Responses to Significant Comments on the 2020 Proposed Rule on the National Ambient Air Quality Standards for Particulate Matter (April 30, 2020; 85 FR 24094)

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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)

> Integrated Science Assessment for Particulate Matter: Final Report. Center for Public Health and Environmental Assessment-RTP Division, Office of Research and Development, Research Triangle Park, NC. EPA/600/R-19/188. December 2019. Available: *https://cfpub.epa.gov/ncea/isa/recordisplay.cfm?deid=347534*.

Policy Assessment (PA)

> Policy Assessment for the Review of the Particulate Matter National Ambient Air Quality Standards. Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Research Triangle Park, NC. EPA 452/R-20-002. January 2020. Available: *https://www.epa.gov/naaqs/particulate-matter-pm-standards-policy-assessments-current-review-0*.

Proposed Rule (Proposal or Proposed Action)

> National Ambient Air Quality Standards for Particulate Matter: Proposed Rule. 85 FR 24094, April 30, 2020.

Preamble to the Final Rule (Final Action)

> Preamble to the Final Rule on the Review of the National Ambient Air Quality Standards for Particulate Matter; To be published in the *Federal Register*.

Responses to Significant Comments on the Proposed Rule on the National Ambient Air Quality Standards for Particulate Matter

1. Introduction

This Response to Comments (RTC) document, together with the preamble to the final rule (or final action)[1]on the review of the national ambient air quality standards (NAAQS) for particulate matter (PM), presents the responses of the Environmental Protection Agency (EPA) to significant public comments received on the 2020 PM NAAQS proposal notice (85 FR 24094, April 30, 2020). This document also includes the EPA's provisional consideration of "new" studies submitted during the public comment period (i.e., those studies considered to be within the scope, but published after the literature cutoff date for the Integrated Science Assessment (ISA; U.S. EPA, 2019), and as such, not considered as part of the EPA and CASAC review of the air quality criteria) (see Appendix A). The responses presented in this document are intended to augment the responses to comments that appear in the preamble to the final rule and to address comments not discussed in that preamble. Although portions of the preamble to the final rule are paraphrased in this RTC document, the preamble itself remains the definitive statement of the rationale for retaining, without revision, the current PM NAAQS.

Accordingly, this RTC, together with the preamble to the final rule and the information contained in the ISA, the PA, and the Notice of Proposed Rulemaking, should be considered collectively as the EPA's response to all of the significant comments submitted on the EPA's 2020 PM NAAQS proposed rule. This document incorporates directly or by reference the significant public comments addressed in the preamble to the PM NAAQS final rule as well as other significant public comments that were submitted on the proposed rule.

Due to the large number of comments received overall, and the number of comments that addressed similar issues, this RTC does not generally cross-reference responses to a particular commenter or commenters. However, commenters are identified in some cases where they provided particularly detailed comments that were used by the EPA to frame the overall response on an issue.

Consistent with the decisions presented in the preamble to the final rule, comments on the primary standards for $PM_{2.5}$ and for PM_{10} are addressed separately in this document in sections II and III, respectively. Comments on secondary standards for fine and coarse particles are addressed below in section IV. Comments on other topics, including legal, administrative, procedural, or miscellaneous comments, are addressed in section V.

II. Responses to Comments on the Proposed Decision to Retain the Primary $PM_{2.5}$ NAAQS

We received a large number of comments on the proposed decision to retain the current primary $PM_{2.5}$ standards. Most comments simply expressed the commenters' views without stating any rationale or provided general reasons for their views without reference to the factual

[1] Consistent with CAA section 307(d)(2), we at times refer to the final "action" as a "rule" in the preamble to the final action and in this RTC document.

evidence or the rationale presented in the proposal notice as a basis for the Agency's proposed decision. Other comments were more detailed, often referencing particular aspects of the proposed decision, the evidence and analyses evaluated by the EPA in reaching its proposed decision, or additional scientific information identified by the commenter. Below, the EPA provides detailed responses to the full range of significant issues raised in these comments.

A. Comments Related to the Current Primary $PM_{2.5}$ Standards

Numerous commenters support the proposed decision to retain the current primary $PM_{2.5}$ standards. These commenters, primarily those from industries and industry groups and state and local governments and organizations, generally agree with the Administrator's consideration of and conclusions about the scientific evidence available in this review. These commenters generally support the Administrator's proposed decision and supporting rationale including uncertainties related to exposure measurement error and confounding in epidemiological evidence, including cohort studies and accountability studies, in addition to expressing uncertainty in risk assessment estimates due to limitations in the underlying epidemiological evidence. The commenters also note their agreement with the proposed rationale related to experimental studies, noting that these studies are conducted at levels greater than the current standard and calling into question whether potential public health improvements may occur by revising the standard. While the EPA agrees with some points made in these comments, the EPA does not agree with each specific point raised. The Administrator's final decision and supporting rationale are outlined in section II.B.4 of the final action.

On the other hand, a number of commenters, primarily those from national public health, medical, and environmental nongovernmental organizations, tribes and tribal groups, state and local governments and organizations, former CASAC members, and individuals disagree with the EPA's proposed decision to retain the current primary $PM_{2.5}$ standards. These commenters submitted detailed comments on the appropriate level of the primary $PM_{2.5}$ standard, asserting that the current annual and 24-hour $PM_{2.5}$ level should be revised to provide additional public health protection for the general public as well as at-risk groups. These commenters contend that more protective standards are needed to protect public health with an adequate margin of safety. They disagree with the Administrator's conclusions and judgments about the uncertainties in the health effects evidence at ambient $PM_{2.5}$ concentrations below the current standards and suggest that potential public health improvements could be achieved by reducing ambient $PM_{2.5}$ concentrations to levels below the current standards. These comments are addressed below and in section II.B.3 of the final action.

(1) ***Comment:*** A number of commenters contend that the Administrator disregarded epidemiological evidence, and expressed that in previous reviews, the EPA has long relied on epidemiological evidence when determining requisite evidence for $PM_{2.5}$ NAAQS levels. The commenters further contend that the Administrator has rejected the approaches of considering epidemiological evidence relied upon in previous reviews, including the approach to assessing mean concentrations in epidemiological studies. They assert that the body of epidemiological evidence, which includes studies that analyzed various locations and that applied different study designs and statistical approaches, provide clear evidence that the current $PM_{2.5}$ standards are not adequate to protect public health. More specifically, the commenters claim that the EPA did not appropriately

consider issues related to: 1) confounding, (2) exposure measurement error, and (3) the conclusions from the ISA related to a linear, no-threshold concentration-response (C-R) relationship. With respect to confounding, commenters disagree with the suggestion that associations seen consistently in key epidemiological studies could be explained by unmeasured confounding. With respect to exposure measurement error, the commenters cite various studies that explored the impact of exposure measurement error in the reported $PM_{2.5}$-health effects associations and C-R functions, and present several studies that correct for exposure measurement error and exhibit robust $PM_{2.5}$-health effect associations. With respect to a linear, no-threshold C-R relationship, commenters cite studies using various statistical approaches that demonstrate a linear PM-health effect relationship and no evidence of a threshold. They further note that there are studies that indicate that $PM_{2.5}$-mortality associations may be stronger (i.e. steeper slopes) at lower concentrations. Lastly, the commenters also specifically cite epidemiological studies that exhibit positive and significant $PM_{2.5}$-health effect associations in populations living in areas of $PM_{2.5}$ concentrations below the current standards (i.e., analyses that restrict data to concentrations below the standard) and contend that these studies provide further evidence of effects below the level of the standard.

Response: The EPA disagrees with commenters who contend that the EPA has ignored epidemiological evidence. As detailed in section II.A.2 of the final rule, as well as in comments on the proposed decision in the final rule (II.B.3), epidemiological evidence is one piece of evidence used in the ISA's weight of evidence evaluation. Epidemiological studies continue to play a crucial role in supporting and strengthening the body of scientific evidence on PM-related health effects in this review, as in previous reviews, and given that the current PM evidence considered in the final ISA includes hundreds of epidemiological studies, it is clear that epidemiological studies have not been ignored.

The EPA also disagrees with commenters who state that the EPA did not appropriately consider the conclusions from the ISA related to the shape of the concentration-response relationship, including both evidence of a linear, no threshold concentration-response relationship and some studies indicating that the C-R function may actually be steeper at lower levels. First, the EPA has long recognized that the evidence does not identify a threshold for PM-related health effects. Consistent with the last review, while the EPA recognizes that there likely are individual biologic thresholds for specific health responses, the current ISA concluded the overall evidence from existing epidemiological studies does not support the existence of thresholds at the population level, for effects associated with either long- or short-term PM exposures within the ranges of air quality observed in these studies (U.S. EPA, 2019, section 1.5.3). However, as noted in the preamble to the proposed rule, the CAA does not require the Administrator to establish a primary NAAQS at a zero-risk level, see Lead Industries Ass'n v. EPA, 647 F.2d at 1156 n.51, Mississippi v. EPA, 744 F.3d at 1351, but rather at a level that reduces risk sufficiently so as to protect public health with an adequate margin of safety. Moreover, while some studies indicate steeper slopes at lower concentrations, interpreting the shapes of these relationships, particularly at $PM_{2.5}$ concentrations near the lower end of the air quality distribution, can be complicated by relatively low data density in the lower concentration range, the possible influence of exposure measurement error, and

variability among individuals with respect to air pollution (U.S. EPA, 2020, p.3-21). Therefore, the EPA considers it premature to conclude that these studies conclusively demonstrate higher incremental public health effects at lower levels.

Further, the EPA disagrees with the commenters and contends that the Administrator did appropriately consider the strengths and limitations of the epidemiologic evidence when making the proposed decision to retain the current primary $PM_{2.5}$ standards. In making his proposed decision, the Administrator considered the entire body of evidence before the Agency, and considered how to weigh the strengths and limitations of the epidemiological evidence, particularly when considering the strengths and limitations of any supporting information provided by experimental studies. This approach is consistent with setting standards that are neither more nor less stringent than necessary, recognizing that a zero-risk standard is not required by the CAA.

As further detailed in section II.B.4 in the final action and as noted above, the Administrator, in addition to weighing the evidence and taking into consideration the views expressed by CASAC members and public comments, recognizes that epidemiological studies examine associations between distributions of $PM_{2.5}$ air quality and health outcomes, and they do not identify particular $PM_{2.5}$ exposures that cause effects (U.S. EPA, 2020, section 3.1.2). As such, identifying a specific level at which the standard should be set necessarily requires the Administrator's judgement (e.g., weighing the uncertainties and margin of safety). Thus, as further detailed in the final action (section II.B.4), in light of comments received, the Administrator considers the epidemiological evidence in a similar manner as previous reviews. He assesses the mean concentrations of the key short-term and long-term epidemiological studies in the U.S. that use ground-based monitoring (i.e., those studies that can provide information most directly comparable to the current annual standard), and notes that the majority of those studies (i.e., 19 out of 21) have mean concentrations at or above the level of the current annual standard (12.0 $\mu g/m^3$), with the mean of the study reported means or medians equal to 13.5 $\mu g/m^3$, a concentration level above the current level of the primary annual standard of 12 $\mu g/m^3$. However, the Administrator notes that not only must these epidemiological studies be viewed in light of their limitations, he also notes that air quality analyses indicate that study means tend to be lower than their corresponding "design values" by 10-20% and the overall mean of these study reported means (or medians) remains above the annual standard level. Therefore, when taken together, even if the Administrator were to place greater weight on the epidemiological evidence, this information would not call into question the adequacy of the current standards.

(2) ***Comment:*** Some commenters contend that the EPA has ignored multiple studies that have used causal modeling methods to examine the effect of $PM_{2.5}$ on mortality, including studies using difference-in-difference designs, propensity scores, and instrumental variables. The commenters contend that when these types of studies are combined with the toxicologic evidence described in the ISA, the evidence for causality of mortality associations is overwhelming. Furthermore, commenters have identified numerous studies that employ causal modeling methodologies that were not included in the ISA ("new studies").

Response: The EPA agrees with commenters that the body of evidence as a whole, as noted in the ISA (U.S. EPA, 2019, section 11.1 and 11.2), is sufficient to support a conclusion that a causal relationship exists between long-term and short-term $PM_{2.5}$ exposure and total mortality. However, the EPA disagrees with commenters who contend that the EPA has ignored multiple studies that have employed causal modeling methods. Such studies, including those that employ causal-inference and/or quasi-experimental statistical approaches, are explicitly discussed in the PA (U.S. EPA, 2020, p. 3-21). However, the EPA recognizes that causal modeling methods to evaluate the causal nature of PM-health effects relationships are an emerging field of study (U.S. EPA, 2020, p. 3-21). Therefore, the PA identifies causal modeling methods to evaluate the causal nature of relationships between long-term and short-term $PM_{2.5}$ exposure and mortality or morbidity as an area for additional research, based on uncertainties and limitations that remain in the evidence (U.S. EPA, 2020, section 3.6).

In considering the "new" studies cited by commenters, the EPA has provisionally considered these studies in the context of the findings of the ISA (See Appendix A below). As detailed in section I.D of the final action, these studies are generally consistent with the evidence assessed in the ISA, and they do not materially alter our understanding of the scientific evidence or the Agency's conclusions based on that evidence or warrant reopening of the air quality criteria.

(3) ***Comment***: For experimental studies, the commenters criticize the Administrator's proposed conclusions that epidemiological evidence at levels below the standard without supporting evidence from experimental studies at similar concentrations do not support revising the standards. The commenters contend that the EPA arbitrarily preferred animal toxicologic and controlled human exposures studies over epidemiological evidence in the Administrator's proposed decision to retain the primary $PM_{2.5}$ standards. Specifically, they emphasize that although experimental studies are typically conducted at higher than ambient $PM_{2.5}$ concentrations, such studies support the biological plausibility related to numerous health effects associated with $PM_{2.5}$ exposure, including cardiovascular and respiratory effects. They contend that it is unreasonable for the EPA to tie the concept of biological plausibility to a specific concentration. The commenters specifically highlight controlled human exposure studies with high sub-daily exposures (2 hours at 24 to 300 $\mu g/m^3$ $PM_{2.5}$) which exhibit subclinical effects that are equivalent to 24-hour exposure concentrations that are policy relevant (Hemmingsen et al., 2015b; Devlin et al., 2003; Gong et al., 2004; Tong et al., 2015). The commenters also note short-term and long-term exposures in animals provide coherent evidence of cardiovascular effects across scientific disciplines. Thus, the commenters assert that epidemiological evidence is supported by findings from well-designed experimental studies in animals and humans. Additionally, the commenters state that since there are various other ethical or practical concerns, such as conducting experimental studies among susceptible/at-risk populations, the inability to acquire large sample sizes in controlled human exposure studies, and the inability to perform long-term studies in an atmosphere-controlled lab for years, that it would be unreasonable for the EPA to expect supporting experimental evidence at $PM_{2.5}$ concentrations typical of areas meeting the current annual and 24-hour standards. They

contend that this was imposing burden of proof or evidence far beyond what is required by statute.

***Response*:** As a general note, the EPA disagrees with commenters who contend that epidemiological and experimental evidence below the standard are necessary to support decisions regarding whether to retain or revise the NAAQS. Furthermore, we also disagree with the commenters that animal toxicologic and controlled human exposure studies were given more weight than epidemiological studies in the Administrator's proposed decision. As noted in section II.B.4 of the final action, the Administrator's final decision in this review is a public health policy judgment drawing upon scientific and technical information examining the health effects of $PM_{2.5}$ exposures, including how to consider the range and magnitude of uncertainties inherent in that information. This public health policy judgment is based on an interpretation of the scientific and technical information that neither overstates nor understates its strengths and limitations, nor the appropriate inferences to be drawn, and is informed by the Administrator's consideration of advice from the CASAC and public comments received on the proposal notice. In agreement with the commenters, and as detailed in the final action, the EPA believes that animal toxicologic studies are important in providing evidence of biological plausibility of effects associated with $PM_{2.5}$ exposure. However, these studies have limited utility in directly informing conclusions on the appropriate level of the standard given the uncertainty in extrapolating from effects in animals to those in human populations. Moreover, the EPA notes that controlled human exposure studies are useful in considering the adequacy of the 24-hour standard and determining whether additional protection is needed to protect against peak $PM_{2.5}$ concentrations. Based on air quality analyses outlined in the PA (U.S. EPA, 2020, section 2.3.2.2.3) and detailed in the Administrator's conclusions in the final action (section II.B.4), exposure concentrations in controlled human exposure studies are well-above the ambient concentrations typically measured in locations meeting the current standards. While the Administrator acknowledges that controlled human exposure studies provide evidence for health effects following single, short-term $PM_{2.5}$ exposures near the peak concentrations measured in the ambient air, he notes that most of these studies examine exposure concentrations considerably higher than are typically measured in areas meeting the current standards. Additionally, while assessing plausible biological pathways is an important step in evaluating causality determinations, the degree of biological plausibility for different mechanisms and end points can also vary depending on the evidence available. As a result, the Administrator noted in the proposal that he was "cautious about placing too much weight on reported $PM_{2.5}$ health effect associations" observed in epidemiological studies, without further supporting experimental evidence. As discussed in the proposal, the Administrator's proposed decision was based on his evaluation of "the overall body of evidence, including controlled human exposure and animal toxicologic studies, in addition to epidemiological studies". Thus, the experimental evidence does not suggest that the epidemiological evidence must be viewed differently than the Administrator has done in his proposed decision to retain the current primary standards.

B. Responses to Other Comments

1. $PM_{2.5}$-Related Health Effects Evidence in the ISA

(1) ***Comment:*** A number of commenters, primarily those who support the EPA's proposed decision to retain the current standards, assert that the ISA's framework for reviewing the evidence and making causality determinations lacks specificity and detail, including a discussion on limitations of epidemiological evidence as well as the approach used to interpret evidence. Many of these commenters additionally state that a systematic approach to reviewing the evidence must be unbiased and transparent. Moreover, they criticize the EPA's process of evaluating and interpreting studies. They contend that the ISA should have included detailed explanations of the protocol used to review the literature, the approach used to evaluate study quality, the study inclusion and exclusion criteria (e.g., in vitro studies, literature included in previous assessments), the methods and quality control approaches used to extract data, and the processes used to evaluate that data. These commenters assert that the approach used by the EPA within the ISA lacks several critical features of modern systemic review practices, which is needed to improve transparency in the ISA, and its reliability in the decision-making process.

Response: The EPA disagrees with the commenters regarding the approach used to assess the scientific evidence in the ISA. Since the inception of the ISAs in 2008, the EPA has relied on a weight-of-evidence approach to assessing the causal nature of relationships between exposure to criteria pollutants and health and welfare effects, which is similar to frameworks used by numerous scientific organizations (e.g., Institute of Medicine, Centers for Disease Control and Prevention, International Agency for Research on Cancer). Over time this framework has evolved through substantive interactions with the CASAC, as well as ad hoc panels developed to support the chartered CASAC members, during numerous public meetings. Ultimately, the advice of the CASAC and the public contributed to the EPA publishing a separate document, titled Preamble to the ISA (U.S. EPA, 2015) (hereafter "Preamble"), with the sole purpose of clearly articulating each phase of the ISA development process to ensure transparency. The process for developing ISAs was summarized in the Preface and the Executive Summary of the ISA, referring readers to the Preamble for greater detail.

In addition, in the final ISA, the EPA added an Appendix that provided detailed steps on the development of the PM ISA to address comments on the draft ISA from the CASAC and the public (U.S. EPA, 2019). This Appendix provides more detailed information that the commenters contend is lacking from the ISA. Specifically, the Appendix provides extensive details on all phases of the development of the ISA, including the literature search and initial screening and documentation of studies, the detailed evaluation of individual study quality (e.g., study scope, design and methods), the peer review and public participation process, and the quality assurance steps that were taken to ensure accuracy. Also, as noted in the Appendix to the PM ISA, the EPA has undertaken a rigorous process of evaluating individual studies. As part of this process, the Agency relies on various scientific considerations, detailed in Table A-1 of the Appendix. These considerations allow for the Agency to evaluate the strength of inference from studies spanning scientific disciplines and ultimately their utility in informing causality determinations. It is based on these individual study quality evaluations that the strength of the evidence base is assessed. If there are instances where there are inherent limitations

in individual studies and in the overall body of evidence, this is reflected in the causality determination for a health effect category.

Lastly, with respect to comments questioning the inclusion of *in vitro* studies within the ISA and how they are used in the process of evaluating the evidence, the Preamble to the ISAs states "*in vitro* studies may provide mechanistic insight for effects examined *in vivo* or in epidemiologic studies (U.S. EPA, 2015)." It additionally states that "experimental results from *in vivo* studies involving animal models and humans, as well as from *in vitro* studies when appropriate, may be used to establish biological plausibility and to interpret other lines of evidence (e.g., health effects from epidemiologic studies) (U.S. EPA, 2015)." Therefore, *in vitro* studies are sometimes used in the process of assessing biological plausibility, but they do not encompass the main evidence base used to assess causality.

(2) ***Comment:*** Numerous public commenters convey that they support statements made by the chartered CASAC with respect to the consideration of evidence from epidemiologic studies in informing causality determinations. Specifically, they contend that the associations reported in the epidemiologic studies do not necessarily indicate causality, and in some instances, even though there is evidence of statistically significant associations, it is plausible that they do not support a causal relationship. In addition, because the categories of the causal framework lack clear definitions, it is not possible to interpret the evidence of association as evidence of causation.

Response: Epidemiologic studies represent one line of evidence considered in the process of making conclusions on causality. In assessing the causal nature of relationships between PM exposures and health effects, the EPA employs a weight-of-evidence approach that relies on the integration of evidence across scientific disciplines (U.S. EPA, 2015). The EPA agrees with the CASAC and the commenters that the results from epidemiologic studies provide evidence of associations. However, the EPA disagrees with the commenters' assertion that the Agency correlates association with causation. The EPA does not use epidemiologic evidence alone in making causality determinations. Causality determinations within the ISA represent conclusions based on the collective body of evidence spanning scientific disciplines including epidemiology, exposure science, animal toxicology, controlled human exposure studies, and dosimetry, as well as evidence informing biological plausibility. This is reflected in the overall discussion of the ISA development process in the Preamble to the ISAs (U.S. EPA, 2015). However, the results from epidemiologic studies represent a critical piece of the collective body of evidence that is used to make conclusions regarding causality.

(3) ***Comment:*** Some commenters criticize the EPA's consideration of PM components in evaluating the health effects evidence. Some commenters contend that crustal components of $PM_{2.5}$, like silicon and aluminum, are not associated with health effects, citing to specific studies included in previous ISAs. Other commenters suggest that individual components of $PM_{2.5}$ contribute to health effects and should be included in the EPA's consideration of causality. For example, commenters contend that studies of black carbon should have been considered in assessing the evidence for both short- and long-term $PM_{2.5}$ exposures in reaching a causality determination for black carbon. These

commenters highlight a number of studies that, in their opinion, demonstrate that black carbon is a good indicator of traffic-related air pollution health effects and can be considered to be causally related to the cardiovascular health effects observed from near-road exposures.

Response: The EPA disagrees with the commenter that the evidence regarding components, including black carbon, is strong enough in the current review to support the presentation of causality determinations for individual $PM_{2.5}$ components. In the process of evaluating the current state of the science for $PM_{2.5}$ mass, the ISA also assessed whether individual components of $PM_{2.5}$ were more toxic than $PM_{2.5}$ itself. In evaluating the evidence in the ISA, the EPA focused on those studies that included both $PM_{2.5}$ mass and individual PM components. While studies did report evidence of positive associations with black carbon, there was also evidence of positive associations with $PM_{2.5}$ mass as well as other components, like aluminum and silicon. As a result, the EPA concluded "that many $PM_{2.5}$ components and sources are associated with many health effects and that the evidence does not indicate that any one source or component is consistently more strongly related with health effects than $PM_{2.5}$ mass" (U.S. EPA, 2019). To the extent commenters are suggesting that black carbon be used as an indicator for traffic-related pollution, the EPA notes that this review is for the criteria pollutant particulate matter and is not reviewing, or seeking to protect against, the health effects of traffic-related pollution generally.

(4) ***Comment:*** Several commenters who support the EPA's decision to retain the PM standards, contend that the ISA incorrectly concludes that the evidence supports a "likely to be causal" relationship between long-term $PM_{2.5}$ exposures and cancer. Commenters assert that the ISA's conclusion is flawed because the epidemiological studies used in evaluating this relationship have considerable methodological limitations, the most critical being that they do not adequately account for: (a) latency (i.e., examine time frames that are appropriate with cancer formation), (b) smoking status, and (c) family history of lung cancer; and that (d) animal toxicological studies do not provide support for a biologically plausible mechanism by which $PM_{2.5}$ exposure could lead to cancer.

Response: As an initial matter, the commenters do not explain how the change in the causality determination for long-term $PM_{2.5}$ exposure and cancer is a material concern given that they support the EPA's proposed decision to retain the primary $PM_{2.5}$ NAAQS. Nevertheless, the EPA disagrees with the commenters assertion that the evidence base used to support the conclusion that there is a "likely to be causal relationship" between long-term $PM_{2.5}$ exposure and cancer has inherent limitations (U.S. EPA, 2019). The EPA's causality determination for long-term $PM_{2.5}$ exposure and cancer is based on the extensive number of recent epidemiological studies that provide evidence of generally consistent positive associations for lung cancer incidence and mortality in cohorts with diverse demographic characteristics as well as in populations of never smokers (U.S. EPA, 2019). Both epidemiological and experimental studies also provide evidence of $PM_{2.5}$-related genotoxicity, epigenetic effects, and carcinogenic potential. Additionally, $PM_{2.5}$ has been shown to exhibit several characteristics of carcinogens which provides biological plausibility for cancer development.

The EPA also disagrees with the commenters' assertion regarding specific inherent limitations in this evidence. We address the comments on each of the uncertainties raised by the commenters below.

(a) Latency: As described in the proposed rule, "it is well recognized that air pollution exposures experienced over an extended historical time period are likely more relevant to the etiology of lung cancer than air pollution exposures experienced in the more recent past' (Turner et al., 2011). However, many epidemiological studies conducted within the U.S. that examine long-term $PM_{2.5}$ exposure and lung cancer incidence and lung cancer mortality rely on more recent air quality data because routine $PM_{2.5}$ monitoring did not start until 1999-2000. An exception to this is the American Cancer Society (ACS) study that had $PM_{2.5}$ concentration data from two time periods, 1979-1983 and from 1999-2000. Turner et al. (2011), conducted a comparison of $PM_{2.5}$ concentrations between these two time periods and found that they were highly correlated ($r > 0.7$), with the relative rank order of metropolitan statistical areas (MSAs) by $PM_{2.5}$ concentrations being 'generally retained over time.' Therefore, areas where $PM_{2.5}$ concentrations were high remained high over decades (or low remained low) relative to other locations. Long-term exposure epidemiological studies rely on spatial contrasts between locations; therefore, if a location with high $PM_{2.5}$ concentrations continues to have high concentrations over decades relative to other locations a relationship between the $PM_{2.5}$ exposure and cancer should persist. This was confirmed in a sensitivity analysis conducted by Turner et al. (2011), where the authors reported a similar hazard ratio (HR) for lung cancer mortality for participants assigned exposure to $PM_{2.5}$ (1979-1983) and $PM_{2.5}$ (1999-2000) in two separate analyses" (85 FR 24112, April 30, 2020).
(b) Smoking: As noted in the ISA in section 10.2.5.1.1, epidemiological studies examining long-term $PM_{2.5}$ exposure and lung cancer mortality have either relied upon individual-level data on smoking status or proxy measures to estimate the prevalence of smoking within a population. To make the distinction between these sets of studies, the ISA clearly delineates the discussion to separate the two categories of studies. The EPA, therefore, disagrees with the commenters that epidemiologic studies have not taken adequate measures to account for the potential confounding effects of smoking status on the relationship between long-term $PM_{2.5}$ exposure and lung cancer incidence and mortality.
(c) Family history: The majority of cancers, and in particular lung cancer, are linked with a number of environmental factors. As discussed in Kanwal et al. (2017), "hereditary predisposition…has been implicated in 10-15% of cancer cases…[with] breast, colon, bladder, and ovarian cancers [being] commonly associated with a hereditary predisposition." Lung cancer is not considered a form of cancer with familial history. The EPA, therefore, disagrees with the commenters' assertion that not considering familial history represents an omission from the confounders included in statistical models used in epidemiological studies of lung cancer mortality.
(d) Biological plausibility: The EPA disagrees with the commenters' assertion that there is no evidence of biological plausibility for $PM_{2.5}$ and cancer. As noted in the proposed rule, "[w]hile experimental studies showing a direct effect of $PM_{2.5}$ on cancer formation were limited to an animal model of urethane-induced tumor initiation, an extensive number of experimental studies demonstrate that $PM_{2.5}$

exhibits several key characteristics of carcinogens, as indicated by genotoxic effects, oxidative stress, electrophilicity, and epigenetic alterations, all of which provide biological plausibility that $PM_{2.5}$ exposure can contribute to cancer development" (85 FR 24113, April 30, 2020).

2. Comments on the Risk and Exposure Assessment

(1) ***Comment:*** The EPA received a number of comments specifically related to the technical approaches for quantitative analyses included as a part of the risk and exposure assessment in this review. The commenters provide varying comments on the approach and considerations used to inform these analyses. Comments generally include the following topics: (1) estimates of policy-relevant background, including characterizing wildfires as a part of background PM; (2) model precision and associated variability and uncertainty; (3) criteria for selecting study areas and C-R functions; (4) air quality scenarios evaluated; (5) assumptions to inform and approaches used for modeling (e.g., emissions reductions scenarios, hybrid modeling); (6) interpolation/extrapolation of air quality scenarios; (7) methodological limitations for estimating risk (e.g., exposure measurement error, insufficient covariate adjustment, lack of evaluation of copollutants), and; (8) underestimation of risk.

Response: With respect to comments related specifically to analytical considerations in estimating risk, the EPA has considered the comments and is actively engaged in efforts to evaluate potential improvements to these methodologies. We note that the scientific evidence and available information is always evolving and can inform and contribute to refinements of future analyses of risk and exposure. However, we note that at the time of the proposal, in considering the risk estimates, the Administrator judged "it appropriate to place little weight on quantitative estimates of $PM_{2.5}$-associated mortality risk in reaching conclusions on the primary $PM_{2.5}$ standards." In so doing, the Administrator first noted that all risk assessments have limitations and that, in previous reviews, the limitations have often resulted in less weight being placed on quantitative estimations of risk than on the underlying scientific evidence itself (85 FR 24120, April 30, 2020). In addition to the uncertainties with risk assessments, the Administrator noted the concerns expressed by the CASAC members that largely reflect their overall views on the limitations in the $PM_{2.5}$ epidemiological evidence, which provides key inputs to the risk assessment. He further noted the CASAC's concerns regarding the characterization of uncertainty in the risk assessment and the evaluation of modeling assumptions (Cox, 2019a; 85 FR 24120, April 30, 2020). Consistent with his approach at the time of the proposal, the Administrator again considered the implications of the risk assessment for his final decision, including the limitations associated with the risk assessment, the CASAC advice, and public comments. Taken together, as described in section II.B.4 of the final action, the Administrator judges it appropriate to place little weight on quantitative estimates of $PM_{2.5}$-associated mortality risk in reaching his final conclusions on the primary $PM_{2.5}$ standards. The technical issues addressed by these commenters would not resolve the fundamental limitations that led the Administrator to place little weight on the risk estimates in reaching his final decision. Accordingly, the comments regarding the technical approaches of the quantitative analyses do not inform the final decision to retain

the current primary $PM_{2.5}$ standards, without revision.

III. Responses to Comments on the Proposed Decision to Retain the Primary PM_{10} NAAQS

The EPA received very few comments on the proposed decision to retain the primary PM_{10} standard. Comments related to retaining or revising the primary PM_{10} standard are addressed in section III.B.3 of the preamble to the final rule. In addition to comments on the standard, some commenters provided additional comments on the scientific evidence and information available in this review. These comments are addressed below.

(1) ***Comment*:** Some commenters who state their support for retaining the current standard additionally provide comments related to the causality determinations for $PM_{10-2.5}$ exposures and health endpoints in the ISA. These commenters contend that the EPA did not consistently apply the causal framework in assessing the evidence for cancer, metabolic, nervous system, and mortality effects when concluding suggestive of, but not sufficient to infer, a causal relationship with $PM_{10-2.5}$. In supporting their position, the commenters also point to the CASAC's review of the draft ISA and the recommendations by some members of the CASAC that causality determinations in the draft ISA were unclear and not well justified. These commenters further encourage the EPA to amend the ISA to defer upgraded causality determinations for reconsideration in the next review of the PM NAAQS.

Response: The EPA disagrees with comments questioning the ISA's approach to assessing the evidence, the causal framework established in the ISA, or the consistent application of that framework across health endpoints. We note that while the causality determinations were revised from "inadequate" to "suggestive of, but not sufficient to infer, a causal relationship" for long-term $PM_{10-2.5}$ exposures for a few of the health outcome categories (i.e., mortality, cardiovascular effects, cancer) and causality determinations were made for the first time for long-term $PM_{10-2.5}$ exposures and new health endpoints in this review (i.e., nervous system and metabolic effects), there are still extensive uncertainties in the evidence base. As described in the 2019 ISA (U.S. EPA, 2019), the conclusion of a "suggestive of, but not sufficient to infer, a causal relationship" reflects continued uncertainties in the available evidence, including differences in methods for estimating $PM_{10-2.5}$ concentrations and uncertainty as to how well correlated the $PM_{10-2.5}$ concentrations are both spatially and temporally between these methods. Therefore, as detailed in the final ISA, the available evidence, with its inherent uncertainties and limitations, supports "suggestive of, but not sufficient to infer, a causal relationship" between $PM_{10-2.5}$ exposures and health effects (U.S. EPA, 2019).[2]

Further, the new and revised causality determinations for $PM_{10-2.5}$-related health effects

[2] The 2019 ISA concluded that the evidence was "suggestive of, but not sufficient to infer, causal relationships" for short-term $PM_{10-2.5}$ exposures and mortality, cardiovascular effects, and respiratory effects and for long-term $PM_{10-2.5}$ exposures and mortality, cardiovascular effects, nervous system effects, metabolic effects, and cancer.

did not result in revisions to the standard in this review, and therefore, the commenters' objections are not material to the proposed decision to retain the current standard. At the time of the proposal, recognizing the limitations in the available evidence, the EPA recognized that there is considerable uncertainty with regard to the public health implications of a revised primary PM_{10} standard (85 FR 24125-24126, April 30, 2020). In considering the body of available scientific evidence, with its inherent uncertainties and limitations as reflected by the "suggestive of, but not sufficient to infer," causal determinations for $PM_{10-2.5}$ exposures and health effects, the EPA concluded that there is not adequate evidence to support to consider revisions to the primary PM_{10} standard in this review.

(2) ***Comment:*** A number of commenters assert that the epidemiological studies of PM_{10}-related health effects are not applicable to all areas of the U.S. due to differences in sources and composition of coarse PM that are influenced by geographical (i.e., urban versus rural) distribution. As such, these comments contend that the differences in coarse PM in the health effects studies should be taken into account when considering revisions to the primary PM_{10} standard.

Response: As an initial matter, we note that there are number of uncertainties and limitations associated with the available health effects evidence for exposure to $PM_{10-2.5}$. These uncertainties are described in detail in section III.A.2 in the final action and in responding to other comments on the primary PM_{10} standard in section III.B.3 of the final action. As noted just above, these uncertainties in the evidence base are reflected by the "suggestive of, but not sufficient to infer, a causal relationship" conclusion for $PM_{10-2.5}$ and health effects in the current review. It is also important to recognize that epidemiological studies have not demonstrated that coarse particles of varying geographic origin (i.e., non-urban) do not cause health effects, and the commenters did not provide additional evidence on this point. While there are fewer studies of non-urban coarse PM than urban coarse PM, several studies have reported positive and statistically significant associations between coarse particles of crustal, non-urban origin and mortality or morbidity. These studies formed part of the basis for the causality determinations for $PM_{10-2.5}$ exposures in the final ISA.

Further, the EPA notes that the available health effects evidence did not result in revisions to the standard in this review, and therefore, the commenters' contention that differences in coarse PM location, source of origin, or composition should be considered in setting the primary PM_{10} standard is not material to the proposed decision to retain the current standard. As noted in the response above, the EPA recognized that the limitations in the available evidence and the considerable uncertainty with regard to the public health implications of a revised primary PM_{10} standard (85 FR 24125-24126, April 30, 2020). As such, the EPA concluded that there is not adequate evidence to support to consider revisions to the primary PM_{10} standard in this review.

(3) ***Comment:*** Given that 24-hour PM_{10} concentrations have decreased by ~30% since 2000 and positive associations are still present between PM_{10} and health effects, some commenters assert that it is difficult to justify retaining the current level and form of the

primary PM_{10} standard. These commenters suggest that more analyses are needed to demonstrate that the current primary PM_{10} standard is adequate to protect public health.

Response: The EPA agrees with the commenters that more information is needed to inform consideration of the public health protection afforded by the current primary PM_{10} standard. As recognized by the commenters themselves, there is a lack of measurement data (e.g., network design, ambient monitoring, and chemical speciation) to support evaluating the health effects associated with $PM_{10-2.5}$ in ambient air. Moreover, we note that, even for those areas that have expanded monitoring efforts for $PM_{10-2.5}$, there are a lack of epidemiological studies that use these data to inform our understanding of the health effects attributable to $PM_{10-2.5}$ exposures. The EPA identified a number of areas for future research to address such data gaps in the PA that could provide important evidence for informing future reviews of the PM NAAQS (U.S. EPA, 2020).

Further, as described in section III.B.3 of the final action, the EPA disagrees that the information available in this review calls into question the adequacy of the current primary PM_{10} standard. As described in detail in section III.A.2 of the final action and in the proposal (85 FR 24125, April 30, 2020), there are a number of uncertainties associated with the available health effects evidence that contribute to the determinations in the ISA that the evidence for key $PM_{10-2.5}$ health effects is "suggestive of, but not sufficient to infer, a causal relationship" (U.S. EPA, 2019). In the absence of more robust health effects evidence, including epidemiological studies that use expanded $PM_{10-2.5}$ monitoring data, the public health implications of changes in ambient PM_{10} concentration as $PM_{2.5}$ concentrations decrease remain unclear. Taken together, at the time of the proposal and in reaching his final decision, the Administrator concluded that these and other limitations in the $PM_{10-2.5}$ evidence raised questions as to whether additional public health improvements would be achieved by revising the existing PM_{10} standard. Therefore, the EPA does not agree with commenters that the level and form of the primary PM_{10} standard should be revised in this review.

(4) ***Comment:*** The EPA also received a number of comments related to the primary PM_{10} standard that were not directly related to consideration of the current standard. These comments included recommendations for future research and data collection efforts that could address data gaps and uncertainties to inform future reviews.

Response: The EPA agrees with many of the suggestions from the commenters and notes that the PA highlighted key uncertainties and data gaps associated with reviewing and establishing NAAQS for PM_{10} and also areas for future health-related research and data gathering. We encourage research in these areas, although we note that research planning and priority setting are beyond the scope of this action.

IV. Responses to Comments on the Proposed Decision to Retain the Secondary PM NAAQS

The EPA received relatively few comments on the proposed decision to retain the secondary PM standards. Comments related to retaining or revising the secondary PM standards are

addressed in section IV.B.3 of the preamble to the final rule. In addition to comments on the standards, some commenters provided additional comments on the scientific evidence and information available in this review. These comments are addressed below.

(1) ***Comment:*** Some commenters assert that the existing secondary $PM_{2.5}$ NAAQS does not provide the protection necessary to achieve visibility goals, even in Class I areas that have made incremental progress under the Regional Haze Rule (RHR) for reducing visibility impairment.

Response: While the EPA has concluded not to revise secondary standard at this time, this decision was based on the degree of protection afforded by the existing secondary $PM_{2.5}$ standards, particularly the secondary 24-hour $PM_{2.5}$ standard of 35 $\mu g/m^3$. CAA section 109(b) requires the Agency to establish *national* standards to protect the public welfare, which means that the NAAQS are designed to protect against adverse impacts in both urban and rural areas. The goal of the Regional Haze Program under sections 169A and 169B of the CAA, which specially targets visibility protection in Federal Class I areas, is to address all man-made impairment of visibility, and the program specifically targets the widespread, regionally uniform type of haze caused by a multitude of sources. Over time, the Regional Haze Program will provide a level of protection of visual air quality in Class I areas beyond the level of protection envisioned for a secondary NAAQS under section 109(b). The EPA notes that any national ambient air quality standard for visibility would be designed to work in conjunction with the Regional Haze Program as a means of achieving appropriate levels of protection against PM-related visibility impairment in all areas of the country, including urban, non-urban, and Federal Class I areas.

(2) ***Comment:*** A number of commenters contend that the EPA's quantitative analyses of visibility impairment were based on outdated data. First, these commenters assert that the EPA did not consider changes in $PM_{2.5}$ composition over time in their assessment of visibility impairment, pointing to analyses in the ISA in particular. Second, the commenters question whether the EPA's analyses included evaluation of all three IMPROVE equations available in this review, and if the estimates for the 2015-2017 time period were compared to those from 2005-2008. The commenters also assert that the EPA failed to consider recently available information to inform the selection of inputs for the IMPROVE equations (e.g., scattering coefficients for PM components, OM/OC ratios) and cited several studies to support their claim (Chen et al., 2015; Chow et al., 2015; Chow et al., 2018; Chow et al., 2019). Commenters also suggested that the EPA adopt a new "contrast of distance" methodology based on a new meta-analysis by Malm et al. (2019).

Response: The EPA disagrees with these commenters. First, the analyses that were referenced by the commenters were included as a part of the ISA (U.S. EPA, 2019, Figures 13-1 through 13-4) and it summarized the spatial and temporal patterns of $PM_{2.5}$ composition and its contribution to light extinction from IMPROVE and CSN monitoring sites, which are mostly urban and rural, respectively. The data included for 2005-2008 are from the most recent IMPROVE report on the spatial and temporal patterns of $PM_{2.5}$

composition and its contribution to light extinction from IMPROVE and CSN monitoring sites (Hand et al., 2011; U.S. EPA, 2019, section 13.2.4.1). During the development of the ISA, Jenny Hand and others developed the same kind of figures as were presented in the IMPROVE report for 2005-2008 (Hand et al., 2011) using more recent data (2011-2014) for inclusion as a part of the ISA. These analyses, and the discussion in section 13.2.4 of the ISA (U.S. EPA, 2020), consider changes in $PM_{2.5}$ composition spatially and temporally between the two time periods.

Secondly, with regard to the quantitative analyses for visibility impairment included in the PA (U.S. EPA, 2020, section 5.2.1.2), the EPA clearly describes the methods used for estimating light extinction in the current review. As detailed in Appendix D of the PA, the EPA estimated light extinction at those monitoring locations in the U.S. that met the data completeness criteria using all three versions of the IMPROVE equation (original IMPROVE equation, revised IMPROVE equation, and Lowenthal and Kumar (2016) IMPROVE equation; U.S. EPA, 2020, Appendix D, Equations D-1 through D-3). The commenters question whether the estimates of light extinction for the 2015-2017 time period evaluated in the PA were compared to the 2005-2008 time period in the ISA analyses. We note that the analyses in the PA (for the 2015-2017) and in the ISA (for the 2005-2008 and 2011-2014 time periods) are different analyses with different methods and purposes, and therefore such a comparison would not be appropriate. However, the results of the analyses in this review were compared to those conducted in support of the final decision at the time of the last review for the time period of 2008-2010 (U.S. EPA, 2020, section 5.2.1.2, Appendix D; Kelly et al., 2012; 78 FR 3201, January 15, 2013).

Third, the EPA disagrees with the commenters that newly available information that could inform the selection of inputs to the IMPROVE equations was not considered in this review. With regard to the studies identified by the commenters (Chen et al., 2015; Chow et al., 2015; Chow et al., 2018; Chow et al., 2019), we note that only two of these studies were published prior to the literature cutoff date for the ISA, while the other two studies were published after the literature cutoff date. Three of the studies cited by the commenters (Chen et al., 2015; Chow et al., 2015; Chow et al., 2019) do not estimate PM species contributions to visibility impairment, and as a result, were considered to be beyond the scope of the ISA. Therefore, the studies do not provide additional information in this review that informs or refines inputs to the IMPROVE equations. One of the studies published after the literature cutoff date (Chow et al., 2018) was provisionally considered, but does not materially change the scientific conclusions of the ISA in the current review, this study has the potential to be informative in the next review of the PM NAAQS with regard to PM species their contributions to light extinction. As explained above, in considering the "new" studies cited by commenters, the EPA has provisionally considered these studies in the context of the findings of the ISA (see Appendix A below). As detailed in section I.D of the final action, these studies are generally consistent with the evidence assessed in the ISA, and they do not materially alter our understanding of the scientific evidence or the Agency's conclusions based on that evidence or warrant reopening of the air quality criteria. However, we note that the available scientific information and monitoring data allowed for several refinements to the quantitative analyses for visibility impairment in this review compared to the last

review. These include: (1) the evaluation of three versions of the IMPROVE equation to calculated light extinctions (U.S. EPA, 2020, Appendix D, Equations D-1 through D-3) in order to better understand the influence of variability in equation inputs; (2) the use of 24-hour relative humidity data, rather than monthly average relative humidity as was used in the last review (U.S. EPA, 2020, section 5.2.1.2, Appendix D); and (3) the inclusion of the coarse fraction in the estimation of light extinction in the subset of areas with $PM_{10-2.5}$ monitoring data available for the time period of interest (U.S. EPA, 2020, Appendix D, Figure D-1).

Finally, the EPA disagrees that it would be appropriate to adopt an entirely new methodology for assessing the effect on public welfare of PM impacts on visibility. The commenters proposed "contrast of distance" approach was never discussed or evaluated by the EPA in the PA, was never reviewed by the CASAC as part of its review of the air quality criteria, and was not included in the proposal to allow for public comment on it as a possible basis for a decision on the standards. Moreover, the EPA does not believe the comments spicy the proposed alternative methodology with sufficient detail to enable it to be use for consideration of a distinct secondary standard for visibility at this time. Thus, the EPA concludes that adoption of the commenters' alternative methodology is not warranted or appropriate at this time.

(3) ***Comment:*** Several commenters contend that the EPA failed to consider the ecological effects of PM and if the current secondary PM standards provide protection against such effects as a part of this review.

Response: The EPA is separately reviewing the ecological effects associated with PM in conjunction with reviews of other pollutants that, along with PM, contribute jointly to atmospheric deposition. As explained in both the PM IRP (U.S. EPA, 2016, p. 1-17) and the IRP for review of the secondary NAAQS for oxides of nitrogen and oxides of sulfur (U.S. EPA, 2017, p. 1-1), and discussed in the proposal (85 FR 24127, April 30, 2020), oxides of nitrogen, oxides of sulfur, and PM are being reviewed together because they are interrelated through complex chemical and atmospheric processes and because they all contribute to nitrogen (N) and sulfur (S) deposition, which in turn contributes to well-documented ecological effects including reduction in growth and survival of various species, as well as altering species richness, species composition and biodiversity. Addressing the pollutants together enables the EPA to take a comprehensive approach to considering the nature and interactions of the pollutants, which is important for ensuring that all scientific information relevant to ecological effects is thoroughly evaluated.

Furthermore, the commenter cites no authority for the proposition that the EPA must conduct all aspects of a NAAQS review for a pollutant at one time or for the proposition that completing one aspect of a review amounts to a decision to take no action on any other aspect of that review. The EPA's decision to combine the review of the ecological effects associated with oxides of nitrogen, oxides of sulfur and PM is reasonable. See *City of Las Vegas v. Lujan*, 891 F.2d at 925 (finding that "agencies have great discretion to treat a problem partially").

This combined review of the ecological criteria for oxides of nitrogen, oxides of sulfur, and particulate matter is ongoing. The EPA initiated the review of the secondary standards for oxides of nitrogen, oxides of sulfur, and PM in August 2013 with a call for information in the Federal Register (78 FR, 53452, August 29, 2013). The current review of the secondary standards for oxides of nitrogen, oxides of sulfur and PM considers secondary standards for these three pollutants together with regard to protection against adverse ecological effects on public welfare. This review differs from the review completed in 2012 in that the current review includes consideration of the secondary PM standards, in addition to the secondary standards for oxides of nitrogen and sulfur. Given the contribution of nitrogen compounds to PM, including but not limited to those related to oxides of nitrogen, the current review provides for an expanded and more integrated consideration of nitrogen deposition and the current related air quality information. The EPA finalized the IRP for this review in January 2017 and finalized the ISA in October 2020. The EPA also developed a Risk and Exposure Assessment Planning Document in August 2018. The draft PA, including the quantitative analyses for the review, is anticipated to be released in 2021, with a proposed and final action to follow. More information about and documents associated with the review of the secondary standards for oxides of nitrogen, oxides of sulfur, and PM are available at: *https://www.epa.gov/naaqs/nitrogen-dioxide-no2-and-sulfur-dioxide-so2-secondary-air-quality-standards*.

(4) ***Comment:*** Some commenters assert that the EPA failed to consider the latest scientific information on best practices in preference studies and that the EPA failed to apply those concepts to further study of public preferences.

Response: As an initial matter, section 108 of the CAA directs the Administrator to identify and list certain air pollutants and then to issue air quality criteria for those pollutants. Air quality criteria are intended to "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 [a] pollutant in ambient air…" (42 U.S.C. 7408(a)(2)). Although, in order to inform the 2006 PM NAAQS, a pilot focus group study on visibility was conducted in Washington, DC on behalf of the EPA to inform the 2006 PM NAAQS (Abt Associates Inc., 2001), there is no requirement for the Agency to conduct new studies to address uncertainties or data gaps in the available evidence as a part of issuing the air quality criteria. In this review, studies identified for the ISA were based on the review's opening "call for information" (79 FR 71764, December 3, 2014), as well as literature searches conducted routinely to identify and evaluate "studies and reports that have undergone scientific peer review and were published or accepted for publication between January 1, 2009 and March 31, 2017. A limited literature update identified some additional studies that were published before December 31, 2017" (U.S. EPA, 2019, Appendix, p. A-3).

(5) ***Comment:*** Some commenters contend that the EPA failed to coordinate with other Federal agencies and failed to consider research studies and data from these agencies in reaching its conclusions on the secondary PM standards. The commenters note a research study related to dust suppression that they contend was not considered in the ISA (Chang

et al., 2016). These commenters further assert that the EPA's proposal is inconsistent with previous ozone NAAQS reviews where the Agency considered the effects of pollutants in areas with special federal protections and lands set aside by states, tribes, and public interest groups.

Response: The EPA disagrees with the commenter. In considering the available welfare effects evidence as a part of the ISA, numerous studies are cited that are authored or coauthored by individuals associated with other Federal agencies. For example, Bret Schichtel, from the National Park Service, was a contributing author to several IMPROVE research papers cited in the ISA. Moreover, research by National Park Service scientists are heavily cited, including several papers by Jenny Hand, who also was consulted extensively for the IMPROVE data analyses in the ISA. With regard to the study by Chang et al. (2016) cited by the commenter, we note that the ISA generally includes peer-reviewed publications rather than government reports in evaluating the available scientific evidence. The Chang et al. (2016) research study was conducted by the Argonne National Laboratory for the Bureau of Land Management and is a study of dust suppression. The ISA generally considers studies on emission control methods, such as dust suppression, to be beyond the scope and therefore, these types of the studies were not included in evaluating the PM-related materials effects on photovoltaic panels. Moreover, the commenters' general assertion that we should have considered additional studies and data from the Federal Family does not specify how any of the data or the studies cited in the comments undermine the EPA's decision to retain the secondary PM NAAQS. The EPA also utilized the interagency review process under Executive Order 12866 to receive feedback from other federal agencies on the proposed and final action.

With regard to the commenters' assert that the EPA's proposal is inconsistent with previous ozone NAAQS reviews where the Agency considered the effects of pollutants in areas with special federal protections and lands set aside by states, tribes, and public interest groups, we note that the commenters reference a statement in the 2008 ozone review concerning about ecological effects, specifically ozone-related visible foliar injury. As noted above in responding to other comments, the EPA is separately reviewing the ecological effects associated with PM in conjunction with the review of oxides of nitrogen and oxides of sulfur that, along with PM, contribute jointly to atmospheric deposition (U.S. EPA, 2016, p. 1-17; U.S. EPA, 2017, p. 1-1). For visibility impacts, the EPA did consider federal Class I areas in defining a target level of protection against visibility impairment and in considering the need for a distinct secondary PM standard to protect against visibility effects. At the time of the last review, the EPA noted that any national ambient air quality standard for visibility would be designed to work in conjunction with the Regional Haze Program as a means of achieving appropriate levels of protection against PM-related visibility impairment in all areas of the country, including urban, non-urban, and federal Class I areas. While the Regional Haze Program is focused on improving visibility in federal Class I areas and a secondary visibility index NAAQS would focus on protecting visual air quality principally in urban areas, both programs could be expected to provide benefits in surrounding areas. Thus, in considering a distinct standard to protect visibility impairment under the NAAQS program, in the last review, the EPA focused particular attention on areas not already

covered by the Regional Haze Program (U.S. EPA, 2012). The manner in which the EPA considered Class I areas in the last review applies in this review as the EPA's determination that the PM NAAQS would work with the Regional Haze Program to achieve appropriate levels of protection in all areas of the country remains valid.

(6) ***Comment:*** A number of tribes and tribal organizations state that the current secondary annual $PM_{2.5}$ standard does not respect or protect important cultural values of tribal communities against visibility impairment. These commenters, in support of their recommendations to revise the current secondary PM standards, specifically note that the current secondary annual $PM_{2.5}$ standard does not provide sufficient protection for federal or tribal Class I areas from decreased visibility.

Response: The EPA disagrees with the commenters that the secondary annual $PM_{2.5}$ standard should be revised to provide additional protection against visibility impairment, as detailed in section IV.3.B of the final action. With regard to the commenters assertion that the current secondary annual $PM_{2.5}$ standard does not provide sufficient protection in Class I areas, the EPA notes that, as described above, visibility protection in federal Class I areas is specifically targeted by the Regional Haze Program under sections 169A and 169B of the CAA. Over time, the Regional Haze Program will provide a level of protection of visual air quality in Class I areas beyond the level of protection envisioned for a secondary NAAQS under section 109(b). The EPA notes that any national ambient air quality standard for visibility would be designed to work in conjunction with the Regional Haze Program as a means of achieving appropriate levels of protection against PM-related visibility impairment in all areas of the country, including urban, non-urban, and federal Class I areas. Furthermore, the commenters do not specify how or why the standard fails to protect the cultural values of tribes against decreased visibility.

(7) ***Comment:*** Commenters claim that the EPA's assertion that a 90^{th} percentile form for the visibility index, consistent with the Regional Haze Program, is a "false equivalency." In so doing, they note that the Regional Haze Rule uses the 90^{th} percentile form to focus on improving conditions on the worst days. They contend that using the same percentage for the form of the visibility index ignores the 36 worst visibility days, excusing them from being tracked and improved.

Response: We disagree with the commenters. The EPA notes that there is a significant lack of information on, and a high degree of uncertainty regarding, the impact on public welfare of the number of days with visibility impairment over the course of the year. For example, the visibility preference studies used to derive the candidate protection levels for the visibility index in the last review, and once again considered in this review, offer no information regarding the frequency of time that visibility levels should below those values. Based on this limitation, at the time of the last review, the EPA concluded that it would not be appropriate to consider eliminating all exposures above the level of the visibility index and that it was reasonable to consider allowing some days with reduced visibility (78 FR 3210, January 15, 2013). We note that the Regional Haze Program focuses attention on the 20 percent worst visibility days (i.e., those at or above the 80^{th} percentile of visibility impairment). Consistent with the decision in the last review, the

EPA continues to believe that a percentile well above the 80th percentile would be an appropriate target to increase the likelihood that all days in this range would be improved by control strategies intended to attain the standard. Focusing on the 90th percentile, which represents the median of the distribution of the 20 percent worst visibility days, could be reasonably expected to lead to improvements in visual air quality on the 20 percent most impaired days. Given the lack of new evidence or information to further inform the consideration of a different form of the visibility index, the EPA again concludes that it is appropriate to focus on the 90th percentile of visibility impairment values.

(8) ***Comment:*** Commenters submitted a number of images and photographs of visibility impairment to support their opinion that the secondary PM standards were inadequate and should be revised. Some images were generated using the WinHaze model and compared a clear day view to the same view modified to depict visibility under the current secondary PM standards. Others were photographs from the Camnet Network paired with IMPROVE data for a number of locations. The commenters contend that these images depict an "extreme degree of visibility impairment" at levels that meet the current standard.

Response: In considering the commenters' assertion that the current secondary PM standards should be revised, the EPA reviewed the images and photographs provided by the commenters. While these images depict visibility conditions in various locations at levels that meet the current secondary PM standards, the commenters' analyses do not include any additional information to inform consideration of public preferences or "acceptability" of visibility impairment associated with such levels of visibility impairment. Therefore, the EPA does not believe that the commenters have provided new information that can be used to inform consideration of a distinct secondary PM standard to protect against visibility impacts.

(9) ***Comment:*** Commenters assert that the EPA's assessment neglects to include any studies on the public benefits and improved welfare for enhancing visibility. The commenters cite a number of recently available studies and contend that the EPA must consider such studies in its current assessment. These studies include research on economic effects of scenic views (Jeong et al., 2019; Mittal and Byahut, 2017; Nicholls and Crompton, 2018; Walls et al., 2015; Boyle et al., 2016, Haider et al., 2019; Yao et al., 2019) as well as impacts on visitation to national parks and reduced tourist dollars (Keiser et al, 2018).

Response: While the EPA recognizes that these studies of economic effects and tourism impacts provide information on the public welfare implications of visibility impairment, the EPA notes that these types of studies were considered to be outside of the scope of the ISA, and therefore were not included in this review (U.S. EPA, 2019, p. P-16). The ISA considered the PM-related effects of visibility impairment in its literature search and evaluation of the available evidence but did not consider the downstream economic effects of visibility impairment in the current review. Nonetheless, the EPA reviewed these studies and they do not materially change any of the broad scientific conclusions regarding the welfare effects on PM in ambient air made in the air quality criteria, nor do

they provide information to consider alternative approaches for quantitative analyses in the current review. For example, the Boyle et al. (2016) study applies an alternative approach to estimating economic benefits of implementing the Regional Haze Rule. It does not relate economic benefits to PM concentration, deciview, contrast, or other visibility metrics. As such, this study, and the others which are similar in nature, do not provide information that is relevant to informing consideration of a distinct secondary PM standard to protect against visibility effects in this review.

(10) ***Comment:*** The EPA also received a number of comments related to the secondary PM standards that were not directly related to consideration of the current standard. These comments included recommendations for future research and data collection efforts that could address data gaps and uncertainties to inform future reviews.

Response: The EPA agrees with many of the suggestions from the commenters and notes that the PA highlighted key uncertainties and data gaps associated with reviewing and establishing secondary PM NAAQS and also areas for future welfare-related research and data gathering. We encourage research in these areas, although we note that research planning and priority setting are beyond the scope of this action.

V. Responses to Comments on Legal, Administrative, and Procedural Issues and to Miscellaneous Comments

A large number of commenters, primarily those from national public health, medical, and environmental nongovernmental organizations, tribes and tribal groups, state and local governments and organizations, former CASAC members, and individuals, provided comments related to the revised and streamlined review process for the current review, including the accelerated schedule for this review. These commenters also disagree with the disbanding of the previously established PM CASAC Review Panel for this review, as well as the process by which the chartered CASAC provided advice in its review of the EPA science and policy assessments. There were also a limited number of comments provided on monitoring and implementation-related issues in this review, as well as some other miscellaneous comments on the proposal. These comments are addressed below. Other commenters, primarily those from industries and industry groups as well as some state and local governments and organizations, generally agree with the EPA's approach, particularly its efforts to streamline the process. They assert that the streamlined process used by the EPA in this review fully adhered to all requisite provisions in the Clean Air Act (CAA).

A. NAAQS Review Process and Schedule

(1) ***Comment:*** Several commenters focus on the EPA's changes to the NAAQS review process in this review as compared to previous reviews and contend those changes were *ad hoc* and inappropriate. These commenters state that if the EPA had determined that changes to the NAAQS review process were needed, then it should have considered the needed changes in a systematic way that provided for public comments and public input, as was done in 2006 when the agency previously revisited the NAAQS reviews. Another comment expands upon the criticism regarding the changes to the review process by

noting that courts have held that federal agencies must supply a 'good reason' for departing from prior policy. In the view of these commenters, in this review, the EPA departed from past practice without adequately describing why that was necessary. Finally, commenters assert that Administrator Pruitt's 2018 "Back to Basics" memo, which describes some of the revisions to the NAAQS review process, improperly requires simultaneous consideration of health-based standards and implementation issues involving economic and technological considerations, potentially in violation of previous Court holdings.

Response: We disagree with the comments suggesting that the EPA has not provided a rationale for the changes in process in this review. The NAAQS review process has evolved continuously since the Agency began conducting reviews in the 1970s while continuing to meet the CAA requirements for such reviews. Each review has had its own unique characteristics that are driven by the specific nature of the pollutant being evaluated and any distinctive circumstances that affected the schedule with which the EPA was operating under at the time of the review. While the scientific review process here may have differed in format from previous PM 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 PM and the adequacy of the existing standards.

Administrator Pruitt's 2018 "Back to Basics" memo explains the rationale for the process changes that the EPA incorporated into this particular NAAQS review (Pruitt 2018). Two of the key reform principles specifically centered on adherence to the CAA statutory requirements in Section 109(d) in 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. Changes can be made to these procedures without public comment. 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. With respect to the comment asserting that the Pruitt memo set the EPA on an improper path to simultaneously consider the requisite standards needed to protect public health with economic implementation considerations, in violation of previous court decisions such as the Supreme Court's decision in *Whitman v. American Trucking Associations, Inc.*, the EPA disagrees. In fact, the Pruitt memo was explicit in its acknowledgement that the EPA charge questions to the CASAC to frame their review "may elicit information which is not relevant to the standard-setting process, but provides important policy context for the public, co-regulators, and EPA." Further, the EPA did not consider the costs of implementation in reaching a final decision to retain the NAAQS. Accordingly, the

changes publicly announced in the Pruitt memo and the EPA's decision to retain the PM NAAQS are entirely consistent with previous Court holdings, as well as CAA Sections 108 and 109.

(2) ***Comment:*** Several commenters criticize the compressed timeline employed for this review as insufficient to allow for adequate public review of the scientific basis for the decision. These groups believe that, given the importance of the NAAQS as a mechanism to protect human health, it is far more important that the standard is set appropriately, considering the best available science, and adequately reviewed by the leading experts in the field, than rushed to reach a randomly-selected deadline. Other comments expand upon this theme by noting that statutory deadlines do not excuse substantive deficiencies created by a rushed and truncated review process. These comments cite historical examples of NAAQS reviews for which the EPA entered into a consent decree or was under court order to complete a review, where the court-supervised schedules considered the need for the EPA staff to thoroughly conduct the requisite analyses. Other comments note that while the EPA should certainly work to meet the five-year review timeframe for the NAAQS established in the CAA, starting the process late and then skipping steps is not an appropriate process for considering the public health implications of criteria pollutants. In the view of these commenters, a highly compressed schedule that does not allow adequate time for the sequential preparation and review of the science, risk and policy documents is not consistent with the "thorough review" required by the CAA. They assert that the EPA must allow for adequate time for the CASAC and the public to review the major planning documents associated with the NAAQS review process and that the review and revision of those documents have been hampered by an unusually compressed schedule, which prevented a complete review of drafts of those documents in sequence. Some state air agencies assert that the EPA must allow for adequate time for the CASAC and the public to review the major planning documents associated with the NAAQS review process. Finally, several comments observe that this review is being completed during a global pandemic caused by a respiratory virus, which in their view, raises serious concerns about the adequacy of the opportunity for public comment and other issues with statutory requirements under the CAA.

Response: As noted above, the NAAQS review process has evolved and changed over the years, including a period where there was no policy assessment or staff paper, and the recent changes spelled out in the Pruitt memo are just another example of a decision to change the NAAQS review process (Pruitt, 2018). The goal for completing the review on a particular schedule is a decision that is within the Administrator's discretion as is his emphasis on completing reviews within, or as close as possible to, the timeframe contemplated by the statute. As noted above, the scientific review process here 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 PM and the adequacy of the existing standards. Further, the statute does not require a specific sequential order to the review documents and the commenters do not provide evidence in their comments to suggest that that the process or schedule for this review impacted the opportunity for CASAC review or public comment on documents associated with this review, nor did the process or

schedule impact the Administrator's final decision 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 the Federal Register notice describing the final decision in this review, in December 2014, the EPA announced the initiation of the current periodic review of the air quality criteria for PM and of the primary and secondary $PM_{2.5}$ and PM_{10} NAAQS and issued a call for information (79 FR 71764, December 3, 2014). On February 9 to 11, 2015, the EPA held a public workshop to inform the planning for the current review of the PM NAAQS (announced in 79 FR 71764, December 3, 2014). This workshop provided for a public discussion of the key science and policy-relevant issues around which the EPA has structured the current review of the PM NAAQS and of the most meaningful new scientific information that would be available in this review to inform understanding of these issues. The input received at the workshop guided the EPA staff in developing a draft IRP, which was reviewed by the CASAC Particulate Matter Panel and discussed on public teleconferences held in May 2016 (81 FR 13362, March 14, 2016) and August 2016 (81 FR 39043, June 15, 2016). Advice from the CASAC, supplemented by the Particulate Matter Panel, and input from the public were considered in developing the final IRP (U.S. EPA, 2016). The final IRP discusses the approaches to be taken in developing key scientific, technical, and policy documents in this review and the key policy-relevant issues.

The EPA released the draft ISA in October 2018 (83 FR 53471, October 23, 2018). The draft ISA was reviewed by the chartered CASAC at a public meeting held in Arlington, VA in December 2018 (83 FR 55529, November 6, 2018) and was discussed on a public teleconference in March 2019 (84 FR 8523, March 8, 2019). The CASAC provided its advice on the draft ISA in a letter to the EPA Administrator dated April 11, 2019 (Cox, 2019b). Given the Administrator's timeline for this review, as noted above (Pruitt, 2018), the EPA did not prepare a second draft ISA (Wheeler, 2019). Rather, the EPA has addressed the CASAC's comments on the Final ISA (U.S. EPA, 2019, Appendix A, section A.4.5). The Agency also responded in a letter from the Administrator to the CASAC chair dated July 25, 2019. In that letter, based on a request from the CASAC for additional expertise, the Administrator announced his intention to identify a pool of non-member subject matter expert consultants to support the CASAC's review activities for the PM and ozone NAAQS. A Federal Register notice requesting the nomination of scientists from a broad range of disciplines "with demonstrated expertise and research in the field of air pollution related to PM and ozone" was published in August 2019 (84 FR 38625, August 7, 2019). The Administrator selected consultants from among those nominated, and input from members of this pool of consultants informed the CASAC's review of the draft PA.

The EPA released the draft PA in September 2019 (84 FR 47944, September 11, 2019). The draft PA drew from the assessment of the evidence in the draft ISA. It was reviewed by the chartered CASAC and discussed in October 2019 at a public meeting held in Cary, NC. Public comments were received via a separate public teleconference (84 FR 51555, September 30, 2019). A public meeting to discuss the chartered CASAC letter and response to charge questions on the draft PA was held in Cary, NC in December 2019 (84

FR 58713, November 1, 2019), and the CASAC provided its advice on the draft PA, including its advice on the current primary and secondary PM standards, in a letter to the EPA Administrator dated December 16, 2019 (Cox, 2019a). In response to the CASAC's comments, the final PA incorporated a number of changes, as described in detail in section I.C.5 of the proposal (85 FR 24100, April 2020). Drawing from his consideration of the scientific evidence assessed in the ISA and the analyses in the PA, including uncertainties in the evidence and analyses, and from his consideration of advice from the CASAC, on April 14, 2020 the Administrator proposed to retain all of the primary and secondary PM standards, without revision. These proposed decisions were published in the Federal Register on April 30, 2020 (85 FR 24094, April 30, 2020). The EPA held virtual public hearings on the proposal on May 20-22, 2020 and May 27, 2020 (85 FR 26634, May 5, 2020). In total, the EPA received more than 66,000 comments on the proposal from members of the public and various stakeholder groups by the close of the public comment period on June 29, 2020. The written public comments, as well as the oral testimony provided at the public hearings, were considered along with the available scientific and technical information and the CASAC's advice by the Administrator in reaching his conclusions about the primary and secondary standards. This timeline allowed for a thorough review that considered the best available science, allowed for independent review by the CASAC and opportunities for participation by the public and met the legal requirements for CASAC review and public participation on NAAQS decisions.

(3) ***Comment:*** Several commenters disagree with the EPA's deviation from the plan outlined in the EPA's 2016 Integrated Review Plan (IRP) which was the EPA document intended to communicate the Agency's plan for reviewing the air quality criteria and the NAAQS for PM. These commenters note that the IRP depicted a process of multiple drafts of the ISA, REA and PA to allow for additional CASAC and public input, consistent with prior review processes, but that the Agency arbitrarily did not follow that approach. Other commenters expand upon this issue by noting that the CASAC approved the original schedule outlined in the IRP. These comments assert that by negating that agreed-upon process (i.e., timeline and multiple drafts of documents), the EPA has disregarded CASAC advice. Further, other comments object to the EPA's failure to inform the CASAC or the public about the changes to the plan and schedule as outlined in the IRP. In the view of these commenters, the lack of transparency in this review, including the changes to the review process and the schedule for the review, undermine the scientific integrity of the process and render the review arbitrary and capricious.

Response: The IRP is a planning document, and while the EPA includes an anticipated schedule for the review as a part of this planning stage, it is often subject to changes throughout the review process and does not bind the Agency. The EPA notes that the IRP contemplated multiple drafts of various document only "as warranted" (U.S. EPA, 2016) and presented only an "anticipated schedule" (U.S. EPA, 2016). To the extent that the EPA departed from the "anticipated schedule" or the overall review approach set forth in the IRP, it was within the Administrator's discretion to do so. The Administrator explained his decision to streamline the NAAQS review process to expedite its completion in an efficient and transparent manner (Pruitt, 2018). Further, although the

CASAC did review and provide comments on the draft IRP, which were considered in finalizing the IRP, any CASAC comments on the IRP concerning schedule and process are not recommendations concerning the NAAQS or the air quality criteria that are addressed by CAA section 109.

(4) ***Comment:*** Many commenters contend that the accelerated schedule adopted in this review of the PM NAAQS resulted in a less rigorous peer review than is required for the draft ISA and draft PA. In particular, these commenters contend that the EPA should have given the CASAC and the public an opportunity to review and provide comments on second drafts of these assessment documents. They assert that by not providing multiple drafts of the ISA and PA, the EPA failed to provide sufficient opportunity for feedback on the key elements of the NAAQS review process. Further, they object to the EPA's approach of developing a draft PA before the ISA was finalized, asserting that the draft PA should have been fully informed by the final version of the ISA. These commenters maintain that changes made to accelerate the EPA's process for reviewing the PM NAAQS undermined the quality and credibility of that process, potentially leading to ill-informed decisions that might negatively impact human health and environmental protection. Other commenters note that the CASAC itself requested that additional drafts of documents key to the process be developed. These commenters note that the Administrator denied the CASAC's request without explanation and has not addressed how his review accounted for this scientific gap. In the view of these commenters, the Administrator's failure to provide the requested opportunity to review and comment on a second draft ISA without explanation and without alternative measures being taken to address the scientific shortfalls the CASAC identified is arbitrary and capricious. Further, the commenters assert that the proposal violates Section 108 by failing to base the decision on "the latest scientific knowledge" and that the failure of the EPA to provide a second external review draft of the ISA compromises the credibility and integrity of the NAAQS review process. The commenters continue to note that many important scientific issues were raised regarding the draft ISA that required revision prior to their interpretation in the PA and that the CASAC never had the opportunity to review the final ISA or PA. Other commenters assert that it was inappropriate for the EPA to commingle the development, review, and finalization of the ISA and PA, such that the draft PA was reviewed before the ISA was finalized.

Response: The EPA disagrees with commenters that the process by which the draft and final ISAs and PAs were completed limited the opportunity for review by and input from the CASAC and the public. As part of NAAQS review, the EPA is committed to allowing sufficient time for input from the public and for advice from CASAC. As described above, as well as in section I.D of the final action, the CASAC reviewed and advised the EPA on the draft ISA and the draft PA. The public also had opportunities to provide written and oral comments on these documents. While the EPA did not prepare a second draft ISA in this review, the advice of the CASAC and public comments were considered by the EPA in finalizing the ISA, as described in detail in the proposal (85 FR 24100, April 30, 2020). With regard to the CASAC's request to review a second draft ISA, the Agency's responses to these recommendations were described in a letter from the Administrator to the CASAC chair (Wheeler, 2019). Moreover, the CASAC advice and

public comments on the draft ISA, including the revisions to the ISA to address this input, were considered in the development of the draft PA. Finally, as detailed in section I.D of the final action, the EPA has provisionally considered "new" studies raised by the commenters in the context of the findings of the ISA (see Appendix A of this RTC). Overall, the EPA's provisional consideration of "new" studies concludes that, taken in context, the "new" information and findings do not materially change any of the broad scientific conclusions regarding the health and welfare of effects of PM in ambient air made in the air quality criteria. The CASAC advice and public comments on the draft PA were considered in finalizing the PA, as described in sections 3.4, 4.3, and 5.3 of the PA and in the proposal (85 FR 24094, April 30, 2020, see sections II.C.2, III.C.2, and IV.D.2). Furthermore, with regard to the commenters' assertion that a single draft of the ISA did not meet the requirements of section 108 of the CAA, the EPA notes that there is no requirement to prepare more than one external review draft of the supporting documents in a review, nor is there a requirement that science assessment must be finalized prior to developing policy options in a review. Several previous NAAQS reviews have established precedent for single drafts of the PA (e.g., the lead and SO_2 NAAQS reviews completed in 2016 and 2018, respectively). The evaluation of the science and policy often overlap in Agency rulemakings or other actions, and such overlap does not impede the EPA's ability to separate or distinguish policy from science. The EPA also notes that, in addition to public comment periods for the draft ISA and draft PA, the public had the opportunity to provide written comments on the proposal, as well as to provide oral testimony at the multiple public hearings that were held on the proposed decision. For all of these reasons, the EPA disagrees with the commenters that the lack of more than one external review draft of the ISA and PA resulted in limiting the CASAC or the public's opportunity for input in this review or that the timeline during which these documents were developed compromised the EPA's science and policy assessments in this review.

(5) ***Comment:*** Commenters state that, in keeping with previous NAAQS review processes, the EPA should have developed a separate Risk and Exposure Assessment (REA) document. These commenters contend that the absence of a separate REA inappropriately minimizes how risk informs policy determinations. One individual CASAC member asserts that "[r]eview of an updated risk assessment may lead to different policy recommendations on the current annual and 24-hour $PM_{2.5}$ standards".

Response: As noted above, while the scientific review process here may have differed in format from previous PM 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 PM and the adequacy of the existing standards. 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 does not require a separate document for quantitative risk and exposure analyses as a part of the review of a NAAQS. Integration of quantitative analyses, including those focused on human exposure and health risk, environmental exposure and various welfare effects, in the PA is consistent with other reviews (e.g., 2015 primary NO_2 review, 2016 lead review, current O_3 review) in which the risk and exposure analyses, along with other relevant

quantitative information and analyses were included as a part of the PA. The health-based $PM_{2.5}$ risk assessment approach is summarized, and the policy-relevant considerations of these analyses are described in Chapter 3 of the final PA (U.S. EPA, 2020). Appendix C of the PA presented a more detailed explanation of the risk assessment methodology, analysis of uncertainty, and results (U.S. EPA, 2020). The quantitative analyses of visibility impairment and their implications for the welfare-based PM standards are summarized and described in Chapter 5 of the final PA, with greater detail provided in Appendix D (U.S. EPA, 2020). The CASAC provided advice on the risk assessment and quantitative analyses, as did several public commenters, in reviewing the draft PA. Therefore, we disagree with the commenter that a separate REA is required to allow for a technically rigorous analysis of risk or a well-informed review by the CASAC and input from the public.

(6) ***Comment:*** Several commenters express concern about the absence of a provisional assessment, suggesting that this means that the EPA only considered the scientific information available before January 2018, and therefore, the CAA Section 108 obligation to reflect the latest science was not met. In the view of these commenters, the EPA must at least consider these later studies, then issue a supplemental proposal, or, as in past reviews, prepare a Provisional Assessment and make that assessment available for public comment, to give the public an opportunity to comment on the agency's consideration of these studies. Other comments highlight that the CASAC majority selectively relied on some post-January 2018 studies in their comments on the ISA and PA, while ignoring others. These comments observe that the EPA then relied on CASAC advice to set the standard and concluded that it is arbitrary and capricious to selectively consider some newer studies and not others.

Response: Some public comments on the proposed decision in this review have referred to, and in some cases, discussed publications that were not included in the ISA. As explained in more detail in section I.D of the Federal Register notice describing the final decision in this review, the EPA has provisionally considered the cited studies in the context of the findings of the ISA. A list of these peer reviewed publications cited in public comments related to the primary and secondary standards are listed in Appendix A below. The EPA has provisionally considered these "new" studies identified by commenters and concluded that none of the studies materially change any of the broad scientific conclusions of the ISA regarding the health and welfare effects of PM or warrant reopening the air quality criteria for this review. The decision to rely on studies and related information included in the ISA and PA, which have undergone CASAC and public review, is consistent with the EPA's practice in prior NAAQS reviews and its interpretation of the requirements of the CAA. Under section 109(b) of the Act, primary and secondary NAAQS are to be based on the air quality criteria issued under section 108, and the EPA must periodically conduct a "thorough review" of the criteria under section 109(d), taking into account the advice and recommendations of the CASAC, as the basis for periodic decisions on whether revisions of NAAQS are appropriate. When Congress enacted the latter requirement in 1977, it was well aware that implementation of the NAAQS can have profound economic and social, as well as environmental, consequences. Understandably, it required that the Administrator's periodic decisions on whether to revise the NAAQS be based on scientific studies that had been rigorously

assessed and incorporated into air quality criteria, and whose implications for public health and welfare had been carefully considered by both the EPA and the CASAC. In practice, there is a necessary delay between completion of a criteria document and a final decision on whether to revise the corresponding NAAQS; studies published after completion of the criteria document are ordinarily considered in the next round of review. Otherwise, review and revision of criteria documents would be an endless process because of the continuous need to incorporate new studies, and decisions on whether to revise the standards would never be made. Further, the EPA has not typically provided an opportunity for the public to comment on the provisional consideration and did not do so for the provisional assessment prepared for the 2012 review of the PM NAAQS.

B. Clean Air Scientific Advisory Committee (CASAC)

(1) ***Comment:*** Numerous commenters disagree with the process that the EPA used to establish the CASAC in this review. These commenters cite to the EPA's policy on eligibility for serving on an advisory panel, stating that this policy bars certain scientists from serving on these committees, and reference recent court decisions in which multiple courts which have cast doubt on the legality of this policy. In particular, these commenters disagree with the EPA's policy to prohibit scientists that receive EPA grants from concurrently serving on advisory committees and assert that this decision undermines the scientific credibility of the review and that the revised selection criteria biased the membership of the CASAC towards those individuals who would support stringent standards. Based on these issues, some commenters conclude that the Administrator's reliance on certain CASAC recommendations during this NAAQS review was unlawful and arbitrary because the Agency illegally limited the pool of potential appointees when selecting most of the members. Further, commenters suggest that the EPA should have recognized the value of staggered terms for chartered CASAC members given the steep learning curve associated with providing scientific advice for a NAAQS review. These commenters note that established Science Advisory Board (SAB) criteria for advisory panels call for "continuity of knowledge." These commenters additionally note that only one CASAC member had prior experience with a NAAQS review and that member was particularly critical of the process used in this review.

Response: The process by which the chartered CASAC was established was proper and met all applicable CAA and Federal Advisory Committee Act (FACA) requirements and was consistent with 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 and had expertise across a broad range of disciplines, including: health and environmental risk analysis; air quality modeling; pulmonary medicine; toxicology; air pollution engineering; and biochemistry and molecular carcinogenesis.[3] 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. In any event, the grants portion of the directive was never applied to exclude any person from membership on the chartered CASAC. 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 the EPA grants states that it 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). 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, as the commenter notes, 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.

(2) ***Comment:*** Numerous commenters assert that the chartered CASAC does not have the expertise necessary and is not qualified to provide a comprehensive and holistic review of the scientific criteria as required under Section 108 of the CAA. Commenters criticize the EPA for disbanding the CASAC PM Review Panel established at the beginning of this review of the PM NAAQS, citing to previous reviews where the chartered CASAC has been supplemented by review panels that include scientific experts representing a broad range of disciplines, in particular highlighting that these panels generally included multiple epidemiologists. They express concern that the chartered CASAC, even when supplemented by a pool of subject matter experts appointed by the Administrator for consultation during their review of these documents, does not have the breadth and depth of scientific expertise necessary to provide a thorough review of the scientific evidence for PM-related health and welfare effects and the adequacy of the current standards. These commenters specifically note the lack of epidemiologists among the chartered CASAC and the subject matter experts. Other commenters argue that the EPA placed too much weight on geographic location and affiliation, instead of scientific expertise and coverage of key scientific disciplines, especially epidemiology, in its revised appointment criteria. These commenters conclude that this decision resulted in a panel that was unqualified to provide thorough and accurate advice to the Administrator. Many

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

commenters point out that the CASAC itself acknowledged that "the breadth and diversity of evidence to be considered exceeds the expertise of the statutory CASAC members." In the view of these commenters, in light of this alleged lack of qualification, the recommendations of the CASAC and the non-member consultants would not provide a basis for any judicial deference in a legal challenge to the proposed action and further assert that the Administrator's decision to appoint such non-member consultants was arbitrary and unlawful. Finally, other commenters assert that the CASAC's lack of expertise was exacerbated by the fact that only six CASAC members participated in the review of the PM Policy Assessment as opposed to the seven-member panel required by the CAA and note that the CASAC was unable to provide a consensus recommendation for the EPA.

Response: 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 EPA policy and procedure as outlined in the CASAC Charter. 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 seven-member chartered CASAC meets these statutory requirements and had expertise across a broad range of disciplines, including: health and environmental risk analysis; air quality modeling; pulmonary medicine; toxicology; air pollution engineering; and biochemistry and molecular carcinogenesis.[4] The CAA does not require an epidemiologist on the review committee, and it would be unreasonable to expect that the broad reaching range of topic areas included when considering the air quality criteria for a given NAAQS pollutant (U.S. EPA, 2019) to be explicitly and comprehensively represented by the seven-member chartered CASAC itself. This does not prohibit or compromise a complete and thorough review of the air quality criteria as defined in Section 108(a)(2) of the CAA.

In its review of the draft ISA, the chartered CASAC recommended "that the EPA reappoint the previous CASAC PM panel (or appoint a panel with similar expertise" (Cox, 2019b). The Agency's response to this advice was provided in a letter from the Administrator to the CASAC chair dated July 25, 2019 (Wheeler, 2019). In that letter, the Administrator announced his intention to identify a pool of non-member subject matter expert consultants to support the CASAC's review activities for the PM and ozone NAAQS. A Federal Register notice requesting the nomination of scientists from a broad range of disciplines "with demonstrated expertise and research in the field of air pollution related to PM and ozone" (84 FR 38625, August 7, 2019). The Administrator selected consultants from among those nominated, and input from members of this pool of

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

consultants informed the CASAC's review of the draft PA. The non-member consultants had 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; and environmental and genetic epidemiology.[5] This approach represents a modification of the process used in past reviews. Rather than having additional experts participate on a specialized CASAC panel providing advice to the chartered CASAC, as has been common in other NAAQS reviews in the past, in this review, a pool of additional subject matter expert consultants provided advice to CASAC through the use of specific questions regarding aspects of the documents being reviewed, providing CASAC subject matter expertise in written responses to their questions. These written responses contributed to the CASAC's review of the draft PA in a focused, efficient, and transparent manner, and were included as an attachment to the CASAC's final report to the Agency on its review of the draft PA (Cox, 2019a). 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 subject matter experts as in this review, goes beyond the requirements of the Act.

With regard to the commenters' assertion that the review of the draft PA by six of the seven CASAC members further exacerbated the lack of expertise on the panel, we note that the CAA does not require each and every member of the seven-member chartered CASAC to participate in every aspect of the NAAQS review process. In this case, the seventh CASAC member was unable to participate in the NAAQS review due to scheduling constraints. In the absence of an explicit statutory requirement that all seven chartered CASAC members participate in a NAAQS review, and given the timeline for completion of this review, the Agency found it to be reasonable to proceed with the review of the draft PA with six members of the chartered CASAC, which in the EPA's view constitutes a quorum of the committee. This is not the first instance when a chartered CASAC member was unable to participate in a review. At the time of the review of the draft REA and draft PA for the primary SO_2 NAAQS review, one chartered CASAC member was recused from the reviews and did not participate.

Finally, with respect to the comment highlighting the absence of a consensus recommendation from the CASAC, the EPA notes that section 109(d)(2)(B) of the CAA only requires the CASAC to "complete a review of the criteria … and the national primary and secondary ambient air quality standards … and [to] recommend to the Administrator any new … standards and revisions of the existing criteria and standards as may be appropriate …" It does not require the CASAC to reach consensus on the criteria or the standards. There have been previous NAAQS reviews where the CASAC did not reach consensus (e.g., 1997 PM NAAQS review).

(3) ***Comment:*** In light of the concerns listed above with the CASAC, some commenters recommend that the EPA disregard the advice of the CASAC and instead heed the advice

[5] Biosketches for the consultants are available at: *https://yosemite.epa.gov/sab/sabproduct.nsf/987D80B31DBC5CBE852584780063FD83/$File/consultant+biosketches.pdf*.

of the Independent PM Review Panel, a group of former CASAC members who provided written comments on the draft PA. The commenters believe that this group of individuals is more qualified to provide a review of the "latest scientific knowledge" as required by Section 108.

Response: The EPA notes that the review of the air quality criteria and the standards by the seven-member chartered CASAC was consistent with the statutory requirements on the CAA. All public comments received on the draft ISA and draft PA were considered, along with CASAC advice, in finalizing those documents, and all public comments on the proposed decision were considered in reaching the final decision in this review, including those comments submitted by the Independent PM Review Panel.

(4) ***Comment:*** One commenter asserts that the chartered CASAC made statements that were out of step with the wider scientific community when expressing their views of how epidemiological evidence was evaluated and applied in the current review. This commenter further claims that the chartered CASAC engaged in "cherry picking" of the evidence in order to obstruct and obfuscate in such a manner as to create the impression that the scientific information cannot reliably be known. Additionally, they add that the chartered CASAC also "cherry picked" the most favorable written opinions from the ad hoc panel of consultants. Some commenters criticize the EPA's reliance on CASAC advice contending that the CASAC's lack of expertise and the revisions to the review process interfered with the CASAC's ability to provide adequate and scientifically sound advice such that the EPA's reliance on that advice undermines the basis for the EPA's final decision. Further, these commenters note that the proposal relies heavily on CASAC recommendations with respect to uncertainty in PM health benefits below the current NAAQS, but the CASAC's letter states this recommendation is hindered by "limitations in the underlying science basis for making policy recommendations" due to deficiencies in the draft ISA. Finally, these commenters state that the EPA cited scientific uncertainty as its justification for leaving the standards unchanged but that this purported uncertainty does not reflect a careful evaluation of the science, but rather the Agency's own decisions to limit its expertise in its revised process.

Response: In reaching final decisions on the primary and secondary PM NAAQS, the EPA has taken into account information and assessments presented in the ISA and PA, the advice from the CASAC, and public comments. The EPA notes, as explained elsewhere in this RTC, that the CASAC met all of the statutory requirements for the scientific review committee identified in CAA 109(d) and also that the CASAC was given access to – and made use of – a wide array of additional expertise through an additional pool of consultants. Thus, the EPA disagrees that the CASAC lacked the ability to provide scientifically sound advice. The preamble to the final rule explains the EPA's rationale for the decision to retain the NAAQS and specifies how that decision took into account CASAC advice on the standards. The EPA notes that on some issues the CASAC did not provide unanimous advice, and the EPA could not, and does not, rely on or agree with every aspect of advice provided by the CASAC. Further, as is evident from the rationale presented in the preamble, the EPA agreement with a general conclusion of some or all members of CASAC does not necessarily mean that the EPA agrees with all aspects of the CASAC's rationale for such general conclusions.

(5) ***Comment:*** Commenters contend that the EPA ignored and completely dismissed CASAC advice concerning consideration of scientific information in the draft ISA and the draft PA.

Response: The EPA disagrees with the commenter that the EPA ignored CASAC advice regarding scientific information in the draft ISA and the draft PA. As the commenter notes, the EPA has discretion to determine how to address comments from the CASAC. In the final ISA, the EPA notes the process by which they addressed CASAC comments considering the accelerated timeline they were under based on the Administrator's directive. The Administrator responded to the CASAC's letter on the External Review Draft of the PM ISA on July 25, 2019, and indicated the Agency will "incorporate the CASAC's comments and recommendations, to the extent possible, and create a final PM ISA so that it may be available to inform a proposed decision on any necessary revisions of the NAAQS in early 2020." The EPA focused on addressing comments presented in the main body of the CASAC letter (i.e., the cover letter and consensus responses to charge questions), and to the extent possible, addressed individual CASAC member comments as well as public comments on the draft PM ISA. The consensus CASAC comments on the draft PM Policy Assessment (December 16, 2019) stated "…the Draft PM ISA, does not provide a … comprehensive, systematic review of relevant scientific literature; inadequate evidence and rationale for altered causal determinations; and a need for clearer discussion of causality and causal biological mechanisms and pathways." To address these comments in the Final PM ISA, the EPA: (1) added text to the Preface and developed a new Appendix to more clearly articulate the process of ISA development; (2) revised the causality determination for long-term UFP exposure and nervous system effects to suggestive of, but not sufficient to infer, a causal relationship; and (3) added additional text to the Preface (Section P.3.2.1) as well as text in the health effects chapters to clarify the discussion of biological plausibility and its role in forming causality determinations.

In the final PA, the EPA detailed the changes that were made in response to the CASAC's review of the draft PA (U.S. EPA, 2020). The CASAC specifically recommended that a revised PA include (1) additional discussion of the current CASAC and NAAQS review process; (2) additional characterization of PM-related emissions, monitoring and air quality information, including uncertainties in that information; (3) additional discussion and examination of uncertainties in the $PM_{2.5}$ health evidence and the risk assessment; (4) updates to reflect changes in the ISA's causality determinations; and (5) additional discussion of the evidence for PM-related welfare effects, including uncertainties (Cox, 2019a). The EPA incorporated a number of changes into the final PA to address these recommendations, including (1) adding text to clarify the process for this review of the PM NAAQS and how the process evolved since the initiation of the review; (2) adding text and figures on emissions of PM and PM precursors, as well as a discussion of uncertainty in emissions estimations and measurement uncertainty for FRM, FEM, CSN, and IMPROVE monitors; (3) edits to reflect changes to the causal determination for long-term ultrafine particle exposures and nervous system effects in the final ISA; (4) expanding the characterization and discussion of the evidence related to

exposure measurement error, the potential confounders examined by key studies, the shapes of concentration-response functions, and the results of causal inference and quasi-experimental studies; (5) providing additional detail on the procedure used to derive concentration-response functions used in the risk assessment; and, (6) adding summaries to each of the chapters on the CASAC advice on the PM standards and expanding the discussions of the data gaps and areas for future research in the available evidence.

C. Other Comments

(1) ***Comment:*** Multiple commenters assert that the failure to adequately consider the impact of changes in emissions over time undercuts the Administrator's final decisions regarding the adequacy of the current standards. Some commenters point to improvements in recent air quality driven by emissions reductions over time that demonstrate that a more stringent PM NAAQS is not necessary. Other commenters state that the impacts of climate change, including frequent droughts and wildfires, support consideration of a more stringent standard to ensure a greater level of public health protection.

Response: The EPA disagrees with commenters that reductions in emissions are relevant to judging the adequacy of the existing standards. The goal of a NAAQS review is to determine whether the current standards are requisite to protect public health and welfare, irrespective of whether air quality in specific locations is above or below those standards or whether emissions are increasing or decreasing. While the EPA does examine recent air quality conditions as part of its evaluation of the public health burden associated with ambient air pollution, decisions about what level is requisite for the NAAQS rests on the Administrator's careful consideration of the lines of scientific evidence available in each review, including toxicologic, controlled human exposure, and epidemiological information. Furthermore, the EPA disagrees with commenters that the separate challenge of climate change necessitates an adjustment to the level of the PM NAAQS. Commenters do not make an argument that climate change increases vulnerability to exposure to fine or coarse particles. Rather, they claim only that climate change is likely to increase PM emissions; even if this is true, it relates only to the relative ease or difficulty an area may have in attaining or maintaining the NAAQS, not the level at which the standards must be set to provide requisite protection.

(2) ***Comment:*** Numerous commenters highlight emerging evidence that suggests that $PM_{2.5}$ exposure is associated with increased risk of COVID-19 mortality. These commenters point to a number of recently published studies from across the world that examine the association between long-term $PM_{2.5}$ exposure and associations with COVID-19 health outcomes. Given the extent and urgency of the global pandemic, the commenters contend that the Administrator should consider these findings when setting the primary $PM_{2.5}$ standards. Some commenters additionally point to the potential for specific groups of people, identified as at-risk populations for $PM_{2.5}$-related effects by the EPA (i.e., people of color), to be disproportionately affected by COVID-19. Other commenters cite the same evidence, but suggest that the relationship between $PM_{2.5}$ mortality and COVID-19 is either non-existent or is based on preliminary research.

Response: There are many variables related to COVID-19 health outcomes, and, as COVID-19 is an emerging disease, there are still many unknowns. Understanding the links between air pollution exposure and COVID outcomes is a complicated process that will take many years. The research in this area is new and emerging. As discussed in section I.D of the preamble to the final rule, the EPA has provisionally considered studies that were highlighted by commenters and that were published after the ISA. These studies are generally consistent with the evidence assessed in the ISA, in particular those studies that evaluated associations between PM exposures and respiratory illnesses and diseases, and they do not materially alter our understanding of the scientific evidence or the Agency's conclusions based on that evidence or warrant reopening of the air quality criteria. The EPA will consider these new studies for inclusion in the air quality criteria for the next PM NAAQS review, along with future studies related to this topic, including studies related to at-risk populations.

(3) ***Comment:*** Some commenters contend that, where there is scientific uncertainty, the CAA mandates that the EPA err on the side of protecting public health. Some commenters include this in their comments as a part of their overall rationale for revising the current standards, while others point to specific scientific uncertainties in the health effects evidence, including those associated with COVID-19. These comments point to *Am. Trucking Ass'ns*, 283 F.3d at 369 (citing CAA section 109(b)(1)'s "margin of safety requirement was intended to address uncertainties associated with inconclusive scientific and technical information ... as well as to provide a reasonable degree of protection against hazards that research has not yet identified") as support for the Administrator to consider whether a revised NAAQS standard is necessary to protect human health. Additionally, in comments on the secondary PM standards, commenters assert that the EPA did not consider the implications of retaining the current secondary PM standards or if further protection is warranted until uncertainties associated with visibility impairment are resolved.

Response: The EPA acknowledges that primary NAAQS must be set with an adequate margin of safety to address uncertainties, but disagrees that primary NAAQS must be set to protect against all uncertain risks. The CAA does not require the Administrator to establish a primary NAAQS at a zero-risk level, *see Lead Industries Ass'n v. EPA*, 647 F.2d at 1156 n.51, *Mississippi v. EPA*, 744 F.3d at 1351. The Administrator is required to exercise his judgment in the face of scientific uncertainty to establish the NAAQS to provide appropriate protection against risk to public health and welfare, both known and unknown. As discussed in the final action, the Administrator judges that the existing primary and secondary PM NAAQS are requisite to protect public health and welfare with an adequate margin of safety, a judgment that is consistent with the CASAC's conclusions that the available scientific evidence and technical information do not call into question the adequacy of the primary and secondary PM standards and that the standards should be retained. Further, in sections II.B.4, III.B.4, and IV.B.4 of the final action, the Administrator has provided a thorough explanation for his rationale for concluding that the current primary and secondary standards are requisite to protection public health and welfare with an adequate margin of safety, explaining the various scientific uncertainties in this review, and how he exercised his "judgment" (per section

109(b)(1) of the CAA) in concluding that the current standards should be retained.

(4) ***Comment:*** The EPA received a number of comments specifically related to potential implications of a revised NAAQS with respect to implementation of the standard. Comments include the following topics: (1) the socioeconomic consequences of implementation of a more stringent NAAQS; (2) the implications of PM background in dispersion modeling for permitting; (3) the ability of the monitoring network to capture peak PM levels; (4) the degree to which federal equivalent method (FEM) $PM_{2.5}$ monitors should be used; (5) redesigning the CSN and IMPROVE networks; (6) initiation of monitoring of UFP now to inform future NAAQS reviews assumptions to inform and approaches used for modeling; (7) augmenting the PM monitoring network; (8) the availability of monitoring data and the use of continuous FEM monitors for tracking visibility; and, (9) issues with the coverage, accuracy, and relationship of CSN filter samples to the standard.

Response: In setting primary and secondary standards that are "requisite" to protect public health and welfare, respectively, as provided in section 109(b), the EPA's task is to establish standards that are neither more nor less stringent than necessary. In so doing, the EPA may not consider the costs of implementing the standards. See generally *Whitman v. American Trucking Associations*, 531 U.S. 457, 465-472, 475-76 (2001). Likewise, "[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 Corporation v. EPA*, 936 F.3d 597, 623-24 (D.C. Cir. 2019). As such, the Administrator has not considered implementation costs in his decision. Since the standard is not being modified in this action, there will be no corresponding PM NAAQS implementation rule. With respect to comments related specifically to air quality monitoring, the EPA is actively engaged in ways to improve the measurements and will provide updates on those efforts to our State, local, and tribal partners through our partnerships with multi-state and tribal monitoring forums. The EPA did not propose and is not making any changes to monitoring requirements in this action.

(5) ***Comment***: One commenter asserted that the EPA must consult under Section 7(a)(2) of the Endangered Species Act ("ESA") with the U.S. Fish and Wildlife Service and the National Marine Fisheries Service when reviewing and revising the PM NAAQS.

The commenter claims that without consultation, the EPA cannot ensure that any final standard is not likely to jeopardize the continued existence of any endangered or threatened species or result in the destruction or adverse modification of critical habitat and further states that Section 7 "consultation" is required for "any action [that] may affect listed species or critical habitat." The commenter asserts that agency "action" is broadly defined in the ESA's implementing regulations at 50 CFR 402.02 to include:

> "all activities …of any kind …carried out, in whole or in part, by Federal agencies in the United State[sic] …. Examples include, but are not limited to: … (b) the promulgation of regulations; … or (d) actions directly or indirectly causing modifications to the land, water, or air."

The commenter also notes that ESA regulations at 50 CFR 402.03 provide that section 7 applies to all actions in which there is discretionary Federal involvement or control 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 argues that the protection of listed species and critical habitat is required in reviewing the secondary NAAQS 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 claims that that the protection of listed species and critical habitat is required in reviewing the primary NAAQS 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 commenter cites the 2018 NO_X/SO_X/PM ISA and the 2009 PM ISA in detailing the adverse ecological effects of PM. The commenter also notes animal toxicological studies in the 2019 PM ISA regarding the concept that PM affects lung growth in mice and that the EPA should extrapolate that study to other species in the same family or order, including listed rodent species.

The commenter also cites to a USFW-NMFS study on nitrogen pollution regarding alleged harm from nitrogen pollution, which includes $PM_{2.5}$ substances such as nitrates including ammonium nitrate, for at least 78 federally protected species and discusses several other species that may be harmed by PM.

Response: 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.[6] Both the Code of Federal Regulations and the status quo regarding 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 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 PM NAAQS were found to be an "action" for ESA purposes, the EPA's decision to leave the PM 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.

Further, even if the ESA consultation requirement applied to the EPA's review of the secondary NAAQS for ecological welfare effects, the ESA would not apply to this review because the EPA's review of the secondary PM NAAQS has been bifurcated, and ecological effects of PM deposition, including effects on species and habitats, are not a part of this review. Rather, this review addresses non-ecological welfare effects. The

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

ecological effects of PM deposition are beyond the scope of this review. As explained in both the PM IRP (U.S. EPA, 2016) and the NO_X/SO_X/PM IRP (U.S. EPA, 2017) and discussed in the preamble to the proposed rule, in recognition of the linkages between oxides of nitrogen, oxides of sulfur, and PM with respect to atmospheric chemistry and deposition, and with respect to ecological effects, the reviews of the ecological effects evidence and the secondary standards for these pollutants are being conducted together. Addressing the pollutants together enables the EPA to take a comprehensive look at the nature and interactions of the pollutants, which is important for ensuring that all scientific information relevant to ecological effects is thoroughly evaluated. Conducting the PM NAAQS review in two separate phases is eminently reasonable and supported by considerations of atmospheric science.

Finally, the EPA does not believe it is necessary or appropriate to consider PM impacts on species and habitats as part of this review of the primary 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. Rather, even assuming the ESA consultation requirement could apply to a decision to revise the NAAQS, which is not the decision in this review, these impacts on species and habitats should be evaluated in reviewing the secondary NAAQS, insofar as such evaluation is needed. As the commenter notes, the definition of effects on welfare in CAA section 302 clearly encompasses effects on animals and vegetation. Thus, any evaluation of these PM effects on species and habitats would be done in the context of setting and reviewing the secondary standard.

Similarly, 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 EPA finds those effects would fall within the scope of the review of the secondary standard. In considering the public welfare protection provided by the secondary NAAQS, the Administrator considers the potential for welfare effects to occur and the associated public welfare implications of those effects. In assessing public welfare implications, the Administrator considers the value placed by the public on the welfare effects that are being evaluated. The commenters' assertion that there are people who place great value on the continued existence of a particular species would, therefore, be most relevant in assessing public interest in such an effect and fall within the scope of the review of the secondary standard. Furthermore, the EPA would be unable to consider how effects on species can affect people without assessing the effects on species, which is done as part of the secondary review. Thus, any such effects on people are beyond the scope of this review. In addition, the EPA finds that, even if such effects were within the scope of this review, the EPA lacks sufficient information in the

air quality criteria to base a standard on these effects. The commenter has not submitted published studies that might support consideration of effects on people, such as long-term stress, attributable to the effects on species, nor has the CASAC provided advice in this area.

(6) ***Comment***: Some commenters state that the proposed decision does not adequately consider environmental justice (EJ) and equity concerns as stipulated by Execute Order (E.O.) 12898. Specifically, some commenters state that the EPA has not demonstrated that consideration of at-risk groups fulfills its obligations under E.O. 12898, particularly in light of the commenters' assertion that low-income communities and communities of color, including the American Indian Community, disproportionately suffer adverse health and environmental effects as a result of the Agency's policies. Commenters also claim that the EPA's failure to set a PM NAAQS that protects sensitive subpopulations is irrational and a violation of legal requirements under E.O. 12898. Lastly, they add that the EPA did not prepare a Regulatory Impact Assessment (RIA), an analysis that would highlight EJ issues associated with exposure to PM levels in sensitive groups and minority populations.

Response: Section 109(b)(1) of the CAA defines primary standards as ones "the attainment and maintenance of which in the judgment of the Administrator, based on such criteria and allowing an adequate margin of safety, are requisite to protect the public health."[7] In addressing the requirement for an adequate margin of safety, the EPA considers such factors as the nature and severity of the health effects involved, the size of the sensitive population(s), and the kind and degree of uncertainties. This rule reaffirms the current PM NAAQS and is not expected to have disproportionate negative impacts on minority or low-income populations. As discussed in section II.A.2.b and section V. K of the preamble to the final rule, the EPA expressly considered the available information regarding PM exposure and health effects among sensitive populations, including populations that are of low socioeconomic status and nonwhite populations, in making its determination to retain the PM NAAQS. In accordance with E.O. 12898, the EPA has concluded that the decision to retain the existing primary PM standards, without revision, is not expected to have disproportionate negative impacts on minority or low-income populations or on indigenous peoples. 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 PM. Thus, to the extent that the public health burden of PM air pollution is disproportionately affecting minority or low-income populations, reaching attainment with existing standards will effectively reduce that disparity.

The commenter has provided no evidence that the current PM standards result in a disproportionate impact on the American Indian community, or that revision would

[7] The legislative history of section 109 indicates that a primary standard is to be set at "the maximum permissible ambient air level . . . which will protect the health of any [sensitive] group of the population," and that for this purpose "reference should be made to a representative sample of persons comprising the sensitive group rather than to a single person in such a group." S. Rep. No. 91-1196, 91st Cong., 2d Sess. 10 (1970).

ameliorate any such disproportionate impact that may exist, and the EPA is not aware of such evidence. However, the EPA notes that a standard providing protection for populations identified as at-risk also provides provide protection for other groups.

To the extent any of the commenters is suggesting E.O. 12898 requires a RIA, the EPA disagrees. Because this action does not change the existing PM NAAQS, it does not impose costs or benefits relative to the baseline of continuing with the current NAAQS in effect. Thus, the EPA has not prepared a RIA for this action.

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APPENDIX A: Studies cited in public comments related to the PM standards that were not included in the 2019 ISA and are provisionally considered in responding to the comments

This appendix includes those studies cited in public comments or otherwise identified by the EPA while responding to comments related to the PM standards that were not included in the 2019 ISA (i.e., published after the literature cutoff date for the ISA but would have been considered within the scope of the ISA (U.S. EPA, 2015; U.S EPA, 2019)). These studies were provisionally considered by the EPA, as discussed in section I.D of the preamble to the final rule and in this RTC.

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