Consultation and Coordination with Indian Tribal Governments’’ (65 FR 67249, November 9, 2000), directs federal agencies to develop an accountable process to ensure ‘‘meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.’’ It provides that "‘policies that have tribal implications’ refers to regulations, legislative comments or proposed legislation, and other policy statements or actions that have substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes." This NAAQS decision retains existing national standards to address the health and welfare effects of O_3, providing protection for sensitive groups from adverse effects to public health, with an adequate margin of safety, and protection of public welfare from known or anticipated adverse effects.[15] There are no changes to regulations by this action, and Tribes are not obligated to implement these standards, or to conduct monitoring or adopt monitoring requirements, such that no direct requirements are placed on Tribes by this action. This action does not have tribal implications, as specified in Executive Order 13175, and is therefore not subject to the Executive Order. Even if this action was determined to have tribal implications within the meaning of the Executive Order, it will neither impose substantial direct compliance costs on tribal governments, nor preempt tribal law, and therefore consultation under the Executive Order was not required.

While consultation was not required under the EO, the EPA undertook a number of outreach activities to inform the Tribal community about the O_3 NAAQS review. Specifically, on three occasions, prior to and subsequent to signature on the proposed decision, we participated in National Tribal Air Association (NTAA)/EPA Air Policy calls to describe the status, current and future steps in the O_3 NAAQS review, including with regard to development of review documents and associated opportunities for public review. These NTAA calls occurred on December 12, 2019, May 28, 2020, and July 30, 2020. Additionally, on the date the Administrator signed the proposed O_3 NAAQS decision and the EPA placed a copy on its website, July 14, 2020, we sent an email to the Tribal community and the NTAA about the proposal. We received no requests for further informational meetings or for consultations.

Further, during the public comment period, we received comments on the proposed action from seven tribes and three tribal organizations. These comments were considered in reaching a final decision on the existing primary and secondary standards in this review, and all significant comments are addressed in the preamble to the final action or in this RTC.

[15] The comment related to a potential for Tribes to be increased risk of O_3 health effects is addressed in the NFA.

(5) *Comment:* Some commenters expressed the view that the EPA's approach for the exposure and risk analyses is inconsistent with CAA "which promises air in which people can engage in their normal range of activity free from adverse effects." The commenter goes on to claim that the EPA has failed to establish that the demographic variables such as age and gender provide for appropriate predictions of time spent outdoors with elevated ventilation rates. They further assert that the APEX modeling is flawed and systematically underestimates the likelihood of multiple exposures of concern for simulated individuals.

Response: The premise of this comment seems to be that the Agency's use of an exposure assessment to estimate population exposures to O_3 in ambient air that may occur when the current standard is met does not take into account the "normal range of activity" in which people engage. However, as described in detail in the PA, the exposure model is intended to do just that. Briefly, the APEX model calculates the exposure time-series for a user-specified duration and number of individuals (PA, Appendix 3D, section 3D.2). Collectively and by design, these simulated individuals are intended to be a representative random sample of the population in the chosen study area. To this end, demographic data from the decennial census are used so that appropriate model sampling probabilities can be derived considering personal attributes such as age and sex and used to properly weigh the distribution of individuals in any given geographical area. For each simulated person, the following general steps are performed: (1) Select personal attribute variables and choose values to characterize the simulated individual (e.g., age, sex, body weight, disease status); (2) Construct an activity event sequence (a minute-by-minute time-series) by selecting a sequence of appropriate daily activity diaries for the simulated individual (using demographic and other influential variables); (3) Calculate the pollutant concentrations in the microenvironments that simulated individuals visit; and (4) Calculate the simulated individual's exposure, and simultaneously, their breathing rate for each exposure event and summarize for the selected exposure metric (PA, Appendix 3D, section 3D.2). A simulated individual's complete time-series of exposures (i.e., exposure profile), representing intra-individual variability in exposures, is combined with the exposure profiles for all simulated individuals in each study area and summarized to generate the population distribution of exposures, representing inter-individual variability in exposures. The overarching goal of the exposure and risk analysis is to account for the most significant factors contributing to inhalation exposure and risk, i.e., the temporal and spatial distribution of people and pollutant concentrations throughout the study area and among the microenvironments (PA, Appendix 3D, section 3D.2).

The goal in addressing variability in this exposure and risk analysis is to ensure that the estimates of exposure and risk reflect the variability of O_3 concentrations in ambient air, population characteristics, associated O_3 exposures, physiological characteristics of simulated individuals, and potential health risk across the study areas and for the simulated at-risk populations (PA, Appendix 3D, section 3D.2.9.1). The APEX model is designed to account for variability in the model input data, including the physiological variables that are important inputs to determining exertion levels and associated ventilation rates. The resulting collection of probabilistically sampled individuals represents the variability of the target population, and by accounting for several types of variability, including demographic, physiological, and human behavior, APEX is able to represent much of the variability in the exposure and risk estimates. For example, variability may arise from differences in the population residing within census tracts (e.g., age distribution) and the activities that may affect population exposure to O_3 (e.g., time spent outdoors, performing moderate or greater exertion level activities outdoors). The range of exposure and associated risk estimates are intended to reflect such sources of variability, although we note that the range of values obtained reflects the input parameters, algorithms, and modeling system used, and may not necessarily reflect the complete range of the true exposure or risk values (PA, Appendix 3D, section 3D.2.9.1).

Further, the commenters appear to also fundamentally object to the EPA's consideration of exposure estimates in reaching conclusions on the primary O_3 standard. The EPA disagrees with these commenters' conclusions regarding the appropriateness of considering exposure estimates, and notes that NAAQS must be "requisite" (i.e., "sufficient, but not more than necessary" (*Whitman*, 531 U.S. at 473)) to protect the "public health" ("the health of the public" (*Whitman*, 531 U.S. at 465)). Estimating exposure patterns based on extensive available data[16] is a reasonable means of ascertaining that standards are neither under- nor over-protective, and that standards address issues of public health rather than health issues pertaining only to isolated individuals. Behavior patterns are critical in assessing whether ambient air concentrations of O_3 may pose a public health risk.[17] Exposures to the concentrations of O_3 that occur in ambient air have only been shown to result in potentially adverse effects if the ventilation rates of people in the exposed populations are raised to a sufficient degree (e.g., through physical exertion) (ISA, Appendix 3).[18] Ignoring whether such elevated ventilation rates are actually occurring, as advocated by these commenters, would not provide an accurate assessment of whether the public health is at risk. Indeed, a standard established without regard to behavior of the public would likely lead to a standard which is more stringent than necessary to protect the public health.

While setting the primary O_3 standard based only on ambient concentrations, without consideration of activity patterns and ventilation rates, would likely result in a standard that is over-protective, the EPA also concludes that setting a standard based on the assumption that people will adjust their activities to avoid exposures on high-pollution days would likely result in a standard that is under-protective. The exposure analysis does not make this latter assumption. The time-location-activity diaries that provided the basis for exposure estimates reflect actual variability in human activities. While some diary days may reflect individuals spending less time outdoors than would be typical for them, it is similarly likely that some days reflect individuals spending more time outdoors than would be typical. Considering the

[16] The CHAD database used in the exposure assessment contains data for nearly 180,000 individual diary days, and includes time-location-activity patterns for individuals of both sexes across a wide range of ages (PA, Appendix 3D, section 3D.2.5.5.1).
[17] As the EPA explained in the last review: "The activity pattern of individuals is an important determinant of their exposure. Variation in O_3 concentrations among various microenvironments means that the amount of time spent in each location, as well as the level of activity, will influence an individual's exposure to ambient O_3. Activity patterns vary both among and within individuals, resulting in corresponding variations in exposure across a population and over time" (80 FR 65312, October 26, 2015). This continues to be true in the current review.
[18] For healthy young adults exposed at rest for 2 hours, 500 ppb is the lowest O_3 concentration reported to produce a statistically significant O_3-induced group mean FEV_1 decrement (PA, section 3.3.3; 2013 ISA, p. 6-5).

actual variability in time-location-activity patterns is at the least a permissible way of identifying standards that are neither over- nor under-protective.[19]

Further, the EPA sees nothing in the CAA that prohibits consideration of the O_3 exposures that could result in effects of public health concern. While a number of judicial opinions have upheld the EPA's decisions in other NAAQS reviews to place little weight on particular risk or exposure analyses (i.e., because of scientific uncertainties in those analyses), none of these opinions have suggested that such analyses are irrelevant because actual exposure patterns do not matter. See, e.g. *Mississippi v. EPA*, 744 F.3d 1334, 1352-53 (D.C. Cir. 2013); *American Trucking Ass'ns, v. EPA*, 283 F.3d 355, 373-74 (D.C. Cir. 2002). Further, in upholding the EPA's decision on the 2015 primary O_3 NAAQS, the court noted that the Administrator had considered activity patterns in the exposed population "because adverse health responses to ozone exposure are critically dependent on breathing rates" and concluded that this "use of the exposure assessment was rational." See *Murray Energy Corp. v. EPA*, 936 F.3d 597, 610-11 (D.C. Cir. 2019).

Therefore, because behavior patterns are critical in assessing whether ambient concentrations of O_3 may pose a public health risk, the EPA disagrees with the views expressed by these commenters objecting to the consideration of O_3 exposures in reaching decisions on the primary O_3 standard.

(6) *Comment:* One commenter expresses the view that the EPA failed to consider how action will undermine implementation of Chesapeake Bay total maximum daily load (TMDL) which they note relies on NAAQS for achieving atmospheric N deposition allocation.

Response: The CAA requirements for NAAQS are that the standards provide the requisite protection of public health and welfare. The CAA does not, as implied by this comment, require the NAAQS to be used as a tool for implementing TMDLs established under section 303(d) of the Clean Water Act. Further, the NAAQS pollutant addressed in this review, O_3 and related photochemical oxidants, are not identified in the TMDL referenced by the commenter. The pollutants identified in the TMDL as interfering with attainment of water quality standards for the Chesapeake Bay are nitrogen, phosphorus, and sediment. To the extent atmospheric deposition of nitrogen has implications for the health of the Chesapeake Bay, and related impacts on the public welfare, such a consideration may be germane to the secondary NAAQS for oxides of nitrogen or for particulate matter, standards, which are currently being considered in the separate ongoing review of the secondary standards for oxides of nitrogen, oxides of sulfur and PM. Initial plans for that review are described in publicly available planning documents for the review (U.S. EPA, 2017a, 2018b) accessible on the EPA's website (*https://www.epa.gov/naaqs/nitrogen-dioxide-no2-and-sulfur-dioxide-so2-secondary-air-quality-standards*)

(7) *Comment:* In describing their support for the proposal to retain the existing NAAQS, some commenters identify proximity to background of the air quality under the current standard.

[19] See *Mississippi*, 744 F. 3d at 1343 ("[d]etermining what is 'requisite' to protect the 'public health' with an 'adequate' margin of safety may indeed require a contextual assessment of acceptable risk. See *Whitman*, 531 U.S. at 494-95 (Breyer, J. concurring…))."

These commenters cite comments provided to the CASAC by the pool of expert consultants, a news article, and EPA research. In the commenter's view, the expert consultant comments suggest that the EPA's analysis in the PA implies that natural sources can result in a design value above 70 ppb in some areas and claim that meeting the current 70 ppb NAAQS is impossible in some areas through domestic precursor emissions controls alone. The commenter also cites a COVID-related news article to highlight Phoenix background levels and cites research on lightning emissions. The commenter claims that such information implies USB could prevent attainment of the current NAAQS and accordingly of a more stringent one.

Response: We note that the part of the CASAC consultants' comments referring to the ability for some areas to meet the current NAAQS through implementation of domestic precursor emissions controls is not making the statement that the commenter claims. Rather, the CASAC consultant is asking a seemingly rhetorical question implying non-achievability of a 70 ppb NAAQS. A USB value of 80 ppb on a 4^{th} highest day in a single model year (an observation from the EPA's modeling analysis in the PA that the consultant cites and that the commenter emphasizes) does not suggest the standard is not attainable. First, a design value is made of a multi-year average of 4^{th} highs. Second, the prediction with the maximum USB value is an unmonitored site but appears to be high-biased based on surrounding monitors. Third, there are mechanisms within the Clean Air Act to address USB during implementation. See *Murray Energy*, 936 F.3d at 623.

In support of their view regarding contributions from background, the commenter points to excerpts from a news article about Phoenix Arizona during COVID lock down and highlights "transported and natural emissions resulted in NOx levels within the city that were 12.5 percent higher than the previous year." We note that the article includes many references to USB contributions: highlighting California as a transport source, stagnation that would emphasize local sources, and high temperatures that would favor local production. The 12.5% annual difference cited is from a narrow time window (9-days) with no attempt to account for meteorological variability. The article also references a 6% decrease over a slightly longer time period (March 17 to May 4). Further, "Most of the days of the shutdown period prior to the hot weather had below average pollution compared to 2019 and especially compared to a 10-year average." The excerpts referenced from the article, therefore, do not account for factors other than changes in U.S. emissions that impacted O_3 concentrations during 2019 and 2020, and consequently do not provide any direct information on USB levels in Phoenix.

The commenter additionally highlights research showing that lightning NOx is approximately a "30 percent of total NOx … in certain areas." It is worth noting that the area selected for analysis is, by design, a predominantly rural area with very little anthropogenic emissions. Further, the lightning emissions occur above the planetary boundary layer, so it is unclear to what extent they impact surface-level air pollution. Thus, simply highlighting the large fraction of emissions, as the commenter does, does not convey a true representation of their O_3 contribution to concentrations at non-attainment monitors.

The EPA notes that natural, international, and US domestic emission sources contribute to O_3. The commenter provides no evidence that USB (i.e., O_3 concentrations that would exist in the absence of U.S. anthropogenic emissions) would prevent attainment of the proposed standard. The attainability of the O_3 NAAQS depends on the standard averaging time, level, form, and implementation tools. Furthermore, "[a]ttainability and technological feasibility are not relevant considerations in the promulgation of national ambient air quality standards" (*American Petroleum Institute v. Costle*, 665 F.2d 1176, 1185 [D.C. Cir. 1981]; *accord Murray Energy Corp.*, 936 F.3d at 623-24).

(8) *Comment:* One commenter states that the EPA should help states attain existing standards versus, as they described it, rushing, the current NAAQS review. In support of this position, the commenter presented several examples related to implementation programs where they find a need for action.

Response: As described in section I.A of the final action, this action is being taken pursuant to CAA section 109(d)(1) and relevant case law. Under CAA section 109(d)(1) the EPA has the obligation to periodically review the air quality criteria and the existing NAAQS and make such revisions as may be appropriate. Accordingly, the scope of this action is to satisfy that obligation; it is not to address concerns related to implementation of the existing standards. Thus, comments related to the implementation of the existing O_3 standards are outside the scope of this action and require no further response. State and federal O_3 control programs, such as those discussed in section I.D of the final action, may provide an opportunity for such implementation concerns to be addressed.

(9) *Comment:* One commenter suggest that the EPA establish exceptional events for wildfires without individual state petitions. Another comment recommends that the EPA "encourage states" to invoke exceptional event rules which the commenter claims will assure use of appropriate design values for determination of O_3 NAAQS attainment and proper development of attainment programs.

Response: As described in section I.A of the final action, this action is being taken pursuant to CAA section 109(d)(1) and relevant case law. Under CAA section 109(d)(1) the EPA has the obligation to periodically review the air quality criteria and the existing NAAQS and make such revisions as may be appropriate. Accordingly, the scope of this action is to satisfy that obligation; it is not to address concerns related to implementation of the existing standards or the exceptional event provisions. Thus, this comment is outside the scope of this action and requires no further response. State and federal O_3 control programs, such as those discussed in section I.D of the final action, may provide an opportunity for such implementation concerns to be addressed.

(10) Comment: One commenter suggests that in making a decision to retain the current standard, the EPA should give "additional recognition" to the impact of international emissions.

Response: While the EPA agrees that international transport can be a significant factor influencing O_3 concentrations, as described in Chapter 2 and Appendix 2B of the PA, it disagrees that this is a relevant consideration in the Administrator's decision to retain the current NAAQS in this review. With regard to implementation of the NAAQS and consideration of international contributions, we note proposed guidance, available at:

https://www.epa.gov/ground-level-ozone-pollution/international-transport-air-pollution, regarding a “179B demonstration”.

(11) Comment: Some commenters express the view that revision to more restrictive NAAQS would be premature given that some states are still working to implement the 2008 and/or the 2015 NAAQS.

Response: As described in section I.A of the NFA, this action is being taken pursuant to CAA section 109(d)(1) and relevant case law. Under CAA section 109(d)(1) the EPA has the obligation to periodically review the air quality criteria and the existing NAAQS and make such revisions as may be appropriate. Accordingly, the scope of this action is to satisfy that obligation; it is not to address concerns related to implementation of the existing standards or the exceptional event provisions. Thus, this comment is outside the scope of this action and requires no further response. State and federal O_3 control programs, such as those discussed in section I.D of the final action, may provide an opportunity for such implementation concerns to be addressed.

(12) Comment: One commenter raises a concern regarding the approach used by the EPA to characterize and estimate USB, quoting the ISA with regard to differences in results via different approaches. This commenter highlights multiple methodologies to estimate USB.

Response: The EPA recognizes that estimates of USB are uncertain and that there are multiple methodologies of estimation (PA, section 2.5.2.1; Jaffe et al., 2018). The EPA has extensive experience in considering USB, both in summarizing estimates drawn from the current research (Henderson et al., 2012; U.S. EPA, 2014a), and in developing and comparing estimates using alternate methodologies (Dolwick et al., 2015). That experience informed the methodological choices made in this review.

Though methods can give substantially different results, these differences do not indicate that one approach is more appropriate than another. For example, apportionment-based USB may be substantially lower than zero-out USB when a monitor experiences NOx-titration of O_3. If local US-anthropogenic NOx emissions were controlled, however, the USB would be expected to increase, and the O_3 from USB sources would be conceptually more aligned with zero-out methods. Both zero-out and apportionment-based USB are subject to model biases that can be treated with bias correction. When biases are due to local emission sources, proportional bias correction would incorrectly adjust both USA and USB. The source of bias is often unknown, however, so proportional bias correction provides useful constraints where observations are available. When calculating spatially contiguous maps of USB, bias correction requires a technique like extended Voronoi Neighbor Averaging. This type of bias correction can create obviously unrealistic results, and expert analysis and judgment is necessary to identify problematic corrections. The EPA considered the potential differences from methods in the context of the goals and national-scale of the Policy Assessment and decided to use zero-out for this assessment.

We note that the PA analysis of USB, which is part of the characterization of current air quality, does not play a role the Administrator’s decision in this review.

V. References

Bell, ML, Zanobetti, A and Dominici F (2014). Who Is More Affected by Ozone Pollution? A Systematic Review and Meta-Analysis. Am J Epi 180(1): 15–28.

Binkley, D, Campoe, OC, Gspaltl, M and Forrester, DI (2013). Light absorption and use efficiency in forests: Why patterns differ for trees and stands. Forest Ecol Manag 288: 5–13.

Cox, LA (2020). Letter from Louis Anthony Cox, Jr., Chair, Clean Air Scientific Advisory Committee, to Administrator Andrew R. Wheeler. Re:CASAC Review of the EPA's *Policy Assessment for the Review of the Ozone National Ambient Air Quality Standards (External Review Draft – October 2019)*. February 19, 2020. EPA-CASAC-20-003. Office of the Adminstrator, Science Advisory Board Washington, DC Available at: *https://yosemite.epa.gov/sab/sabproduct.nsf/264cb1227d55e02c85257402007446a4/4713D217BC07103485258515006359BA/$File/EPA-CASAC-20-003.pdf*.

Dolwick, P, Akhtar, F, Baker, KR, Possiel, N, Simon, H and Tonnesen, G (2015). Comparison of background ozone estimates over the western United States based on two separate model methodologies. Atmos Environ, 109: 282–296.

Henderson, B, Possiel, N, Akhtar, F and Simon, H (2012). Regional and Seasonal Analysis of North American Background Ozone Estimates from Two Studies. August 15, 2012 Available at: *https://www.epa.gov/naaqs/ozone-o3-standards-other-technical-documents-review-completed-2015*

Jaffe, DA, Cooper, OR, Fiore, AM, Henderson, BH, Tonnesen, GS, Russell, AG, Henze, DK, Langford, AO, Lin, M and Moore, T (2018). Scientific assessment of background ozone over the U.S.: Implications for air quality management. Elem Sci Anth, 6: 56.

Johnson, TR, Langstaff, JE, Graham, S, Fujita, EM and Campbell, DE (2018). A multipollutant evaluation of APEX using microenvironmental ozone, carbon monoxide, and particulate matter (PM2.5) concentrations measured in Los Angeles by the exposure classification project. Cogent Environ Sci 4(1): 1453022.

King, J.S, Kubiske, ME, Pregitzer, KS, Hendrey, GR, McDonald, EP, Giardina, CP, Quinn, VS and Karnosky, DF (2005). Tropospheric O3 compromises net primary production in young stands of trembling aspen, paper birch and sugar maple in response to elevated atmospheric CO2. New Phytologist 168(3): 623–636.

Langstaff, J (2007). Memorandum to Ozone NAAQS Review Docket (EPA-HQ-OAR-2005-0172). Analysis of Uncertainty in Ozone Population Exposure Modeling. Docket ID No. EPA-HQ-OAR-2005-0172-0174.

Pruitt, E (2018). Memorandum from E. Scott Pruitt, Administrator, U.S. EPA to Assistant Administrators. Back-to-Basics Process for Reviewing National Ambient Air Quality Standards. May 9, 2018. Office of the Administrator U.S. EPA HQ, Washington DC.

Available at: https://www.epa.gov/criteria-air-pollutants/back-basics-process-reviewing-national-ambient-air-quality-standards.

Talhelm, AF, Pregitzer, KS, Kubiske, ME, Zak, DR, Campany, CE, Burton, AJ, Dickson, RE, Hendrey, GR, Isebrands, JG, Lewin, KF, Nagy, J and Karnosky, DF (2014). Elevated carbon dioxide and ozone alter productivity and ecosystem carbon content in northern temperate forests. Glob Chang Biol 20(8): 2492–2504.

U.S. EPA (2006). Air Quality Criteria for Ozone and Related Photochemical Oxidants (Volumes I-III). EPA-600/R-05-004aF, EPA-600/R-05-004bF and EPA-600/R-05-004cF. U.S. Environmental Protection Agency. Washington, DC. Available at: *http://www.epa.gov/ttn/naaqs/standards/ozone/s_o3_cr_cd.html*.

U.S. EPA (2010). Quantitative Risk and Exposure Assessment for Carbon Monoxide. (Final Report, Amended). Office of Air Quality Planning and Standards. Research Triangle Park, NC. U.S. EPA. EPA-452/R-10-009. July 2010. Available at: *https://www.epa.gov/sites/production/files/2020-07/documents/co-rea-amended-july2010.pdf*

U.S. EPA (2013). Integrated Science Assessment of Ozone and Related Photochemical Oxidants (Final Report). Office of Research and Development, National Center for Environmental Assessment. Research Triangle Park, NC. U.S. EPA. EPA-600/R-10-076F. February 2013. Available at: *https://nepis.epa.gov/Exe/ZyPURL.cgi?Dockey=P100KETF.txt.*

U.S. EPA (2014a). Health Risk and Exposure Assessment for Ozone. (Final Report). Office of Air Quality Planning and Standards. Research Triangle Park, NC. U.S. EPA. EPA-452/R-14-004a. August 2014. Available at: *https://nepis.epa.gov/Exe/ZyPURL.cgi?Dockey=P100KBUF.txt.*

U.S. EPA (2014b). Policy Assessment for the Review of the Lead National Ambient Air Quality Standards. Office of Air Quality Planning and Standards. Research Triangle Park, NC. U.S. EPA. EPA -452/R-14-001. May 2014. Available at: *https://www3.epa.gov/ttn/naaqs/standards/pb/data/140501_pa_pb_fin.pdf*

U.S. EPA (2015). Preamble To The Integrated Science Assessments (ISA). U.S. Environmental Protection Agency. Washington, DC. EPA/600/R-15/067. November 2015. Available at: *https://cfpub.epa.gov/ncea/isa/recordisplay.cfm?deid=310244*

U.S. EPA. (2017a). Integrated Review Plan for the Secondary National Ambient Air Quality Standards for Ecological Effects of Oxides of Nitrogen, Oxides of Sulfur and Particulate Matter. U.S. Environmental Protection Agency. Washington, DC. EPA-452/R-17-002. January 2017. Available at: *https://www3.epa.gov/ttn/naaqs/standards/no2so2sec/data/irp-nox-sox-pm-eco.pdf*

U.S. EPA (2017b). Policy Assessment for the Review of the Primary National Ambient Air Quality Standards for Oxides of Nitrogen. Office of Air Quality Planning and Standards. Research Triangle Park, NC. U.S. EPA. EPA-452/P-16-001. September 2016. Available at: *https://www3.epa.gov/ttn/naaqs/standards/nox/data/20160927-no2-pa-external-review-draft.pdf*

U.S. EPA (2018a). Policy Assessment for the Review of the Primary National Ambient Air Quality Standard for Sulfur Oxides. Office of Air Quality Planning and Standards. Research Triangle Park, NC. U.S. EPA. EPA-452/R-18-002. May 2018. Available at: *https://www.epa.gov/sites/production/files/2018-05/documents/primary_so2_naaqs_-_final_pa_-_may_2018.pdf*

U.S. EPA (2018b). Review of the Secondary Standards for Ecological Effects of Oxides of Nitrogen, Oxides of Sulfur, and Particulate Matter: Risk and Exposure Assessment Planning Document. Office of Air Quality Planning and Standards. Research Triangle Park, NC. U.S. EPA. EPA-452/D-18-001. August 2018. Available at: *https://www.epa.gov/sites/production/files/2018-08/documents/rea_plan_final_080618.pdf*

U.S. EPA (2019a). Integrated Review Plan for the Ozone National Ambient Air Quality Standards. Office of Air Quality Planning and Standards. Research Triangle Park, NC. U.S. EPA. EPA-452/R-19-002. Available at: *https://www.epa.gov/sites/production/files/2019-08/documents/o3-irp-aug27-2019_final.pdf.*

U.S. EPA (2019b). Policy Assessment for the Review of the Ozone National Ambient Air Quality Standards, External Review Draft. Office of Air Quality Planning and Standards. Research Triangle Park, NC. US Environmental Protection Agency. EPA-452/P-19-002. October 2019. Available at: *https://www.epa.gov/sites/production/files/2019-10/documents/o3-draft_pa-oct31-2019-erd.pdf*

U.S. EPA (2020a). Integrated Science Assessment for Ozone and Related Photochemical Oxidants. U.S. Environmental Protection Agency. Washington, DC. Office of Research and Development. EPA/600/R-20/012. Available at: *https://www.epa.gov/isa/integrated-science-assessment-isa-ozone-and-related-photochemical-oxidants*.

U.S. EPA (2020b). Policy Assessment for the Review of the Ozone National Ambient Air Quality Standards. U.S. Environmental Protection Agency, Office of Air Quality Planning and Standards, Heath and Environmental Impacts Division. Research Triangle Park, NC. U.S. EPA. EPA-452/R-20-001. 2020 Available at: *https://www.epa.gov/naaqs/ozone-o3-standards-policy-assessments-current-review.*

Wittig, VE, Ainsworth, EA, Naidu, SL, Karnosky, DF and Long, SP (2009). Quantifying the impact of current and future tropospheric ozone on tree biomass, growth, physiology and biochemistry: a quantitative meta-analysis*.* Glob Chang Biol 15(2): 396–424.

WHO (2008). Uncertainty and Data Quality in Exposure Assessment. The International Programme on Chemical Safety. Geneva. WHO. *https://www.who.int/ipcs/publications/methods/harmonization/exposure_assessment.pdf.*

Zahran, HS and Bailey, C (2013). Factors Associated with Asthma Prevalence among Racial and Ethnic Groups—United States, 2009–2010 Behavioral Risk Factor Surveillance System. J Asthma, 50(6): 583–589.

Appendix A. List of Abbreviations and Acronyms

The following acronyms have been used for the sake of brevity in this document:

APEX	Air Pollution Exposure model
AQCD	Air Quality Criteria Document
CAA	Clean Air Act
CASAC	Clean Air Scientific Advisory Committee
CHAD	Consolidated Human Activity Database
CO	Carbon Monoxide
EPA	Environmental Protection Agency
E-R	Exposure-response
FEV_1	Forced Expiratory Volume for 1 second
MSS	McDonnell-Stewart-Smith
NAAQS	National ambient air quality standards
NO_2	Nitrogen dioxide
NO_X	Nitrogen oxides
O_3	Ozone
PA	Policy Assessment
ppm	Parts per million
ppm-hrs	Parts per million-hours
ppb	Parts per billion
RBL	Relative biomass loss
SO_2	Sulfur dioxide
USB	United States background
VOCs	Volatile organic compounds
W126	Cumulative integrated exposure index with a sigmoidal weighting function

Appendix B. Details of Analyses in support of Section III.B(1)

This appendix contains additional details of the response to two points raised by a comment received on the proposal that are addressed in section III.B(1) of this document. The comment concerned the example analysis described in the PA, Appendix 4A, section 4A.3.2. As described there, this analysis estimates aboveground biomass for two patterns of 6-year O_3 exposure of aspen: one in which the seasonal W126 index for each year equals 17 ppm-hrs, and one in which the seasonal W126 index for each year varies (e.g., 10, 17, and 24 ppm-hrs), but the average of each three consecutive years equals 17 ppm-hrs.

As described in the PA (PA, p. 4A-22), in this analysis, the growth rate information (derived from King et al., 2005) was applied over six years of growth (using the yearly growth increment, g/m^2/year, for the stand). The above ground biomass of the aspen stand in each year was compared across the exposure scenarios (Figure 4A-15; Table 4A-7). The difference between the scenarios in total above ground biomass for the stand varied from year to year. After the first year, this difference in the year's total above ground biomass (not to be confused with annual growth in biomass, to which RBL is applied) was less than 2%.

In consideration of the two points raised by the commenter (summarized and addressed in section III.B(1) above), variations on the PA calculations were examined, as presented here.

- The first of the two criticisms concerns application of the RBL (for each W126) to an annual growth increment derived from the "control" trees (represented in the analysis by the trees in King et al. (2005) exposed to unadjusted ambient air). The commenter states that use of this growth rate assumes the effect of O_3 in one year to have no effect on tree growth in a subsequent one, and ignores that smaller trees (presumably including an O_3 exposed tree compared to a control) grow less than larger trees (citing Binkley et al., 2013).
- The second criticism of the analysis was the EPA's use of aspen, for which the E-R relationship is, like the E-R relationships for most of the other 11 species for which functions are established (PA, Appendix 4A, Figure 4A-1), relatively linear.

Consideration of first point: The commenter did not provide a growth function for aspen; nor did the study cited by the commenter. Therefore, to assess the impact of the first point on the comparison of the two multiyear W126 index patterns, we derived a growth model for aspen based on the annual measurements for that species available in the Aspen FACE data collected in the study by King et al. (2005).[20] The model is a function of the form, current year growth increment as a function of the prior year absolute biomass. A linear model was used to represent aspen species ($r^2 = 0.4137$):

W126 scenario annual growth = 0.2395 * Previous Year Biomass + 215.05

[20] Individual tree growth measurements from Aspen FACE (1997-2008) research, including King et al. (2005), received from researchers (Ozone NAAQS Docket, EPA-HQ-OAR-2018-0279).

This function was substituted into the analysis from the PA, Appendix 4A, section 4A.3.2. for the annual growth increment that previously had been drawn from the control scenario biomass measurements. Based on the recalculations resulting from this substitution, we have created an alternate version of Table 4A-7 from the PA, Appendix 4A. This is presented in Table 1 below. Figure 1 is an alternate version of Figure 4A-15 of Appendix 4A in the PA, that presents the comparisons of biomass for the differing W126 scenarios (3-year vs 1-year variables) based on the information in Table 1.

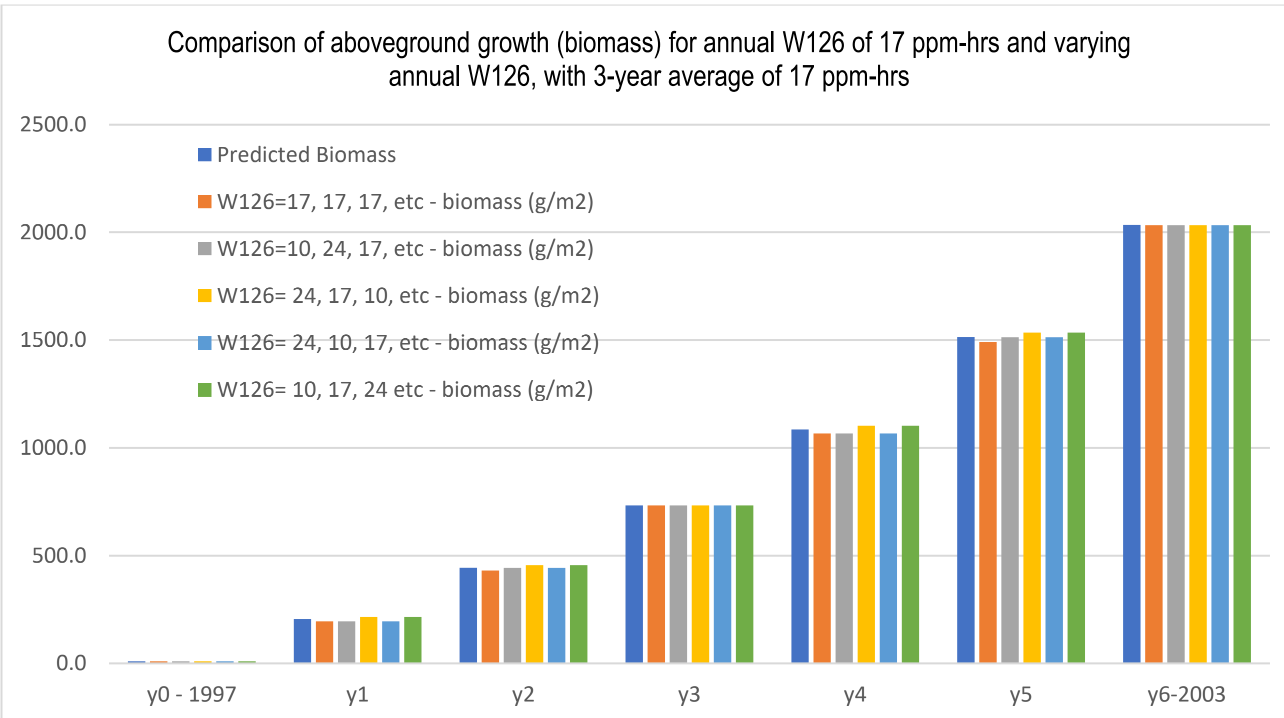

Figure 1. Estimated aboveground biomass of aspen with different patterns of annual seasonal W126 index using annual growth as a function of prior year absolute biomass for trees in the same scenario.

Table 1. Comparison of total aspen above ground biomass estimated for different patterns of varying annual exposures and constant exposure equal to 3-year average (17 ppm-hrs) using annual growth as a function of prior year absolute biomass for trees in the same scenario.

Year	Predicted Biomass*	Growth - % increase	W126=17, biomass (g/m2)	W126=10, 24, 17, etc - biomass (g/m2)	W126= 24, 17, 10, etc - biomass (g/m2)	W126= 24, 10, 17, etc - biomass (g/m2)	W126= 10, 17, 24 etc - biomass (g/m2)	W126 10-17-24 vs 17	W126 10-24-17 vs 17	W126 24-17-10 vs 17	W126 24-10-17 vs 17
y0 - 1997	9.1		9.1	9.1	9.1	9.1	9.1				
y1	226.3	2387.14%	205.0	215.0	194.8	194.8	215.0	4.9%	4.9%	-5.0%	-5.0%
y2	495.6	118.97%	443.3	442.9	430.9	442.9	455.5	2.7%	-0.1%	-2.8%	-0.1%
y3	829.3	67.34%	733.1	732.6	732.6	732.6	732.6	-0.1%	-0.1%	-0.1%	-0.1%
y4	1243.0	49.88%	1085.4	1102.8	1066.5	1066.5	1102.8	1.6%	1.6%	-1.7%	-1.7%
y5	1755.8	41.25%	1513.8	1512.5	1490.8	1512.5	1535.0	1.4%	-0.1%	-1.5%	-0.1%
y6-2003	2391.3	36.20%	2034.8	2033.2	2033.2	2033.2	2033.2	-0.1%	-0.1%	-0.1%	-0.1%

* The value in the first row of this and other columns is the total absolute biomass measurement from King et al., 2005, Table 3 (foliage plus wood). The subsequent rows of the first column utilize the function (above) to derive current year biomass as function of prior year biomass. In the other columns, the annual increment derived with the function is reduced by predicted RBL for the applicable W126 index value. The W126-RBL E-R function used is $1 - \exp[-W126/109.81)^{1.2198}]$.

Consideration of second point: With regard to an E-R function for O_3 RBL with a quite different shape than that for aspen, we note the functions for two species: the sugar maple (raised by the commenter) and the black cherry.[21] As can be seen in Figure 4A-1 from Appendix 4A of the PA (PA, Appendix 4A, section 4A.1.1) presented below, the sugar maple has a function with a slope that changes appreciable at W126 index values above 20-25 ppm-hrs, with increasingly greater O_3 impact on growth with the W126 index value above that.

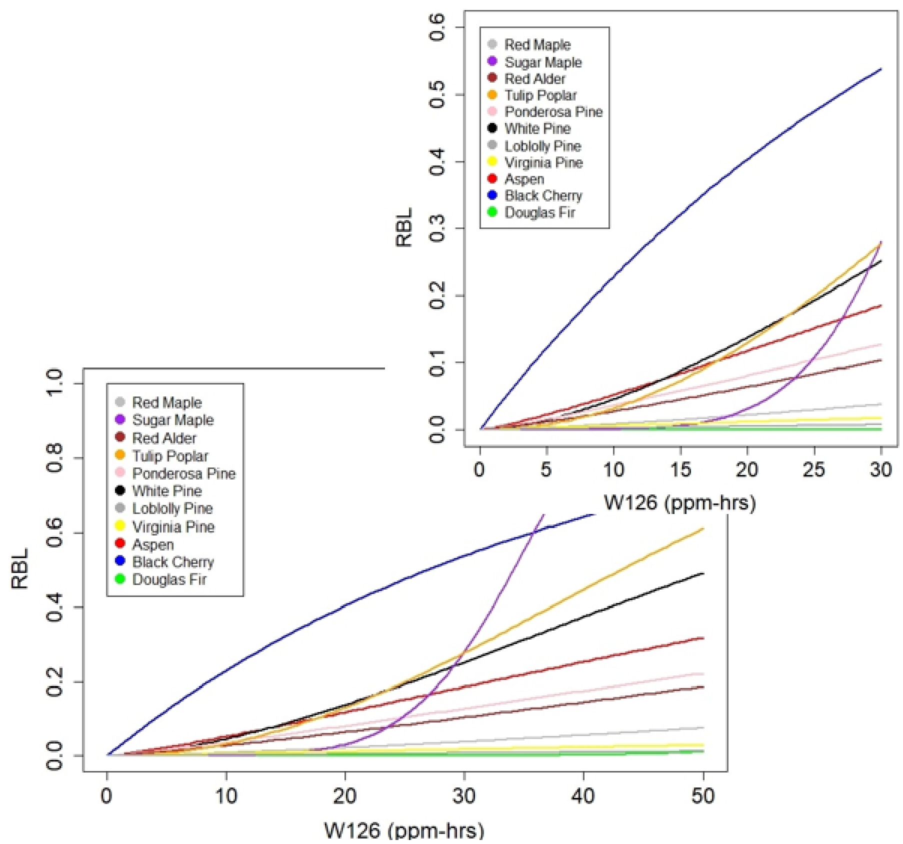

Figure 4A-1. RBL functions for seedlings of 11 tree species.

As discussed in the PA, such W126 index levels are rare in locations that meet the current standard. As can be seen in Figure 4D-8 from Appendix 4D of the PA (PA, Appendix 4A, section 4D.3.2.1), The air quality analyses in the PA show that across the period from 2000 through 2018 for even just the subset of sites meeting the current standard but with design value closest to 70 ppb (66-70), the 99th percentile is below 20 ppm-hrs (PA, Appendix 4D, Figure 4D-8).[22] Focusing just on Class I areas, there are no more than 15 occurrences of a single-year W126 index value above 19 ppm-hrs in the entire time period (200-2018), and all of those occurrences date prior to 2013 (FR 85 49904, August 14, 2020). At W126 index levels below 20, the sugar

[21] The tenth, black cherry, has a slope for the E-R function that presents the opposite pattern to that of red maple (the slope of the curve slowly declines with increasing W126 index).
[22] The established geographical range of sugar maple is predominantly in the Northeast and Upper Midwest (PA, Appendix 4B, Table 4B-3), areas for which W126 index values are among the relatively lower magnitudes occurring across the U.S. (PA, Appendix 4D, Figure 4D-2).

maple slope is relatively linear and much lower than that for the aspen that was the subject of the PA Appendix 4A example analysis.

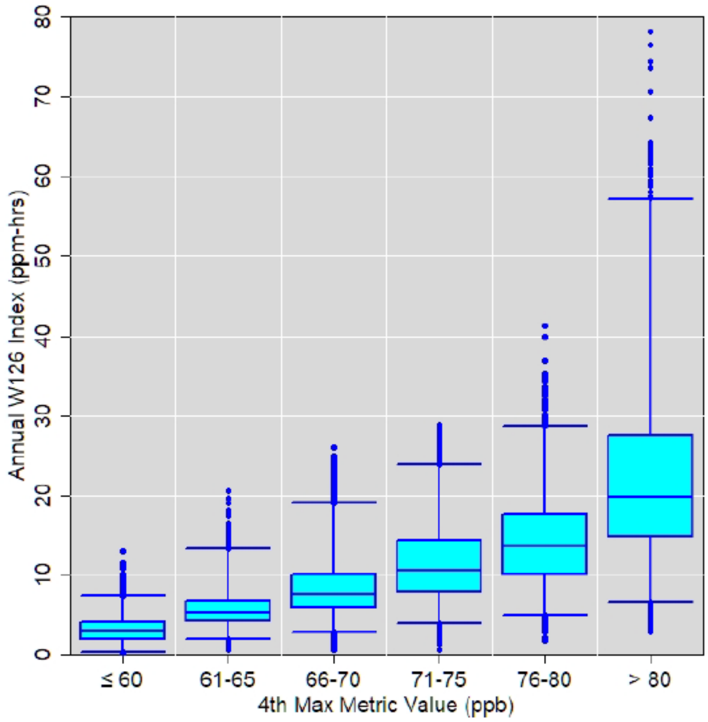

Figure 4D-8. Annual W126 index values in ppm-hrs binned by 4th max metric values based on monitoring data for years 2000-2018. Boxes show 25th, 50th, and 75th percentiles, whiskers extend to the 1st and 99th percentiles, and points below the 1st percentile or above the 99th percentile are represented by dots.

Several Summary Points: Given the limited availability of controlled tree exposure data for individual years/seasons in a multi-year exposure, as well as the simply conceptual or illustrative nature of the analysis, there are assumptions, limitations and uncertainties inherent in the analysis. A few key points are noted here.

- The linear growth function derived for aspen for this example may or may not be the correct model over the life of a tree of this species, but the impact of this uncertainty on this analysis is unclear. The original analysis (in PA) that did not estimate annual growth increment as a function of prior year biomass may have underestimated the effect of the O_3 exposure scenario relative to the control scenario over time, but the amount of underestimate in this example for aspen is not highly affected by the difference in using a 3-year average versus a variable 1-year W126.
- The E-R function for aspen and its derivation is described in the PA, Appendix 4A, section 4A.1. The experimental data from which it was derived were collected from studies of aspen seedlings. Thus, there is some uncertainty in its application in an example describing aspen growth over six years.

- Variables other than O_3 that can affect growth in a given year (e.g., precipitation, temperature, community competition) are not represented in the current analysis other than the extent to which they affect the baseline growth rate provided by the "control" from the aspen study by King et al. (2005).
- This example analysis includes a W126 index value of 24 ppm-hrs every third year. Yet, the frequency of such a value is quite rare, as can be seen from the air quality analyses in the PA, which show that across the period from 2000 through 2018 for even just the subset of sites meeting the current standard but with design value closest to 70 ppb (66-70 ppb), the 99^{th} percentile is below 20 ppm-hrs (PA, Appendix 4D, Figure 4D-8). Focusing just on Class I areas for the full period from 2000 to 2018, there are no more than 15 occurrences of a single-year W126 index value above 19 ppm-hrs, all of which date prior to 2013 (FR 85 49904, August 14, 2020). Thus, this example includes as one of the three years, a magnitude of W126 index that has been quite rarely observed in areas that meet the current standard since 2000.

References

Binkley, D., Campoe, O. C., Gspaltl, M., & Forrester, D. I. 2013. Light absorption and use efficiency in forests: Why patterns differ for trees and stands. Forest Ecology and Management, 288, 5-13.

King, JS, Kubiske, ME, Pregitzer, KS, Hendrey, GR, McDonald, EP, Giardina, CP, Quinn, VS and Karnosky, DF (2005). Tropospheric O3 compromises net primary production in young stands of trembling aspen, paper birch and sugar maple in response to elevated atmospheric CO2. New Phytol 168(3): 623-635.

Talhelm, A. F., Pregitzer, K. S., Kubiske, M. E., Zak, D. R., Campany, C. E., Burton, A. J., ... & Nagy, J. (2014). Elevated carbon dioxide and ozone alter productivity and ecosystem carbon content in northern temperate forests. Global Change Biology, 20(8), 2492-2504.

U.S. EPA (2020). Policy Assessment for the Review of National Ambient Air Quality Standards for Ozone. Office of Air Quality Planning and Standards, Health and Environmental Impacts Divison. Research Triangle Park, NC. U.S. EPA. EPA-452/R-20-001. May 2020.