

NAAQS Regulatory Review and Rulemaking Coalition

COMMENTS OF THE NAAQS REGULATORY REVIEW & RULEMAKING COALITION ON EPA'S POLICY ASSESSMENT FOR THE RECONSIDERATION OF THE NATIONAL AMBIENT AIR QUALITY STANDARDS FOR PARTICULATE MATTER, EXTERNAL REVIEW DRAFT

DOCKET NO. EPA-HQ-OAR-2015-0072

American Chemistry Council
American Coke and Coal Chemicals Institute
American Forest & Paper Association
American Fuel & Petrochemical Manufacturers
American Petroleum Institute
American Wood Council
Corn Refiners Association
Council of Industrial Boiler Owners
National Cotton Council
National Cotton Ginners Association
National Cottonseed Processors Association
National Lime Association
National Mining Association
National Oilseed Processors Association
Texas Cotton Ginners' Association
U.S. Chamber of Commerce

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**COMMENTS OF THE NAAQS REGULATORY REVIEW & RULEMAKING COALITION
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EXECUTIVE SUMMARY

The United States Environmental Protection Agency (“EPA” or “Agency”) announced earlier this year that it would reconsider its decision in December 2020 to retain the existing suite of National Ambient Air Quality Standards (“NAAQS”) for particulate matter (“PM”).¹ Those standards include an annual primary NAAQS for fine particles (measured as PM_{2.5}) of 12 µg/m³, annual primary and secondary PM_{2.5} NAAQS of 15 µg/m³, 24-hour primary and secondary PM_{2.5} NAAQS of 35 µg/m³ and 65 µg/m³, and 24-hour primary and secondary NAAQS for coarse particles (measured as PM₁₀) of 150 µg/m³.² The Clean Air Act (“CAA” or “Act”)³ requires that, in reconsidering the decision to retain these standards, the EPA Administrator must judge, based on the latest scientific knowledge, whether those standards are requisite to protect public health with an adequate margin of safety and protect public welfare.⁴ The Act does not require the Administrator set NAAQS at a zero-risk level.⁵ To inform the Administrator’s judgment, his professional staff has prepared and released for public comment drafts of both an update to the

¹ Press Release, EPA, *EPA to Reexamine Health Standards for Harmful Soot that Previous Administration Left Unchanged* (June 10, 2021), <https://www.epa.gov/newsreleases/epa-reexamine-health-standards-harmful-soot-previous-administration-left-unchanged>.

² 40 C.F.R. §§ 50.6, 50.7, 50.13, & 50.18.

³ 42 U.S.C. §§ 7401-7671q.

⁴ CAA §§ 108(a)(2), 109(b)(1), (2).

⁵ See *Mississippi v. EPA*, 744 F.3d 1334, 1351 (D.C. Cir. 2013) (per curiam). Although this case pertains specifically to primary NAAQS, the same reasoning should be applicable to secondary NAAQS.

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Integrated Science Assessment (“ISA”)⁶ – a Draft ISA Supplement⁷ – that summarizes the relevant scientific information, and a Policy Assessment (“PA”) – the Draft PA.⁸ – that provides the air staff’s advice to the Administrator on options for regulatory actions he should consider at the conclusion of this reconsideration.

These are the comments of the NAAQS Regulatory Review & Rulemaking (“NR3”) Coalition on the Draft PA. The NR3 Coalition is an ad hoc association of industry groups and companies supportive of NAAQS that provide the requisite protection of public health and welfare and that are implemented in ways that provide that protection, consistent with the economic health of the country.⁹ To summarize briefly:

- The Draft PA is deficient because it fails to consider the advice of the Clean Air Scientific Advisory Committee (“CASAC”).
- For the following reasons, based on the Draft ISA Supplement and the entirety of the rulemaking record, retention of the current suite of primary NAAQS for fine PM, measured as PM_{2.5}, remains a valid, health protective option for the Administrator to consider.
 - More recent scientific evidence confirms conclusions that led EPA, in 2020 to identify retention of these standards as an option.
 - Significant uncertainties and weaknesses remain in the scientific evidence concerning health effects attributable to PM_{2.5} levels in ambient air when the current NAAQS are attained.

⁶ EPA, EPA/600/R-19/188, Integrated Science Assessment for Particulate Matter (Dec. 2019), Doc. ID EPA-HQ-OAR-2015-0072-0212, <https://cfpub.epa.gov/ncea/isa/recordisplay.cfm?deid=347534>, (“2019 ISA”).

⁷ EPA, EPA/600/R-21/198, Supplement to the 2019 Integrated Science Assessment for Particulate Matter (External Review Draft) (Sept. 2021), <https://cfpub.epa.gov/ncea/isa/recordisplay.cfm?deid=352823>, (“Draft ISA Supplement”).

⁸ EPA, EPA-452/P-21-001, Policy Assessment for the Reconsideration of the National Ambient Air Quality Standards for Particulate Matter, External Review Draft (Oct. 2021), <https://www.epa.gov/naaqs/particulate-matter-pm-standards-policy-assessments-current-review-0> (“Draft PA”).

⁹ The NR3 Coalition previously filed comments on EPA’s 2020 proposal to retain the existing NAAQS for particulate matter, *see* Comments of the NAAQS Regulatory Review & Rulemaking Coalition on Review of the National Ambient Air Quality Standards for Particulate Matter: Proposed Action (June 29, 2020), Docket ID. EPA-HQ-OAR-2015-0072-0915 (“NR3 Coalition Rulemaking Comments”), and on the Draft ISA Supplement. *See* Comments of the NAAQS Regulatory Review & Rulemaking Coalition on EPA’s Draft Supplement to the 2019 Integrated Science Assessment for Particulate Matter (External Review Draft, September 2021) (Nov. 29, 2021), Doc. ID. No. EPA-HQ-ORD-2014-0859-0085 (“NR3 Coalition Draft ISA Supplement Comments”).

- Estimates of risks from PM_{2.5} exposure, although highly uncertain, are lower than they were in 2020. Moreover, these estimates overstate possible risk reduction as a result of alternative NAAQS.
- Identification of sensitive (or, “at-risk”) populations has not changed since 2020. New evidence in the Draft ISA Supplement raises additional uncertainties that populations differ in their sensitivity to PM.
- Retention of the present forms for the primary PM_{2.5} NAAQS is appropriate.
- EPA staff have reasonably determined that the entire rulemaking record, including the most recent evidence, does not call into question the adequacy of the current primary NAAQS for coarse particles, measured as PM₁₀, to protect public health.
- EPA staff have appropriately recommended, based on the entirety of the rulemaking record, that the Administrator consider retention of the current secondary PM NAAQS.

I. Introduction

Members of the NR3 Coalition and their member companies are committed to reducing emissions as necessary, and consistent with the requirements of the Act, to provide air quality protective of public health and welfare, while continuing to facilitate economic growth in the United States. Our industries have worked for many decades with EPA, states, and local authorities to lower concentrations of PM, its precursors, and other common pollutants in ambient air. As a result, between 1970 and 2020, emissions of criteria air pollutants have steadily declined, while both U.S. gross domestic product and population have grown.¹⁰

With regard to PM specifically, 24-hour levels of PM₁₀ declined 26 percent nationally between 1990 and 2020.¹¹ Between 2000 and 2020, annual average levels of PM_{2.5} fell 41 percent and 24-hour average PM_{2.5} levels fell 30 percent nationally.¹² These reductions of PM in ambient air resulted, in part, from reductions made by companies represented by NR3 Coalition members

¹⁰ See EPA, *Our Nation's Air: Trends Through 2020*, <https://gispub.epa.gov/air/trendsreport/2021/#growth> (last visited Dec. 14, 2021).

¹¹ *Id.*

¹² *Id.*

and members themselves in emissions of direct (primary) PM and of PM precursors. Direct emissions of PM₁₀ declined by 31 percent and those of PM_{2.5} by 38 percent over this period.¹³ Emissions of PM_{2.5} precursors also declined: sulfur dioxide (“SO₂”) by 92 percent, nitrogen oxides (“NO_x”) by 68 percent, volatile organic compounds (“VOC”) by 48 percent, and ammonia (“NH₃”) by 8 percent.¹⁴ Emissions of these pollutants are likely to continue to decline as a result of private sector innovation; existing federal, state, and local programs aimed at reducing emissions; improvements in energy efficiency; and, use of cleaner energy technology.

II. The Draft PA Fails to Consider CASAC’s Advice.

The Act not only requires that the Administrator’s judgment on NAAQS be based on recent scientific knowledge reflected in an ISA,¹⁵ it also charges the Administrator to appoint a committee of independent scientific experts to review that compilation of scientific knowledge.¹⁶ That committee, CASAC, generally reviews and provides advice on revisions to the ISA *before* the release of EPA staff’s recommendations in a PA. Even during the accelerated review leading to the 2020 decision now being reconsidered, CASAC provided its advice on a draft of the ISA in writing several months before a draft PA was produced.¹⁷ In this case, the Draft PA was released well before CASAC had met to discuss the Draft ISA Supplement.¹⁸ CASAC has yet to finalize its advice on the ISA, so the Draft PA clearly does not reflect that advice. By failing to await

¹³ *Id.*

¹⁴ *Id.*

¹⁵ CAA § 108(a)(2).

¹⁶ *Id.* § 109(d)(2)(A) & (B). This Committee is also charged with advising the Administrator on new or revised NAAQS, “as may be appropriate,” and on a variety of other issues related to NAAQS. CAA § 109(d)(2)(B) & (C).

¹⁷ CASAC’s letter on the draft of the ISA is dated April 11, 2019. Letter from Dr. Louis Anthony Cox, Jr., Chair, CASAC, to the Hon. Andrew R. Wheeler, Administrator, EPA (Apr. 11, 2019), EPA-CASAC-19-002, <https://casac.epa.gov/ords/sab/f?p=105:12:13856912016573>. A draft of the PA for that review was not released until September. 84 Fed. Reg. 47944 (Sept. 11, 2019).

¹⁸ *See* 86 Fed. Reg. 56263 (Oct. 8, 2021) (announcing the release of the Draft PA); 86 Fed. Reg. 52673 (Sept. 22, 2021) (announcing CASAC meetings to peer review the Draft ISA Supplement and the Draft PA beginning November 17, 2021).

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CASAC's feedback on the Draft ISA Supplement before preparing the Draft PA, EPA staff have minimized the impact that CASAC's advice on the science has on their recommendations to the Administrator and risks that advice failing to reflect the science accurately. Treating CASAC's advice as an afterthought is contrary to both CASAC's role under the Act and the requirement that the Administrator base NAAQS on the most accurate science.¹⁹

The Act also requires that CASAC provide advice "on the relative contribution to air pollution concentrations of natural as well as anthropogenic activity," and on "any adverse public health, welfare, social, economic, or energy effects which may result from various strategies for attainment and maintenance of such national ambient air quality standards."²⁰ Neither the ISA Supplement nor the Draft PA presents adequate information to allow CASAC to provide this statutorily requested advice.

Background PM air quality, defined in the Draft PA as particles from sources or processes that cannot be influenced by actions within the jurisdiction of concern,²¹ is an important factor that CASAC must consider in advising on these issues. Despite the importance and challenge of estimating current as well as future background PM concentrations, the Draft PA devotes a mere eight of more than six hundred pages to this topic.²² Furthermore, in requesting CASAC's review of the Draft PA, EPA has not asked CASAC a single question that focuses on background concentrations.²³

¹⁹ See CAA § 108(a)(2).

²⁰ *Id.* § 109(d)(2)(C)(iii) & (iv).

²¹ Draft PA at 2-62.

²² See *id.* at 2-62 to 2-70. The Table of Contents of the Draft PA omits this section of the document.

²³ We noted in our comments on the Draft ISA Supplement that neither the 2019 ISA nor the Draft ISA Supplement includes the information CASAC needs to address these issues. NR3 Coalition Draft ISA Supplement Comments at 19-20.

Background PM concentrations are expected to increase relative to domestic anthropogenic emissions as the U.S. continues to implement existing federal, state and local air pollution control programs and industries continue to undertake voluntary actions that reduce emissions into the ambient air. Moreover, a growing number of areas in the U.S. are being impacted more frequently by wildfires and other natural events that dramatically increase PM concentrations.²⁴ In its limited discussion of background air quality, the Draft PM acknowledges, “Invasive species, historical fire management practices, frequency of drought, and extreme heat have resulted in longer fire seasons (Jolly et al., 2015) and more large fires (Dennison et al., 2014) over time.”²⁵ Indeed, Jaffe *et. al.* recently noted that large wildfires are becoming “increasingly common, and smoke from these fires is a national concern.”²⁶ Despite the clear significance of increasing PM emissions from wildfires, the Draft PA has not evaluated the implications of increased PM emissions from this background source for revised standards or for the adequacy of current CAA programs to address prolonged, potentially multi-state, wildfire events that occur with increasing frequency. The inadequate discussion of background air quality in general, and wildfires in particular, in the Draft PA potentially deprives the Administrator of crucial contextual information that he should consider as he evaluates the adequacy of the current, or alternative, NAAQS. Furthermore, without detailed projections of background concentrations from domestic and international sources over time, the Administrator cannot fully evaluate how much of the estimated benefits from lowering the PM_{2.5} standards will be achievable.

²⁴ Earlier this year, the Washington Post reported, “In September [2020], 24 of the world's top 25 most polluted cities [in terms of fine particulate pollution] were in California and Oregon,” a result of wildfires. Hannah Dormido, *et al.*, *Smoke from wildfires wiped out the U.S. pandemic-related clean air gains in 2020*, Washington Post, Mar. 17, 2021, <https://www.washingtonpost.com/climate-environment/2021/03/17/air-pollution-us-wildfires/> (last visited Dec. 14, 2021).

²⁵ Draft PA at 2-64.

²⁶ D.A. Jaffe, *et al.*, *Wildfire and prescribed burning impacts on air quality in the United States*, 70 J. Air & Waste Mgmt. Ass’n 583 (2020).

EPA should remedy this defect by (1) submitting a separate analysis of current and projected background concentrations to CASAC for review and (2) including that analysis in the final PA.

III. EPA Staff Should Continue To Acknowledge that Retention of the Current Suite of Primary PM_{2.5} NAAQS Is a Valid, Health Protective Option Based on the Current Evidence.

In 2020, in their Policy Assessment for Review of the National Ambient Air Quality Standards for Particulate Matter (“2020 PA”),²⁷ EPA staff concluded that, while the available evidence could “reasonably be viewed as calling into question the adequacy of the public health protection afforded by the combination of the current annual and 24-hour primary PM_{2.5} standards,” the Administrator could also conclude that the current suite of standards provided adequate protection of public health if one placed “greater weight on uncertainties and limitations in the evidence and analyses.”²⁸ After considering, *inter alia*, these “staff conclusions and associated rationales,”²⁹ the Administrator determined in 2020 that, “[T]he current annual and 24-hour primary PM_{2.5} standards are requisite to protect public health from fine particles with an adequate margin of safety, including the health of at-risk populations, and . . . retain[ed] the current standards without revision.”³⁰ Now, despite the Draft PA’s recognition that “uncertainties . . . persist from previous reviews,”³¹ and that significant new scientific evidence is lacking from the Draft ISA Supplement,³² the Draft PA no longer acknowledges that retention of the current suite of standards continues to be a viable option.³³ The option of simply retaining the existing primary PM_{2.5} NAAQS should be reinstated when the Draft PA is finalized.

²⁷ EPA, EPA-452/R-20-002, Policy Assessment for the Review of the National Ambient Air Quality Standards for Particulate Matter (Jan. 2020), Doc. ID EPA-HQ-OAR-2015-0072-0237, <https://www.epa.gov/naaqs/particulate-matter-pm-standards-policy-assessments-current-review-0>.

²⁸ 2020 PA at 3-106.

²⁹ 85 Fed. Reg. 82684, 82723 (Dec. 18, 2020).

³⁰ *Id.* at 82718.

³¹ Draft PA at 3-169.

³² NR3 Coalition Draft ISA Supplement Comments at 16-19.

³³ *See* Draft PA at 3-188.

A. The Health Effects Evidence Is Consistent with that Considered in the 2020 PA and Final Rule.

Building on the Draft ISA Supplement, the Draft PA repeatedly explains that the new evidence concerning possible PM_{2.5} health effects is consistent with or confirms the scientific conclusions that underlay the 2020 decision to reaffirm the existing PM NAAQS. Examples include:³⁴

- Studies of long-term PM_{2.5} exposure and mortality “support and extend the evidence base that contributed to the conclusion of a *causal relationship* between long-term PM_{2.5} exposure and mortality.”³⁵
- “Recent evidence . . . provides ‘additional support to the evidence base that contributed to the conclusion of a causal relationship between short-term PM_{2.5} exposure and mortality.’”³⁶
- “Studies evaluated in the [D]raft ISA Supplement support and extend the evidence that contributed to the conclusion of a causal relationship between long-term PM_{2.5} exposure and cardiovascular effects.”³⁷
- The conclusion in the 2019 ISA of a causal relationship between short-term PM_{2.5} exposure and cardiovascular effects is “further supported by recent studies evaluated in the draft ISA Supplement.”³⁸

No meaningful new information that would alter in any critical way the scientific basis for the Administrator’s 2020 decision retaining the NAAQS was included in the Draft ISA Supplement. New studies “confirming” the results of earlier studies do not call into question the basis for that decision when the newer studies suffer from the same weaknesses as the prior studies considered by the Administrator in 2020.

³⁴ The NR3 Coalition does not concur with all of the quoted statements. They are cited solely to illustrate the consistency with the scientific record now with that at the time of the 2020 decision retaining the NAAQS.

³⁵ Draft PA at 3-21, *quoting* Draft ISA Supplement section 3.2.2.2.1 (emphasis in original).

³⁶ *Id.* at 3-29, *quoting* Draft ISA Supplement at 3.2.1.4.

³⁷ *Id.* at 3-32.

³⁸ *Id.* at 3-34 to 3-35.

Those weaknesses continue to include the lack of a transparent, systematic review of the epidemiologic evidence in both the 2019 ISA and the Draft ISA Supplement. In comments on the Draft PA, Dr. Julie Goodman and her colleagues at Gradient explain:³⁹

US EPA’s framework for conducting systematic reviews and making causal determinations has several limitations related to the review protocol itself, the evaluation of study quality and relevance, and the causality framework. One issue is that the protocol lacks sufficient detail. This led to an evaluation that was not conducted in a systematic unbiased, or transparent manner. The protocol should have included well-developed methods for the literature search strategy, study inclusion and exclusion criteria, a process for data extraction and quality control, methods for data analyses; and PM-specific methods for evidence integration and causality determinations.⁴⁰

Dr. Giffe Johnson and his colleagues at the National Council for Air and Stream Improvement (“NCASI”) made similar comments about the lack of a systematic review of the health effects information in the preparation of the 2019 ISA and the Draft ISA Supplement.⁴¹

Specifically:

While the current Particulate Matter Integrated Science Assessment (ISA) does compile a large swath of scientific literature related to the potential health effects from exposure to particulate matter, many, if not most of the critical features of systematic review are absent from the current process. As such, studies presented in the ISA have not been appropriately ranked based on study quality and method veracity. This leads to the reliance on studies that either have disqualifying amounts of uncertainty inherent to their design or are not designed to address the policy relevant question at hand and, in some cases, exclusion of studies from evidence integration

³⁹ Gradient is a risk science consulting firm. These Gradient comments were prepared under the supervision of Dr. Julie Goodman, a Principal at Gradient.

⁴⁰ Gradient, *Gradient Comments on the Policy Assessment for the Reconsideration of the National Ambient Air Quality Standards for Particulate Matter, External Review Draft* (Dec. 13, 2021), at 4 (“Gradient Draft PA Comments”). These comments have been submitted to the rulemaking docket but have not yet been posted.

⁴¹ NCASI is a research organization engaged in conducting research on environmental topics relevant to the forest products industry.

that may be extremely informative for evaluating cause-and-effect relationships between particulate matter and health outcomes.⁴²

The flaws in EPA’s approach to identifying and evaluating relevant studies most directly affect the assessment of the science in an ISA. These flaws bias the assessment towards causal conclusions.⁴³ Because a PA always relies on the information and conclusions in an ISA, , the recommendations contained in a PA will also be biased. For the Draft PA that is the subject of these comments, this means that the Agency is relying on causality determinations from the 2019 ISA and the Draft ISA Supplement that overlook significant limitations and uncertainties in the scientific record, as discussed below. Consequently, the authors of the Draft PA have failed to recognize that these uncertainties and limitations can reasonably be viewed as calling into question the justification for more stringent NAAQS.

1. Uncertainties and Weaknesses Remain in the Scientific Record.

Even without a systematic and transparent review of the scientific evidence, the Draft PA recognizes that many uncertainties and weaknesses identified in previous reviews of the scientific information associating PM_{2.5} exposure with health effects remain.⁴⁴ Indeed, it discusses some of them. For example:

- “[S]tudies evaluating short-term PM_{2.5} exposure and health effects have reported heterogeneity in associations between cities and geographic regions within the U.S.”⁴⁵

⁴² Giffe Johnson, PhD, National Council for Air & Stream Improvement (“NCASI”) to USEPA, Docket ID No. EPA-HQ-ORD-2014-0859-0073, at 2 (Nov. 22, 2021), Doc. ID EPA-HQ-ORD-2014-0859-0076 (“NCASI”). *See also* S.E. Holm, Chief Scientist, American Forest & Paper Association, American Wood Council, Comments on Supplement to the 2019 Integrated Science Assessment for Particulate Matter, External Review Draft, September 2021 (2021 Supplement) at 4 (Nov. 24, 2021), Doc. ID EPA-HQ-ORD-2014-0859-0078 (recommending EPA conduct a systematic review of available studies focusing on study quality, relevance, and risk of bias).

⁴³ Gradient Draft PA Comments at 4.

⁴⁴ Draft PA at 3-169.

⁴⁵ *Id.* at 3-125.

- “[E]pidemiologic studies . . . did not identify particular PM_{2.5} exposures that cause effects”⁴⁶

The Draft PA, however, seems to dismiss other weaknesses and uncertainties that, in fact, are still important. For example, the Draft PA opines, “[A]ssociations . . . are relatively unchanged in copollutant models.”⁴⁷ Gradient explains, however, that copollutant confounding remains a concern:

Although some recent studies have taken into consideration potential confounding by copollutants, others have not, and the evaluation of copollutants itself is subject to methodological issues, such as the mismatch of the copollutant exposure window and mortality, a lack of accounting for collinearity or a nonlinear relationship with PM_{2.5}, and a lack of accounting for temporal variation. In fact, the [Draft] ISA Supplement found that there is some evidence of potential confounding by copollutants in some studies, which is inconsistent with studies evaluated in the 2019 ISA that showed similar results in single and copollutant models.⁴⁸

CASAC PM Panel Member, Dr. Jane Clougherty, shares Gradient’s concerns in her preliminary draft comments on the Draft PA. She emphasizes the challenge of adequately addressing copollutant confounding given the limitations of the spatial scales of current epidemiology studies:

In particular, I have some hesitance regarding *co-pollutant adjustment* and *spatial scale* in the PM_{2.5} epidemiology literature to date.

- There is an assumption throughout the document *that larger studies constitute better epidemiology*, though this is not necessarily the case, as larger studies often have greater exposure misclassification, as compromises are made in estimating exposures across larger populations/ regions.
- Further, these studies are often implemented at larger spatial scales (e.g., 1 km x 1 km or larger), which is much larger than the scale of variance for many important co-pollutants (i.e., NO_x can vary at 100 m or less); as such, studies at

⁴⁶ *Id.* at 3-7.

⁴⁷ *Id.* at 3-128.

⁴⁸ Gradient Draft PA Comments at 8.

larger almost necessarily imperfectly adjust for co-pollutants.

- *P. 3-101 states that “the determination of what spatial scale to use to estimate PM2.5 concentrations does not inherently affect the quality of the epidemiology study.” – I don’t believe this to be quite true. Though larger scales may reasonably capture spatial variation in PM2.5 concentrations, they do not fully capture variation in important co-pollutants, so these studies may well not accurately adjust for co-pollutant exposures.*⁴⁹

Similarly, the Draft PA indicates that the evidence “continues to generally support a linear, no-threshold [concentration-response (“C-R”)] relationship,”⁵⁰ but Gradient explains that the evidence is insufficient to determine whether a threshold exists:

The 2021 draft PA correctly states that, to date, no threshold below which health effects do not occur has been observed in epidemiology studies. However, measurement errors are pervasive in air pollution observational studies . . . which can systematically preclude the ability to detect a threshold, even if one were to exist.⁵¹

In its comments on the Draft ISA Supplement, NCASI also questions whether the available evidence can be used to assess the C-R relationship or the possibility of a threshold.

NCASI notes:

Criteria regarding methods appropriate for threshold detection and non-linearity are needed to evaluate primary lines of evidence that can be useful for generating reliable, non-linear, concentration response curves before conclusions regarding concentration response can be made with certainty.⁵²

⁴⁹ Preliminary Comments from Dr. Jane Clougherty on EPA’s *Policy Assessment (PA) for the Reconsideration of the National Ambient Air Quality Standards for Particulate Matter (External Review Draft – October 2021)*, at 1 (Dec. 2, 2021) (emphases in original), https://casac.epa.gov/ords/sab/f?p=105:19:226329280793:::RP,19:P19_ID:962 (scroll to Meeting Materials).

⁵⁰ Draft PA at 3-48.

⁵¹ Gradient Draft PA Comments at 9.

⁵² NCASI at 7.

Technical comments by Drs. Wonjun Chang and Garrett Glasgow of NERA Economic Consulting further examine whether the evidence can be used to determine the C-R relationship between PM_{2.5} exposure and health effects, specifically mortality. Drs. Chang and Glasgow conclude unmeasured confounding may exist that renders models of C-R relationships unreliable:

[W]e point to evidence within [studies assessing evidence of unmeasured confounding] that suggests that the studies' estimated C-R relationships might still suffer from unmeasured confounding bias, and discuss possible sources of residual bias. We also discuss the limitations in generalizing the direction and magnitude of confounding bias based on these studies as the bias and the effectiveness of adjusting for this bias is largely cohort-specific.⁵³

Gradient has identified numerous uncertainties and biases in several of the epidemiologic studies identified as “key” in the Draft PA, as shown in the table on the next page:⁵⁴

⁵³ W. Chang & G. Glasgow, NERA Economic Consulting, Technical Comments on the Supplement to the 2019 Integrated Science Assessment for Particulate Matter Regarding Controlling for Unmeasured Confounders, at 9 (Nov. 19, 2021), Doc. ID EPA-HQ-ORD-2014-0859-0075.

⁵⁴ Gradient Draft PA Comments at 13, Tbl 4.1.

Table 4.1 Sources of Bias and Uncertainty in Epidemiology Studies of Long- and Short-Term PM_{2.5} Exposure and Total Mortality^a

Sources of Bias and Uncertainty		Long-Term PM _{2.5}		Short-Term PM _{2.5}		
		Turner <i>et al.</i> (2016)	Di <i>et al.</i> (2017a)	Baxter <i>et al.</i> (2017)	Ito <i>et al.</i> (2013)	Zanobetti <i>et al.</i> (2014)
PM _{2.5} Exposure Assessment	Central site monitoring (low spatial resolution)					
	No validation for PM _{2.5} data					
	Temporal variation not accounted for	X				
	Residential mobility not accounted for	X	X	X	NA	X
	No evaluation on multiple exposure windows	X	X	X	X	X
	Personal activity no accounted for (<i>e.g.</i> , time spent indoors)	X	X	X	NA	X
	Mismatch of PM _{2.5} exposure window and mortality		X			
Individual Covariates	No adjustment of individual covariates			NA	NA	NA
	Information bias (<i>e.g.</i> , self-reported covariates)	X	X			
	Temporal variation not accounted for	X	X			
	Unmeasured confounding	X	X			
Ecological Covariates	No adjustment of ecological covariates			NA	NA	NA
	Temporal variation not accounted for	X				
	Residential mobility not accounted for	X	X			
	Unmeasured confounding (<i>e.g.</i> , access to health care, violence)	X	X			
Evaluation of Copollutants	No adjustment of copollutants			X	NA	X
	Central site monitoring (low spatial resolution)					
	No validation for copollutants data	X				
	Temporal variation not accounted for	X				
	Residential mobility not accounted for	X	X			
	Personal activity not accounted for (<i>e.g.</i> , time spent indoors)	X	X			
	Collinearity/nonlinear relationship with PM _{2.5} not addressed/accounted for					
Mismatch of copollutants exposure windows and mortality		X				
Statistical Analyses	Model assumptions not tested/relaxed	X	X	X	X	X
	C-R curves sensitive to <i>df</i> (natural splines)	X		X	X	X
	Nonlinearity not assessed statistically	X				X
	Threshold not assessed	X	X	X	X	X

Notes:

C-R = Concentration-Response; *df* = Degrees of Freedom; PM_{2.5} = Particulate Matter Less Than 2.5 Microns in Diameter; NA = Not Applicable Due to Study Design.

(a) This table summarizes several broad methodological categories where biases and uncertainties could arise in long-term and short-term PM_{2.5} exposure and total mortality studies. Variables considered include exposure assessment, individual-level covariates, ecological covariates, evaluation of copollutants, and statistical analyses. Red shading with an "X" indicates the potential for bias and/or the presence of uncertainty with regard to specific methodological characteristics but does not reflect the magnitude of such a bias/uncertainty on study results. Unshaded cells indicate there are no apparent biases/uncertainties. For example, Zanobetti *et al.* (2014) did not account for potential confounding by copollutants when assessing PM_{2.5} exposure; thus the red shading with an "X" reflects the potential for bias and the presence of uncertainty in this aspect.

In short, critical uncertainties and weaknesses remain in the evidence concerning possible health effects of PM_{2.5}. These remaining uncertainties and weaknesses raise questions about causal associations between PM_{2.5} exposure and health effects. They continue to preclude determination of a C-R relationship for PM_{2.5} and specific effects.

2. Estimated Risks Now Are Lower than in 2020.

The Draft PA acknowledges several sources of uncertainty concerning its updated risk assessment.⁵⁵ Gradient identifies additional uncertainties, including uncertainties about the techniques used to extrapolate and interpolate estimated risks association with annual NAAQS of NAAQS of 8 µg/m³, 9 µg/m³, or 11 µg/m³.⁵⁶ Gradient explains:

These estimated risks directly inform the conclusions of the 2021 draft PA, but are calculated using an unvalidated and highly uncertain approach; the modeled PM_{2.5} concentrations are not shown to scale linearly with changes in selected alternative standards and projected emissions. Further, uncertainty in the 2021 draft PA-modeled PM_{2.5} concentrations is not sufficiently quantified, despite significant potential sources of error, and thus these modeled concentrations should not be used as the basis for a risk assessment.⁵⁷

What may be most notable about the risk assessment in the Draft PA, however, is that, as Gradient points out, its estimates of risks associated with just attaining the current NAAQS are lower than the risk estimates in the 2020 PA for those NAAQS.⁵⁸ Gradient attributes this to the use of different C-R curves in the two risk assessments.⁵⁹ At a minimum, this illustrates the uncertainty in all of the risk estimates.⁶⁰ More significantly, lower estimated risks do not support

⁵⁵ See Draft PA at C-74 to C-80, Tbl. C-18.

⁵⁶ Gradient Draft PA Comments at 14.

⁵⁷ *Id.* at 14.

⁵⁸ *Id.* at ES-1, 15.

⁵⁹ *Id.* at 15.

⁶⁰ *Id.*

eliminating the option of retaining the existing suite of NAAQS. Furthermore, failure to consider the option of retaining the existing NAAQS in the face of lower estimated risks is arbitrary and capricious.

3. “At-Risk” Populations Have Not Changed.

Recently, a great deal of attention has been paid to ensuring protection of vulnerable populations. EPA notes that in setting primary NAAQS, the Agency has always been required to protect sensitive groups.⁶¹ Accordingly, protection of sensitive (or “at-risk”) groups was a factor in EPA’s 2020 decision to retain the existing suite of primary NAAQS.⁶² As the Draft PA acknowledges, “The information available in this reconsideration has not altered our understanding of human populations at risk of health effects from PM_{2.5} exposures.”⁶³ Protection of these same groups does not warrant elimination of the option of retaining the existing NAAQS.

In addition, the Draft PA should recognize the lack of meaningful evidence to support increased health risk for some of the populations it identifies as of concern. Specifically, although the Draft PA reports “PM_{2.5}-related health risk” for Black and Hispanic populations,⁶⁴ the evidence to support elevated health risk for these populations is nil. In fact, the evidence suggests the opposite. Gradient indicates:

[E]vidence to date does not fully support health risk disparities for PM_{2.5}. Specifically, *none of the five studies that evaluated the dose-response relationship between long-term PM_{2.5} and total mortality stratified by race/ethnicity (i.e., Awad et al., 2019; Lipfert and Wyzga, 2020; Parker et al., 2018; Son et al., 2020; Wang et al., 2020) . . . support the conclusion on disparities in health risks based on race/ethnicity. Specifically, both Awad et al. (2019) and Lipfert and Wyzga (2020) reported stronger associations between long-term PM_{2.5} exposure and mortality among Whites than Blacks; Son*

⁶¹ Draft PA at 1-4 n. 5.

⁶² 85 Fed. Reg. at 82718.

⁶³ Draft PA at 3-50.

⁶⁴ *See id.* at 3-52.

et al. (2020) and Wang *et al.* (2020) reported *associations of equal magnitude among Whites and Blacks* . . . Regarding the fifth study by Parker *et al.* (2018), while the [Draft] ISA Supplement stated that "[t]his study reported a larger association, in terms of magnitude, among Black (hazard ratio [HR] = 1.05 [95% confidence interval [CI]: 1.03, 1.09]) and White (HR = 1.02 [95% CI: 1.00, 1.05]) individuals and a null association among Hispanic individuals (HR = 0.98 [95% CI: 0.94, 1.03])," . . . these numbers do not appear to have been reported in the study itself. Rather, *the study result table reported no association between long-term PM_{2.5} exposure and mortality among White* (HR = 1.05 [95% CI: 1.00-1.11]), *Black* (HR = 1.11 [95% CI: 0.97-1.28]), *and Hispanic individuals* (HR = 0.97 [95% CI: 0.88-1.06]).⁶⁵

Importantly, the Draft PA does not cite evidence of additional “at risk” populations relative to the 2020 PA. Nonetheless, the Draft PA implies greater differences than reported in the 2020 PA. It should not overstate the evidence for such differences.

B. Evidence Supports Retention of the Forms of the PM_{2.5} NAAQS.

The Draft PA concludes, “[I]t is appropriate to consider retaining the forms of the current annual and 24-hour PM_{2.5} standards.”⁶⁶ The Draft PA’s conclusion is correct for both scientific and practical reasons. Revision to the form of either the 24-hour or annual PM_{2.5} NAAQS would require significantly more information to support the need for such revision. It would also require completion of a risk assessment evaluating the benefits of a NAAQS using the new standard form. Without this additional information, the Administrator would have an inadequate basis for judging whether such a NAAQS is requisite to protect public health.⁶⁷ Moreover, especially in light of the lack of convincing evidence on the need to change the form of the standard, EPA should recognize that such a change – for example changing from the 98th percentile form for the 24-hour PM_{2.5} NAAQS to a 99th percentile form – would significantly alter compliance strategies and raise the

⁶⁵ Gradient Draft PA Comments at 5 (emphases added).

⁶⁶ Draft PA at 3-193.

⁶⁷ See CAA § 109(b)(1).

likelihood that many more areas would be forced to submit exceptional event petitions to account for infrequent events that tip areas into non-compliance or that prevent attainment.

IV. The Body of the Draft PA Should Present Objective Estimates of Risk, Taking Current Air Quality into Account.

Although levels of PM_{2.5} in ambient air exceed the current NAAQS in some areas,⁶⁸ most of the country meets the current 12 µg/m³ annual and 35 µg/m³ 24-hour primary PM_{2.5} NAAQS.⁶⁹ The Draft PA reports, “At long-term monitoring sites in the U.S., annual PM_{2.5} concentrations from 2017 to 2019 averaged 8.0 µg/m³ . . . and the 98th percentiles of 24-hour concentrations averaged 21.3 µg/m³”⁷⁰ Information on the health risk posed by PM_{2.5} in ambient air should reflect this reality.

In its risk assessment, however, EPA virtually ignored information on current air quality. Instead, the Agency sought to characterize risks in a fictional world in which the current PM_{2.5} NAAQS are just attained everywhere. For this purpose, in selecting sites to be considered for the risk assessment, the Agency first focused on those areas in which either the annual or the 24-hour PM_{2.5} NAAQS, or both, had been exceeded during the 2014 to 2016 period and then added consideration of areas that met, but were close to, those NAAQS.⁷¹ For those areas that met the NAAQS, EPA used a modeling approach to adjust PM_{2.5} air quality data from 2015 upward (i.e., added additional theoretical PM_{2.5} to what was actually present) to reflect what air quality might have been had the area just attained the NAAQS.⁷² It also used modeling to project air quality in these areas if they just attained an alternative annual NAAQS of 10 µg/m³ and an alternative 24-

⁶⁸ EPA identified sixteen core-based statistical areas in which either the annual or the 24-hour PM_{2.5} NAAQS, or both, had been exceeded for the period 2014 to 2016. Draft PA at 3-133.

⁶⁹ *Id.* at 2-26.

⁷⁰ *Id.*

⁷¹ *Id.* at 3-133.

⁷² *Id.*

hour NAAQS of 30 $\mu\text{g}/\text{m}^3$.⁷³ For the areas that did not meet the NAAQS, EPA followed the same modeling approach to adjust PM_{2.5} levels in these areas downward (i.e., to improve PM_{2.5} levels) to just attain the current NAAQS and to just attain the same suite of alternative NAAQS. EPA then used interpolation and extrapolation to simulate air quality with alternative annual NAAQS of 11 $\mu\text{g}/\text{m}^3$, 9 $\mu\text{g}/\text{m}^3$, and 8 $\mu\text{g}/\text{m}^3$.⁷⁴ The Agency modeled and reported risks associated with these alternative NAAQS levels.⁷⁵

Although EPA had air quality data from 2015 for all of the areas it addressed in its risk assessment,⁷⁶ and predicted health risk associated with that air quality,⁷⁷ it nowhere provided information on the specific estimated health risks with this “recent” air quality. Appendix C to the Draft PA includes limited information on predicted PM_{2.5}-related mortality associated with these “recent conditions,”⁷⁸ but the body of the Draft PA omits this information entirely.

As CASAC Member Dr. James Boylan explained in his preliminary draft written comments, the effect of relying on air quality “just meeting” the current standards for core-based statistical areas (“CBSAs”) below the current standard will produce mortality estimates that are “significantly overestimated” when compared to more realistic estimates using current air quality:

EPA’s approach evaluates the change in risk associated with moving from PM_{2.5} air quality “just meeting” the current standards (12/35) to “just meeting” alternative annual and/or 24-hour standards (10/30). While this approach is appropriate for CBSAs that are currently above the current standards, this approach is **not** appropriate for CBSAs that are currently below the current standards and results in estimated reductions in PM_{2.5}-a[ss]ociated mortality [risks] that are significantly overestimated compared to the actual number of prevented deaths. For example, the 2014-2016 annual maximum PM_{2.5} design values (Table C-3) for the Atlanta

⁷³ *Id.* at 3-132 to 3-133, C-12.

⁷⁴ *Id.* at 3-131.

⁷⁵ *See, e.g., id.* at 3-143, Tbl. 3-16.

⁷⁶ *See id.* at C-47, Tbl. C-10.

⁷⁷ *See id.* at C-47, Fig. C-24.

⁷⁸ *Id.* at C-50, Fig. C-25; C-54, Fig. C-29; C-55, Fig. C-30.

CBSA and New York CBSA were 10.38 [μ]g/m³ and 10.20 [μ]g/m³, respectively. The EPA approach increases these design values to 12.0, then reduces them to 11, 10, 9, and 8 to calculate the reductions in PM_{2.5}-associated mortality at each alternative standard. In these two cities alone, the EPA approach calculates thousands of deaths prevented as you go from 12 to 11, 11 to 10, 10 to 9, and 9 to 8. However, the 2018-2020 PM_{2.5} design values for the Atlanta CBSA and New York CBSA are 9.5 [μ]g/m³ and 8.7 [μ]g/m³, respectively. This means that a new standard of 11 [μ]g/m³ or 10 [μ]g/m³ would result in no actual deaths being prevented. This example was given for Atlanta and New York (which accounts for 25% of the total study area population) but is applicable to many of the other CBSAs in the study area that currently have 2018-2020 annual design values that are below 10 [μ]g/m³ or 9 [μ]g/m³. **In order to accurately evaluate the number of actual deaths that will be prevented if the standard was lowered, the starting point for the risk analysis for each CBSA that is already below the current PM_{2.5} NAAQS needs to be the 2018-2020 PM_{2.5} design values, not the current NAAQS.**⁷⁹

This overestimation of deaths avoided also affects EPA's already small estimates of potential mortality benefits from lowering the existing 24-hour PM_{2.5} standard. For example, the 24-hour PM_{2.5} design value for Fulton County, Georgia (home of Atlanta) for 2018-2020 was 20 μ g/m³ and that of New York City was 22 μ g/m³,⁸⁰ both well below the 35 μ g/m³ level of the NAAQS. Accounting for current air quality in these cities would reduce the Agency's existing estimated 1-2 percent reduction in mortality from reducing the current 24-hour daily standard to 30 μ g/m³ to zero in each of these cities. In other cities, the "corrected" estimate may well be within the margin of error of the analysis due to the many assumptions and uncertainties involved.

⁷⁹ Preliminary Comments from Dr. James Boylan on EPA's *Policy Assessment (PA) for the Reconsideration of the National Ambient Air Quality Standards for Particulate Matter (External Review Draft – October 2021)*, at 6-7 (Dec. 1, 2021) (emphasis in original), https://casac.epa.gov/ords/sab/f?p=105:19:226329280793:::RP,19:P19_ID:962 (scroll to Meeting Materials).

⁸⁰ EPA, Air Quality Design Values, <https://www.epa.gov/air-trends/air-quality-design-values#report> (scroll to PM_{2.5} Design Values, 2020).

Furthermore, it is unrealistic to suggest that air quality in areas attaining the NAAQS will degrade in the manner suggested by the risk estimates presented in the body of the draft PA. PM_{2.5} concentrations and emissions contributing to them have declined steadily since 1990.⁸¹ Even apart from the general incentive that areas have to avoid designation as a nonattainment area, several CAA programs serve to protect against such degradation, including programs establishing New Source Performance Standards,⁸² Prevention of Significant Deterioration,⁸³ and emissions standards for motor vehicles standards.⁸⁴

In addition, EPA should acknowledge that reliance on actual, unadjusted 2015 air quality data for the risk assessment will not fully correct the problem. PM_{2.5} levels have continued to decline since the 2015 “recent” air quality data that were used for EPA’s analysis.⁸⁵ The Agency should explain this fact in presenting any estimates based on 2015 air quality data.

Given the significant overestimation of the benefits that might be anticipated from alternative NAAQS, EPA should not include the risk assessment in the final PA or cite the results of the assessment in any public document without first correcting the overestimates.⁸⁶ Failure to do so will misinform decisionmakers and the public, and violate EPA’s duty under both the Information Quality Act and its own information quality guidelines to ensure the objectivity of the information it disseminates.⁸⁷

⁸¹ See *supra* notes 11-14 and accompanying text.

⁸² CAA § 111.

⁸³ *Id.* §§ 160-169.

⁸⁴ *Id.* § 202.

⁸⁵ EPA reports that the mean national PM_{2.5} level in 2015 was 8.54 µg/m³ and had dropped to 8.02 µg/m³ in 2020. See <https://www.epa.gov/air-trends/air-quality-design-values> (follow the link for “Particulate Matter (PM_{2.5}) Trends, then click link to under the National Trends chart to “view the chart data in html”).

⁸⁶ The Agency should also consider conducting an integrated uncertainty analysis of its risk assessment. Doing so would inform the Administrator concerning the overall level of uncertainty in the risk estimates and assist the Administrator to evaluate the weight that he should place on those estimates in evaluating whether revision of the current suite of PM_{2.5} NAAQS is appropriate.

⁸⁷ Information Quality Act, Pub. L. No. 106-554, § 515, 114 Stat. 2763, 2763A-153 to 2763A-154 (2000); EPA, EPA/260R-02-008, *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility and Integrity of*

V. EPA Staff’s Preliminary Conclusion that the Evidence Does Not Call into Question the Adequacy of the Health Protection Provided by the Current 24-hour Primary PM₁₀ NAAQS Is Appropriate.

The Draft PA reaches the preliminary conclusion that “the evidence does not call into question the adequacy of the public health protection provided by the current primary PM₁₀ standard.”⁸⁸ Members of the CASAC PM Panel agree.⁸⁹ The NR3 Coalition concurs.

As the Draft PA explains, the PM₁₀ NAAQS is intended to protect public health against exposure to coarser PM, commonly measured as PM_{10-2.5}.⁹⁰ EPA has not identified any health effect for which a causal or likely causal relationship has been demonstrated with PM_{10-2.5}.⁹¹ EPA does not generally establish NAAQS unless it has found such a relationship between a pollutant and one or more adverse health effects.⁹² Thus, in the absence of evidence of a causal or likely causal relationship between PM_{10-2.5} and any health effect, no basis exists to increase the stringency of the current 24-hour primary PM₁₀ NAAQS.

Information Disseminated by the Environmental Protection Agency (Oct. 2002), https://www.epa.gov/sites/default/files/2020-02/documents/epa-info-quality-guidelines_pdf_version.pdf.

⁸⁸ Draft PA at 4-18.

⁸⁹ See Preliminary Comments from Members of the CASAC PM Panel on EPA’s *Policy Assessment for the Reconsideration of the National Ambient Air Quality Standards for Particulate Matter (External Review Draft – October 2021)*, at 31 (received as of Nov. 15, 2021) (“This panel member feels that the preliminary conclusions regarding the adequacy of the current primary PM₁₀ standard and the public health policy judgments are supported by the data reviewed in this draft PA.”) (Comments of Dr. Stephanie Lovinsky-Desir), https://casac.epa.gov/ords/sab/f?p=105:19:13856912016573:::19:P19_ID:962 (scroll to Meeting Materials); *id.* at 50 (“[T]he rationale for retaining the current primary PM₁₀ standard is adequate and appropriate[] based on the degree of evidence provided.”) (comments of Dr. Neeta Thakur); Preliminary Comments from Dr. Terry Gordon on EPA’s *Policy Assessment (PA) for the Reconsideration of the National Ambient Air Quality Standards for Particulate Matter (External Review Draft – October 2021)*, at 4 (Dec. 2, 2021) (“The preliminary conclusion of retaining the current PM₁₀ standard is appropriate in the eyes of this reviewer.”), https://casac.epa.gov/ords/sab/f?p=105:19:13856912016573:::19:P19_ID:962 (scroll to Meeting Materials); Preliminary Comments from Dr. Stephanie Lovinsky-Desir on EPA’s *Policy Assessment (PA) for the Reconsideration of the National Ambient Air Quality Standards for Particulate Matter (External Review Draft – October 2021)*, at 3 (Nov. 30, 2021) (“I agree with the preliminary conclusions [concerning the primary PM₁₀ NAAQS] based on the evidence that was presented in this document.”), https://casac.epa.gov/ords/sab/f?p=105:19:13856912016573:::19:P19_ID:962 (scroll to Meeting Materials).

⁹⁰ Draft PA at 4-2.

⁹¹ See *id.* at 4-9.

⁹² See, e.g., *id.* at 1-16 & n.25 (explaining EPA’s focus on effects for which the Agency had found a causal relationship with PM in assessing potential alternative NAAQS).

VI. EPA Staff's Recommendation To Consider Retention of the Current Secondary NAAQS Is Appropriate.

The Draft PA reaches the preliminary conclusion that “it is appropriate to consider retaining the current secondary PM standards, without revision.”⁹³ Some CASAC PM Panel members agree,⁹⁴ and none recommend any alternative. The NR3 Coalition concurs that retention of the current secondary NAAQS is appropriate.

The current secondary NAAQS are intended to protect primarily against unacceptable visibility impairment. The Draft ISA Supplement notes atmospheric extinction of light has decreased since 1990.⁹⁵ It identifies a handful of recent studies of visibility effects,⁹⁶ but as the Draft PA notes, “While one new study provides refinements to the methods for estimating light extinction, uncertainties and limitations in the scientific evidence during the previous reviews remains.”⁹⁷ Thus, it is not surprising that, as illustrated in the Draft PA, attaining the current PM_{2.5} NAAQS means that areas attaining the current NAAQS continue to attain the target level of visibility.⁹⁸

The Draft ISA Supplement recognizes that EPA also previously determined that a causal relationship exists between PM and effects on climate and materials.⁹⁹ It does not, however, identify any recent studies of these effects. Thus, as the Draft PA notes, the evidence concerning these effects continues to include “substantial uncertainties with regard to quantitative

⁹³ *Id.* at 5-49.

⁹⁴ *See, e.g.*, Preliminary Comments from Members of the CASAC PM Panel on EPA’s *Policy Assessment for the Reconsideration of the National Ambient Air Quality Standards for Particulate Matter (External Review Draft – October 2021)*, at 38 (received as of Nov. 15, 2021) (“[I]t is appropriate to consider retaining the secondary PM standards.”) (comments of Dr. Alexandria Ponette-González), https://casac.epa.gov/ords/sab/f?p=105:19:13856912016573:::19:P19_ID:962 (scroll to Meeting Materials)

⁹⁵ Draft ISA Supplement at 4-7.

⁹⁶ *Id.* at 4-4, 4-7 to 4-8.

⁹⁷ Draft PA at 5-26.

⁹⁸ *Id.* at 5-28 to 5-32.

⁹⁹ *Id.* at 4-1.

relationships with PM concentrations.”¹⁰⁰ As a result, it remains impossible to set a NAAQS based on these effects. Current NAAQS, however, continue to provide some protection against them.

VII. Conclusion

In summary, the final PA should acknowledge that retention of the present suite of PM NAAQS, including the current primary NAAQS for PM_{2.5}, is a legitimate option for the Administrator to consider in light of the continuing uncertainties and weaknesses of the scientific data base on potential health and welfare effects of PM. In addition, the final PA must provide information on estimates of public health risks associated with recent air quality in order to present a more realistic and unbiased picture of any potential benefits of revised NAAQS. Revising the Draft PA in this manner will assist the Administrator in judging whether to revise the NAAQS and, if so, what revision may be appropriate.

¹⁰⁰ Draft PA at 5-48.