

**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)**

DOCKET No. EPA-HQ-ORD-2014-0859

American Chemistry Council  
American Coke & Coal Chemicals Institute  
American Fuel & Petrochemical Manufacturers  
American Forest & Paper Association  
American Iron and Steel Institute  
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

November 29, 2021

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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).<sup>1</sup> As part of its process for reconsidering that decision, EPA has prepared and released for public comment a draft Supplement to the 2019 Integrated Science Assessment for Particulate Matter (Draft ISA Supplement) to the Integrated Science Assessment (ISA) underlying the 2020 decision.<sup>2</sup> These are the comments of the NAAQS Regulatory Review & Rulemaking (NR3) Coalition on that draft document. 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.

Briefly, the NR3 Coalition concludes:

- The Draft ISA Supplement fails to satisfy the CAA requirement that it “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 [PM] in the ambient air, in varying quantities.”<sup>3</sup> Specifically:
  - Because both the 2019 ISA and the Draft ISA Supplement were prepared without systematic, transparent, and unbiased review of the science

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<sup>1</sup> 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>.

<sup>2</sup> EPA, Integrated Science Assessment (ISA) for Particulate Matter, Doc. ID. EPA/600/R-19/188 (Final Report, Dec. 2019) (“2019 ISA”).

<sup>3</sup> 42 U.S.C. §§ 7401-31, Clean Air Act (“CAA” or “Act”) § 108(a)(2) (2013).

concerning possible health and welfare effects of PM in ambient air, neither document “accurately reflect[s] the latest scientific knowledge.”

- The Draft ISA Supplement fails to correct the significant methodological shortcomings in the 2019 ISA identified by EPA’s independent scientific advisory committee, the Clean Air Scientific Advisory Committee (CASAC), and by commenters on issues including the lack of systematic review of the studies and an inadequate framework for assessing the strength of the evidence for a causal relationship between PM in ambient air and health and/or welfare effects.
  - Discussion in the Draft ISA Supplement of the critical issue of how “varying quantities” of PM in the ambient air affect public health and welfare is inadequate because the body of the document does not discuss levels at which associations with PM<sub>2.5</sub> have been reported and the statements about such levels in the Executive Summary and the Summary and Conclusions lack support.
- Despite its shortcomings, the Draft ISA Supplement illustrates that the scientific record for reconsideration of the 2020 decision to retain the PM NAAQS is substantively similar to the scientific record on which that decision was based.
  - EPA must ensure that CASAC is familiar with all of the scientific information that it needs to perform its duties under the CAA.

## **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 providing air quality protective of public health and welfare, while continuing to facilitate economic growth in the United States.<sup>4</sup> We, and they, 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.<sup>5</sup>

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<sup>4</sup> 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 30, 2020), Doc. ID. EPA-HQ-OAR-2015-0072-0915 (“NR3 Coalition Rulemaking Comments”).

<sup>5</sup> *See* EPA, *Our Nation’s Air*, <https://gispub.epa.gov/air/trendsreport/2021/#growth> (last visited Oct. 25, 2021).

With regard to PM specifically, 24-hour levels of PM<sub>10</sub> declined 26 percent nationally between 1990 and 2020.<sup>6</sup> Between 2000 and 2020, annual average PM<sub>2.5</sub> levels fell 41 percent and 24-hour average PM<sub>2.5</sub> levels fell 30 percent nationally.<sup>7</sup> These reductions of PM in ambient air resulted, in part, from reductions in emissions of direct (primary) PM and of PM precursors by NR3 Coalition members and their members. Direct emissions of PM<sub>10</sub> and PM<sub>2.5</sub> have declined by 31 percent and 38 percent, respectively, over this period.<sup>8</sup> Emissions of PM<sub>2.5</sub> precursors have also declined: sulfur dioxide (SO<sub>2</sub>) by 92 percent, nitrogen oxides (NO<sub>x</sub>) by 68 percent, volatile organic compounds (VOC) by 48 percent, and ammonia (NH<sub>3</sub>) by 8 percent.<sup>9</sup> 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; improving energy efficiency; and using cleaner energy sources and technology.

## **II. The Draft ISA Supplement Fails To Capture the Most Recent Scientific Knowledge on Health and Welfare Effects of PM in Ambient Air in Varying Quantities.**

The CAA requires EPA to set NAAQS that protect the public health and welfare from adverse effects resulting from the presence of certain pollutants in ambient air.<sup>10</sup> The NAAQS must be “based on” air quality criteria that “accurately reflect that 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 the regulated pollutant] in the ambient air in varying quantities.”<sup>11</sup> EPA must review both the NAAQS and the criteria on which they are based at least every five years, revising the criteria and the standards, as appropriate.<sup>12</sup>

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<sup>6</sup> *Id.*, <https://gispub.epa.gov/air/trendsreport/2021/#introduction> (last visited Oct. 25, 2021).

<sup>7</sup> *Id.*

<sup>8</sup> *Id.*, [https://gispub.epa.gov/air/trendsreport/2021/#air\\_trends](https://gispub.epa.gov/air/trendsreport/2021/#air_trends) (last visited Oct. 25, 2021).

<sup>9</sup> *Id.*

<sup>10</sup> CAA § 109(b).

<sup>11</sup> *Id.* §§ 108(a)(2), 109(b).

<sup>12</sup> *Id.* § 109(d)(1).

EPA first set NAAQS for PM in 1971 and has reviewed and revised them – and the air quality criteria on which they are based – several times. EPA’s most recent review of the air quality criteria culminated in its issuance of the 2019 ISA. In 2020, EPA decided, based on that assessment of the latest science, to retain the existing PM NAAQS without revision.<sup>13</sup> In doing so, EPA accepted the advice of “some” (i.e., most) CASAC members who expressed support for retaining both the annual and 24-hour primary PM<sub>2.5</sub> NAAQS.<sup>14</sup>

In June 2021, EPA Administrator Regan decided that the Agency would reconsider the 2020 decision “because available scientific evidence and technical information indicate that the current standards may not be adequate to protect public health and welfare.”<sup>15</sup> He committed that, as part of this reconsideration, EPA would prepare a supplement to the 2019 ISA “that will take into account the most up-to-date science.”<sup>16</sup> The Draft ISA Supplement is intended to fulfill that commitment and “provide[ ] the scientific basis to support a robust and thorough reconsideration of the 2020 PM NAAQS.”<sup>17</sup>

Unfortunately, for reasons discussed below, the current Draft ISA Supplement, in conjunction with the 2019 ISA, does not provide an adequate basis for reconsideration of the 2020 decision to retain the PM NAAQS. It fails to reflect the latest scientific information “accurately” and it fails to explain what this information says about the effect of “varying quantities” of PM in ambient air on public health and welfare.<sup>18</sup> EPA must revise the Draft ISA Supplement to redress these failures.

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<sup>13</sup> Review of the National Ambient Air Quality Standards for Particulate Matter, 85 Fed. Reg. 82,684 (Dec. 18, 2020).

<sup>14</sup> *Id.* at 82,706, 82,718.

<sup>15</sup> *EPA to Reexamine Health Standards for Harmful Soot that Previous Administration Left Unchanged*, *supra* note 1.

<sup>16</sup> *Id.*

<sup>17</sup> See Supplement to the 2019 Integrated Science Assessment for Particulate Matter (External Review Draft) (Sept. 29, 2021), at 1-1, Docket ID. No. EPA-HQ-ORD-2014-0859 (“Draft ISA Supplement”).

<sup>18</sup> CAA § 108 (a)(2).

### **III. The Draft ISA Supplement Continues Flaws from EPA's Preparation of the 2019 ISA.**

#### **A. Lack of a Systematic, Transparent, and Unbiased Review of the Scientific Evidence.**

In preparing the 2019 ISA, EPA staff failed to conduct a systematic, transparent, and unbiased review of the strengths and weaknesses of the key epidemiologic studies despite repeated recommendations for such a review.<sup>19</sup> This lack of a systematic, transparent, and unbiased review has continued in the preparation of the Draft ISA Supplement. The inadequate review of the scientific evidence may have led to conclusions in the Draft ISA Supplement that are biased towards finding causal relationships between PM and various health endpoints. As the Coalition previously explained, the absence of a systematic, transparent, and unbiased review during preparation of the 2019 ISA prevented a full understanding of whether the current NAAQS continued to provide the requisite protection of public health or whether NAAQS that are more protective are necessary.<sup>20</sup> A similar lack of appropriate systematic review of the evidence in preparing the Draft ISA Supplement means that a full understanding of the protection provided by the current PM NAAQS remains impossible.

The failure to conduct a systematic review of the evidence during the preparation of the Draft ISA Supplement and the implications of that failure for reaching sound conclusions concerning health effects of PM levels permitted by existing PM NAAQS is shared by scientific

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<sup>19</sup> See API, Comments on the Integrated Science Assessment for Particulate Matter (External Review Draft October 2018) at 3 & Attachment 3-19, Doc. ID. EPA-HQ-ORD-2014-0859-0060 (Dec. 11, 2018); TCEQ, Comments by the Texas Commission on Environmental Quality Regarding the External Review Draft Integrated Science Assessment for Particulate Matter at 7, Doc. ID. EPA-HQ-ORD-2014-0859-0063 (Dec. 10, 2018); National Council for Air and Stream Improvement, Inc. (NCASI), Comments on the Integrated Science Assessment for Particulate Matter (External Review Draft) at 1-2, Doc. ID. EPA-HQ-ORD-2014-0859-0050 (Dec. 10, 2018).

<sup>20</sup> NR3 Coalition Rulemaking Comments at 19.

experts in data evaluation. In recently filed comments on the Draft ISA Supplement,<sup>21</sup> Julie Goodman and her colleagues at Gradient stated:

As with the ISA itself, the process was not transparent, and there was insufficient detail to ensure that studies were identified and reviewed in a systematic and consistent manner, or integrated in a way that considered study quality and the coherence of results across studies within and across disciplines. [As such, the review of studies in the 2021 draft ISA Supplement did not follow the framework set out in the Preamble.] These limitations [of the Supplement also undermine CASAC’s ability to provide a meaningful review of the 2021 draft ISA Supplement,] do not allow for US EPA’s evaluation to be reproduced by others and may have led to biased conclusions.<sup>22</sup>

Indeed, as Gradient also noted:

Overall, the ISA did not evaluate and integrate the evidence in a transparent, systematic, and unbiased manner. As a result, the causal determinations for health effects are biased towards causation, and undue confidence is placed in observational concentration-response data that contain substantial uncertainties. The Supplement has similar issues and does not increase confidence in any of the ISA conclusions.<sup>23</sup>

Similarly, Giffe Johnson and his colleagues at the National Council for Air and Stream Improvement (NCASI) recently reported:

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 that may

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<sup>21</sup> See Gradient, Comments on EPA’s 2021 Integrated Science Assessment for Particulate Matter Supplement (External Review Draft), Doc. ID. EPA-HQ-ORD-2014-0859-0077 (Nov. 23, 2021) (“Gradient (2021)”).

<sup>22</sup> *Id.* at 6.

<sup>23</sup> *Id.* at ES-2.

be extremely informative for evaluating cause-and-effect relationships between particulate matter and health outcomes.<sup>24</sup>

After working with other subject-matter experts to conduct a systematic review of three large cohort studies of cardiovascular mortality discussed in the Draft ISA Supplement, NCASI concluded, “[N]o body of evidence of sufficient quality is available to demonstrate a clear cardiovascular mortality risk from particulate matter exposures at current levels of the NAAQS.”<sup>25</sup>

## **B. Overlooked and Dismissed Uncertainties and Limitations of the Scientific Record**

In 2020 the NR3 Coalition explained that if EPA had conducted a full systematic review of the evidence, as would have been appropriate, the Agency would have confronted the many important weaknesses affecting the scientific studies and their use in forming judgments regarding possible causal relationships between varying levels of PM in ambient air and adverse effects on public health or welfare.<sup>26</sup> In the continuing absence of a full systematic review of the scientific evidence, the Draft ISA Supplement continues to overlook or dismiss many important uncertainties or limitations of the scientific evidence.

### **1. Bias and Uncertainty**

All epidemiological studies suffer from some degree of confounding, uncertainty, or bias.<sup>27</sup> Exposure measurement error, lack of temporality, confounding by copollutants or socioeconomic status, and uncertainties in statistical analyses are among the key sources of uncertainty and bias in epidemiological studies of PM health effects.<sup>28</sup>

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<sup>24</sup> Giffe Johnson, PhD, National Council for Air & Steam Improvement (NCASI), to USEPA Doc. ID. EPA-HQ-ORD-2014-0859-0073, at 2, Doc. ID. EPA-HQ-ORD-2014-0859-0076 (Nov. 22, 2021) (“NCASI (2021)”). Although this quotation refers to the ISA, NCASI’s comments, in fact, address the Draft ISA Supplement. *See id.* at 1.

<sup>25</sup> *Id.* at 4.

<sup>26</sup> NR3 Coalition Rulemaking Comments at 19-23.

<sup>27</sup> NCASI (2021), at 5.

<sup>28</sup> Gradient (2021), at 7.



In its review, CASAC emphasized the importance of copollutant confounding and the limitations of current monitoring/modeling approaches to adequately assess exposures at the scale needed. For example, in preliminary comments concerning the Draft ISA Supplement, CASAC PM Panel member Dr. Jane Clougherty observed:

It is noted on p. 3-60 that only one multi-city US study investigated co-pollutant confounding (Lavigne et al, 2018). My concern is that many of the larger US studies have leaned on larger-scale regional models for PM<sub>2.5</sub> at 1 km<sup>2</sup> resolution or larger, which is appropriate to the spatial scale of variation for PM<sub>2.5</sub>, but either not thoroughly adjusted for NO<sub>2</sub> or other local emissions indicators, or not done so at the much finer spatial scales at which local sources vary.<sup>29</sup>

The following table, taken from Gradient (2021),<sup>30</sup> illustrates the continuing presence of these issues in recent epidemiologic studies examining long-term PM<sub>2.5</sub> exposure and mortality.

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<sup>29</sup> Preliminary Comments from Dr. Jane Clougherty on EPA's Supplement to the 2019 Integrated Science Assessment for Particulate Matter (External Review Draft – September 2021), at 1 (Nov. 18, 2021), [https://casac.epa.gov/ords/sab/f?p=105:19:1773865229976:::RP,19:P19\\_ID:962](https://casac.epa.gov/ords/sab/f?p=105:19:1773865229976:::RP,19:P19_ID:962) (scroll to Meeting Materials).

<sup>30</sup> Gradient (2021), at 8, Tbl. 4.1.

**Table 4.1 Key Sources of Bias and Uncertainty in Epidemiology Studies of Long-Term PM<sub>2.5</sub> Exposure and Total Mortality<sup>a</sup>**

Sources of Bias and Uncertainty		Christidis <i>et al.</i> (2019)	Crouse <i>et al.</i> (2020)	HEI (2019)	Erickson <i>et al.</i> (2019)	Erickson <i>et al.</i> (2020)	Eum <i>et al.</i> (2018)	Pinault <i>et al.</i> (2017)	Wang <i>et al.</i> (2020)	Wu <i>et al.</i> (2019)	Wu <i>et al.</i> (2020a)	Zhang <i>et al.</i> (2021)
Exposure measurement error	Temporal variation not accounted for								x			
	Residential mobility not accounted for			x						x	x	
Confounding	Copollutants not adjusted			x	x	x	x	x		x	x	
	Socioeconomic status not adjusted for <sup>b</sup>											
Temporality	Mismatch between PM <sub>2.5</sub> exposure period and mortality follow-up period											
	Mismatch between co-pollutant exposure period and mortality follow-up period	x		NA	NA	NA	NA	NA		NA	NA	
Statistical analysis	C-R curves sensitive to <i>df</i> (natural splines)		x	x	x	x	x			x	x	
	Nonlinearity not assessed statistically		x	x	x	x	x			x	x	
	Threshold not assessed	x	x	x	x	x	x	x		x	x	x
	Multiple comparisons		x			x			x			x

Notes:

C-R = Concentration-Response; *df* = Degrees of Freedom; PM<sub>2.5</sub> = Particulate Matter Less Than 2.5 Microns in Diameter.

NA = Not Applicable due to study design.

(a) 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.

(b) We considered the study to be not biased on socioeconomic status adjustment if it adjusted for education, income, or employment status at individual or contextual level.

As this table illustrates, bias and uncertainty continue to be significant factors in evaluating the epidemiological evidence. Properly acknowledged, these biases and uncertainties limit the value of the available epidemiologic studies for evaluating the adequacy of the current PM NAAQS. In particular, EPA’s conclusion that copollutants and other potential factors such as temporal trends and meteorological variables are “unlikely” to bias the evidence concerning long-term PM<sub>2.5</sub> exposure and mortality must be reconsidered.<sup>31</sup>

<sup>31</sup> See Draft ISA Supplement at 3-120.

## 2. Consistency and Coherence

The Draft ISA Supplement describes the studies that it reviews as providing “consistent” evidence of positive associations between long-term PM<sub>2.5</sub> exposure and cardiovascular effects and mortality.<sup>32</sup> That conclusion, however, is an oversimplification of the scientific record. In particular, it downplays the heterogeneity of the results “with respect to the magnitude of effects, particularly at the local level.”<sup>33</sup>

For example, although the Draft ISA Supplement recognizes that recent studies using statistical techniques provided evidence of potential residual confounding,<sup>34</sup> it concludes that these studies did not call into question the existence of a positive association with long-term PM<sub>2.5</sub> exposure.<sup>35</sup> Others, however, have indicated that the evidence suggests unmeasured confounding that may bias the study results in either direction remains.<sup>36</sup> That bias may be of varying size.<sup>37</sup> As NCASI has stated, “The body of evidence that evaluates the potential association between particulate matter and health effects at current NAAQS standards wholly lacks the insulation of robust measures of association to protect against the impact of uncertainty, bias, and confounding completely altering the directionality of association in these studies.”<sup>38</sup>

## 3. Concentration-Response Analyses and Risk Assessment

Evaluating and applying concentration-response (C-R) functions to estimate risk is an area of investigation that still suffers from significant limitations. EPA’s evaluation of the C-R

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<sup>32</sup> *Id.* at ES-2.

<sup>33</sup> Gradient (2021), at 11.

<sup>34</sup> Draft ISA Supplement at 3-97.

<sup>35</sup> *Id.* at 3-99.

<sup>36</sup>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, Doc. ID. EPA-HQ-ORD-2014-0859-0075 (Nov. 19, 2021).

<sup>37</sup> *Id.*

<sup>38</sup> NCASI (2021) at 5.

relationship “has not been sufficiently scientific and robust.”<sup>39</sup> We concur with public comments that EPA should apply “well-accepted and commonly use scientific methods” to improve its evaluation in the Draft ISA Supplement of the evidence concerning C-R relationships between PM<sub>2.5</sub> exposure and health responses.<sup>40</sup>

Members of CASAC’s PM Panel and commenters to CASAC have acknowledged the limitations and uncertainties of evidence concerning the C-R relationship, particularly at lower PM concentration levels:

- “Although the evidence presented for consideration of alternative annual standards of 10ug/m<sup>3</sup> and 8 ug/m<sup>3</sup> is strong and compelling, the evaluations rely on evidence that includes more uncertainty than the evidence at higher concentrations (e.g., the shape of the C-R down to 8 and the relative uncertainty of the estimates a [sic] lower concentrations). Thus, these sections may be [sic] benefit from a thorough discussion of the different approaches of the various studies to estimate the shape of the C-R function.”<sup>41</sup>
- “Uncertainties regarding the shape of the C-R function at low concentrations is both critical and currently unresolvable. In the Supplement to the PM ISA the approaches for estimating the shape of the C-R curve, for a range of endpoints including mortality, were clearly presented. In this PA, the EPA authors take and clearly articulate what I feel is an appropriately cautious view of these observed functions at low concentrations due to the ‘[r]elatively low data density in the lower concentration range, the possible influence of exposure measurement error, and variability among individuals with respect to air pollution health effects. These sources of variability and uncertainty tend to smooth and “linearize” population-level concentration-response functions and thus could obscure the existence of a threshold or nonlinear relationship.”<sup>42</sup>

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<sup>39</sup> S. E. Holm, 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 1 (Nov. 24, 2021). These comments have been filed, but have not yet been given a Doc. ID.

<sup>40</sup> *Id.* at 4.

<sup>41</sup> 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 32 (comments of Dr. Jennifer Peel, Nov. 15, 2021), [https://casac.epa.gov/ords/sab/f?p=105:19:1773865229976:::RP,19:P19\\_ID:962](https://casac.epa.gov/ords/sab/f?p=105:19:1773865229976:::RP,19:P19_ID:962) (scroll to Meeting Materials).

<sup>42</sup> *Id.* at 45 (comments of Dr. Jeremy Sarnat).

- Dr. Richard Smith noted these uncertainties and what he described as highly sensitive nature of the study results to minor changes in statistical methodology in his comments to CASAC.<sup>43</sup>

The challenges surrounding the appropriate use of C-R functions are so serious that certain industries, including some members of the NR3 Coalition, have been working with EPA to improve the value of epidemiologic research for use in decision-making. An industry-sponsored workshop in which a diverse group of EPA researchers, industry scientists, national and international academics, and other government scientists participated resulted in two publications with EPA co-authors. The first publication developed a matrix for communicating essential risk assessment “asks” of epidemiologic research.<sup>44</sup> That matrix describes characteristics that should be considered for inclusion in epidemiologic studies to make those studies more useful for regulatory decision-making. These characteristics include confirming exposures and outcomes and determining the directions and magnitude of errors surrounding exposure and concentration-response assessments. The second publication, which applied the matrix developed in the first paper to the epidemiological literature used in the most recent ISA for NO<sub>2</sub>, found that the epidemiologic literature did not meet the need of risk assessors to reach fully informed risk assessment conclusions.<sup>45</sup>

The Draft ISA Supplement concludes, “[R]ecent studies provide evidence that continues to support a generally linear, no-threshold [concentration-response] relationship for long-term PM<sub>2.5</sub> exposure and all-cause or cause-specific mortality.”<sup>46</sup> This suggests that these studies can be used to assess the remaining public health risk once the current primary PM NAAQS are

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<sup>43</sup> RL Smith, Public Comment for CASAC, at 3 (Nov. 17, 2021), [https://casac.epa.gov/ords/sab/f?p=105:19:1773865229976::RP:19:P19\\_ID:962](https://casac.epa.gov/ords/sab/f?p=105:19:1773865229976::RP:19:P19_ID:962) (scroll to Meeting Materials).

<sup>44</sup> CJ Burns, JS LaKind, DR Mattison, et al., *A matrix for bridging the epidemiology and risk assessment gap*, Global Epidemiology, Volume 1, at 100005 (Nov. 2019).

<sup>45</sup> JS LaKind, CJ Burns, H. Erickson, SE Graham, S. Jenkins, & GT Johnson, *Bridging the epidemiology risk assessment gap: an NO<sub>2</sub> case study of the Matrix*, Global Epidemiology, Volume 2, at 1000017 (Nov. 2020).

<sup>46</sup> Draft ISA Supplement at 3-120.

attained. Given the issues with confounding, uncertainty, bias, and lack of consistency and coherence discussed above, however, it should be clear that this conclusion needs to be revised. Exposure measurement error, for example, “can lead to an underestimate of risks at higher exposures and an overestimate of risk at low exposure.”<sup>47</sup> The Draft ISA Supplement should acknowledge that – as emphasized by CASAC PM Panel members – the shape of the C-R curve with regard to mortality or cardiovascular effects associated with exposure to PM<sub>2.5</sub> remains highly uncertain. Such an acknowledgement would serve to caution against reliance on epidemiologic studies of PM<sub>2.5</sub> to estimate risks from exposure to low levels – or indeed any level – of PM<sub>2.5</sub>.

#### **IV. The Discussion in the Draft ISA Supplement of the Effects of Varying Quantities of PM in Ambient Air Is Inadequate.**

The CAA requires that EPA prepare air quality criteria to consider the effects of pollutants such as PM in ambient air in varying quantities.<sup>48</sup> The Draft ISA Supplement, however, follows the lead of the 2019 ISA and focuses on issues related to establishing causality in lieu of primarily considering the exposures for which a causal relationship may have been demonstrated. In doing so, it fails to explain the bases for its conclusions on the levels of PM<sub>2.5</sub> in ambient air at which positive associations between short-term and long-term PM<sub>2.5</sub> exposure and cardiovascular and mortality effects have been reported.<sup>49</sup>

Although both the Executive Summary and the Summary and Conclusions of the Draft ISA Supplement indicate that recent studies in the United States and Canada report positive associations between short-term PM<sub>2.5</sub> levels in the range of 7.1 µg/m<sup>3</sup> and 15.4 µg/m<sup>3</sup> and cardiovascular effects,<sup>50</sup> the body of the Draft ISA Supplement does not identify a study of

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<sup>47</sup> Gradient (2021), at 10.

<sup>48</sup> CAA § 108(a)(2).

<sup>49</sup> See Draft ISA Supplement at 5-2 to 5-3.

<sup>50</sup> *Id.* at ES-1, 5-2.

cardiovascular effects involving exposure to either of those levels of PM<sub>2.5</sub>. Investigation of the 64-page appendix to the document suggests that Evans, *et al.* (2017) may be the source of the cited 7.1 µg/m<sup>3</sup> exposure level and that Krall, *et al.* (2018) may be the source of the 15.4 µg/m<sup>3</sup> exposure level.<sup>51</sup> The sources for such critical information on exposure levels must be clearly identified in the body of the document. The reader should not have to turn to the appendices or have to speculate on the source of this information.

The bases for the conclusions that recent U.S. and Canadian studies report positive associations between long-term PM<sub>2.5</sub> exposures in the range of 5.9 µg/m<sup>3</sup> and 16.5 µg/m<sup>3</sup> and cardiovascular effects and mortality is similarly unclear from the body of the Draft ISA Supplement.<sup>52</sup> The appendix to that document suggests that the 5.9 µg/m<sup>3</sup> exposure may be derived from Christidis, *et al.* (2019),<sup>53</sup> and that the 16.5 µg/m<sup>3</sup> exposure level may be taken from Duan, *et al.* (2019).<sup>54</sup> Alternatively, these exposure levels could refer to somewhat older studies referenced in the 2019 ISA: Lepuele *et al.* (2012)<sup>55</sup> and Bilenko *et al.* (2015).<sup>56</sup> The 2019 ISA does not include the same effects range reported in the Draft ISA Supplement, however.

Moreover, exposure levels from these studies should not be cited in summaries of or conclusions with regard to the scientific evidence without accompanying acknowledgement of the limitations of the studies from which these exposure levels are drawn. The Evans study, for example, involved a relatively small number of subjects (362) and hourly average concentrations at a single monitor.<sup>57</sup> Furthermore, it did not include any modeling controlling for the presence of

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<sup>51</sup> See *id.* at A-2 to A-3, Tbl. A-1

<sup>52</sup> See *id.* at ES-1, 5-3.

<sup>53</sup> See *id.* at A-28, Tbl. A-7.

<sup>54</sup> See *id.* at A-12, Tbl. A-3.

<sup>55</sup> See 2019 ISA at 11-86, Tbl. 11-7.

<sup>56</sup> See *id.* at 6-179, Tbl. 6-43.

<sup>57</sup> Draft ISA Supplement at A-2.

copollutants.<sup>58</sup> The 15.4  $\mu\text{g}/\text{m}^3$  level from the Krall study apparently came from Atlanta, Georgia, one of five cities studied.<sup>59</sup> The Draft ISA Supplement notes, “[T]he city specific estimates [in the Krall study] were relatively uncertain and heterogeneous across cities when there were a small number of daily [emergency department (ED)] visits.”<sup>60</sup> Furthermore, Krall *et al.* reported no association between 24-hour  $\text{PM}_{2.5}$  levels and emergency department visits for cardiovascular disease generally.<sup>61</sup> Moreover, like the Evans study, the Krall study did not control for copollutants.<sup>62</sup> Christidis, *et al.* (2019), which *did* include copollutant modeling, found a “null” association with  $\text{PM}_{2.5}$  when ozone was included and an “attenuated” association with  $\text{NO}_2$  in the model.<sup>63</sup>

Information on PM exposure levels at which associations with effects have been reported is key for assessing the adequacy of the current NAAQS. PM is already regulated under the NAAQS program for its effects on both public health and welfare. The issue in the current reconsideration proceeding is not whether PM should be regulated, but whether the current NAAQS protect public health or welfare appropriately. The Draft ISA Supplement must be revised to focus on identifying the quantities of PM in ambient air that are associated with adverse health and welfare effects and the specific scientific bases for concluding that specific PM exposures pose an unacceptable risk to health or welfare. It must note the limitations of the evidentiary bases for concluding certain quantities of  $\text{PM}_{2.5}$  in ambient air are of concern. In doing so, it must take into account the 2019 ISA and develop an integrated, comprehensive assessment

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<sup>58</sup> *Id.* at A-2.

<sup>59</sup> *Id.* at A-3.

<sup>60</sup> *Id.* at 3-9.

<sup>61</sup> *Id.* at 3-19.

<sup>62</sup> *Id.* at A-3. The 2019 ISA mentions a 2011 study by Brook, *et al.* of short-term  $\text{PM}_{2.5}$  exposure and blood pressure at a mean ambient  $\text{PM}_{2.5}$  level of 15.4  $\mu\text{g}/\text{m}^3$ . 2019 ISA at 6-56, Tbl. 6-14. It also notes, however, that the available studies as a whole “do not provide strong support for a consistent relationship between [blood pressure] and short-term exposure to  $\text{PM}_{2.5}$ .” *Id.* at 5-52.

<sup>63</sup> Draft ISA Supplement at 3-94.



of the evidence. Only if the focus of the Draft ISA Supplement is changed in this manner, will the document provide the Administrator with the information he needs to evaluate the adequacy of the current NAAQS.

**V. The More Recent Evidence Discussed in the Draft ISA Supplement Does Not Significantly Alter the Evidentiary Record on Health and Welfare Effects of PM in Ambient Air.**

Despite the flaws discussed above in how the Draft ISA Supplement selects, assesses, and reports on the evidence concerning possible health and welfare effects at PM levels permitted by the current NAAQS, it is clear that the more recent evidence discussed in the Draft ISA Supplement does not require revision of the conclusions of the 2019 ISA concerning effects associated with PM in ambient air. This new evidence supports the conclusions of that document.<sup>64</sup>

- “Overall, these recent studies further support the conclusions of the 2019 PM ISA with respect to short-term PM<sub>2.5</sub> exposure and mortality.”<sup>65</sup>
- “Although there is extensive evidence of a relationship between long-term PM<sub>2.5</sub> exposure and mortality . . . potential residual confounding remains a concern as reflected in the studies discussed above.”<sup>66</sup>
- “In conclusion, the results of recent studies evaluated in the Supplement to the 2019 PM ISA support, and in some instances extend, the scientific conclusions of the 2019 PM ISA.”<sup>67</sup>
- “Additional recent studies further support the conclusions in the 2019 PM ISA.”<sup>68</sup>

Indeed, the evidence is consistent with that in the earlier document and, in some cases, expands it:

- “Overall, recent studies support and extend the findings of the 2019 PM ISA with additional studies reporting positive associations between short-term PM<sub>2.5</sub>

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<sup>64</sup> The NR3 Coalition does not concur with all of the statements quoted below. They are cited solely to illustrate that EPA’s conclusions have not changed in light of the more recent scientific evidence.

<sup>65</sup> *Id.* at 3-69.

<sup>66</sup> *Id.* at 3-97.

<sup>67</sup> *Id.* at 5-1.

<sup>68</sup> *Id.* at 4-7.

exposure and both [ischemic heart disease] and [myocardial infarction] hospital admissions and [emergency department] visits.”<sup>69</sup>

- “Consistent with the evidence evaluated in the 2019 PM ISA, some recent studies report evidence of a positive association with stroke while others report null or inverse associations.”<sup>70</sup>
- “These studies support and extend the limited evidence in the 2019 PM ISA, reporting positive associations between short-term PM<sub>2.5</sub> exposure and [heart failure].”<sup>71</sup>
- “Overall, these studies [of cardiac arrhythmia] support and extend the limited evidence in the 2019 PM ISA.”<sup>72</sup>
- “Consistent with studies evaluated in the 2019 PM ISA, recent studies indicate that associations between short-term PM<sub>2.5</sub> exposure and cardiovascular mortality are relatively unchanged in copollutant models and may be larger in magnitude in the presence of some co-occurring pollutants (e.g., oxidant gases).”<sup>73</sup>
- “Recent epidemiologic studies published since the 2019 PM ISA support and extend the evidence that contributed to the conclusion of a *causal relationship* between short-term PM<sub>2.5</sub> exposure and cardiovascular effects in the 2019 ISA.”<sup>74</sup>
- “Recent studies continue to support an immediate effect of short-term PM<sub>2.5</sub> exposure on the cardiovascular system that was described in the 2019 PM ISA.”<sup>75</sup>
- “Recent studies support the evidence in the 2019 ISA and extend the evidence relating to the observation of associations among patients that are followed after a cardiac event or procedure.”<sup>76</sup>
- “Recent epidemiological studies published since the 2019 PM ISA support and extend the evidence that contributed to the conclusions of a *causal relationship* between long-term PM<sub>2.5</sub> exposure and cardiovascular effects.”<sup>77</sup>
- “Recent North American cohort studies that examined the relationship between long-term PM<sub>2.5</sub> exposure and mortality support and expand upon the cohort studies

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<sup>69</sup> *Id.* at 3-10.

<sup>70</sup> *Id.* at 3-13.

<sup>71</sup> *Id.* at 3-15.

<sup>72</sup> *Id.* at 3-17.

<sup>73</sup> *Id.* at 3-19.

<sup>74</sup> *Id.* at 3-23 (emphasis in original).

<sup>75</sup> *Id.* at 3-24.

<sup>76</sup> *Id.* at 3-34.

<sup>77</sup> *Id.* at 3-48 (emphasis in original).

evaluated in the 2019 PM ISA that spanned diverse geographical areas and study populations.”<sup>78</sup>

- “[T]hese additional studies provide further evidence that lower [socioeconomic status] communities are exposed to higher concentrations of PM<sub>2.5</sub> compared to higher [socioeconomic status] communities.”<sup>79</sup>

The Draft ISA Supplement also acknowledges the limitations of other types of recent evidence. For example:

- A recent human exposure study, Wyatt *et al.* (2020), included “no Bonferroni corrections . . . to account for the multiple comparisons made in the study.”<sup>80</sup>
- Recent studies of PM<sub>2.5</sub> and COVID-19 infection or death “were subject to methodological issues that may influence results.”<sup>81</sup>

These limitations together with other uncertainties discussed above, mean that the evidence is too uncertain to warrant changes to any conclusions from the 2019 ISA.

Thus, the scientific record for reconsideration of the 2020 decision to retain the PM NAAQS is scientifically consistent with the record for the 2020 decision. Although the record for reconsideration of the 2020 decision involves a number of new studies, significant scientific uncertainties and limitations remain. Accordingly, the more recent studies do not necessitate reevaluation by EPA of its prior conclusions concerning effects associated with PM in ambient air, particularly when remaining uncertainties are taken into account. In finalizing the ISA Supplement, EPA should acknowledge more clearly the consistency of the scientific record now, including its uncertainties, with that in 2020.

Moreover, given the consistency of the newer evidence with that in the 2019 ISA, it is unclear that even a newly-formed CASAC should reach a different conclusion than that it reached

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<sup>78</sup> *Id.* at 3-76.

<sup>79</sup> *Id.* at 3-128.

<sup>80</sup> *Id.* at 3-122.

<sup>81</sup> *Id.* at 5-3.

based on the 2019 ISA. To the extent EPA intends to seek CASAC’s advice again on whether revision of the primary NAAQS for PM<sub>2.5</sub> is warranted, EPA should again provide CASAC with an opportunity to review the 2019 ISA. Only in this manner can EPA ensure that CASAC’s advice is based on the complete scientific record.

**VI. EPA Must Provide CASAC with the Information the Committee Needs To Fulfill its Statutory Duties.**

Section 109 of the Act charges EPA with completing a thorough review of air quality criteria and related NAAQS at least every five years and to recommend revisions to those criteria and NAAQS, “as may be appropriate.”<sup>82</sup> Current EPA practice is that the ISA serve as the required air quality criteria. For this reconsideration, EPA formed a new CASAC PM Panel with only 2 of its 22 members having served on the prior CASAC. Instead of providing the current CASAC PM Panel with the 2019 ISA, EPA submitted to the Panel the Draft ISA Supplement. That document contains only brief summaries of the evidence in the 2019 ISA on endpoints previously determined to be “causal” and omits any information on the decision framework that supported the causal determinations and the detailed information normally included in an ISA. EPA must ensure that the members of the CASAC PM panel are provided with the 2019 ISA before they make recommendations on NAAQS. The 2019 ISA – together with the final ISA Supplement – must provide the basis for CASAC’s advice to the Administrator on whether, and if so, how, to revise the 2020 decision retaining the existing NAAQS.

Section 109(d) of the Act also requires CASAC to, *inter alia*, “advise the Administrator of any adverse public health, welfare, social, economic, or energy effects which may result from various strategies for attainment and maintenance” of NAAQS.<sup>83</sup> Neither the 2019 ISA nor the

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<sup>82</sup> CAA § 109(d)(2)(B).

<sup>83</sup> *Id.* § 109(d)(2)(C)(iii).

Draft ISA Supplement provide CASAC with the scientific and technical information that Committee needs to provide this advice to the Administrator. The Draft ISA Supplement should do so when it is finalized.

## **VII. Conclusion**

The Draft ISA Supplement is a seriously flawed document. Its preparation does not appear to have involved appropriate systematic review to guide selection and evaluation of the studies discussed in the document. Moreover, the document fails to present in a straightforward and useful manner the most important information to be derived from those studies, i.e., the levels of PM in ambient air that have been associated with adverse health and welfare effects. These flaws should be corrected in the final ISA Supplement. Even with its flaws, however, the Draft ISA Supplement indicates that the more recent evidence is consistent with and supportive of the conclusions in the 2019 ISA that formed the basis for the 2020 decision to retain the existing NAAQS.