

Date: September 20, 2019
To: Members of the Independent Particulate Matter Review Panel
From: H. Christopher Frey
Subject: Context and Charge Questions for October 10-11, 2019 Meeting to Review the EPA Draft Policy Assessment for Particulate Matter

Under Section 108 of the Clean Air Act (CAA), the National Ambient Air Quality Standards (NAAQS) “shall accurately reflect the latest scientific knowledge useful in indicating the kind and extent of all identifiable effects on public health and welfare which may be expected from the presence of such pollutant in the ambient air.” Section 109(d)(2)(B) provides that an independent scientific review committee “shall complete a review of the criteria...and the national primary and secondary ambient air quality standards...and shall recommend to the Administrator any new...standards and revisions of existing criteria and standards as may be appropriate...”. Since the early 1980s, this independent review function has been performed by the U.S. Environmental Protection Agency (EPA) Clean Air Scientific Advisory Committee (CASAC). More detail on the overarching context for NAAQS review is given in **Attachment A**.

For four decades, the chartered 7-member CASAC has been augmented with additional experts to have the breadth, depth, and diversity of expertise needed to review multidisciplinary scientific issues relevant to each of the criteria pollutants regulated under the NAAQS. Under the authority of CASAC’s Charter, a Particulate Matter (PM) Review Panel was appointed in November 2015 to augment the CASAC for the current review of NAAQS for PM. On October 10, 2018, the CASAC PM Review Panel was involuntarily separated from the EPA by press release. This was done without advance notice to the full chartered CASAC and without prior consultation with the panel or the full chartered CASAC. There is no precedent for disbanding a review panel in the middle of a review cycle. Additional details on the role of CASAC review panels, and of the CASAC PM Review Panel specifically, are given in **Attachment B**.

Since that time, members of the disbanded CASAC PM Review Panel have formed this Independent Particulate Matter Review Panel (IPMRP). The criteria for membership of the IPMRP is given in **Attachment C**. On December 10, 2018, the IPMRP submitted public comments to the CASAC and EPA pertaining to the EPA’s Integrated Science Assessment (ISA) for Particulate Matter (External Review Draft – October 2018) and pertaining to recent ad hoc changes to the NAAQS review process. The IPMRP subsequently submitted additional comments to the CASAC and EPA on March 27, 2019 on the draft ISA and the NAAQS review process.

In early September of 2019, EPA released an external review draft of the Policy Assessment (PA) for the PM NAAQS review. The IPMRP will have a face-to-face meeting on Thursday October 10, 2019 and Friday, October 11, 2019 to deliberate on the draft Policy Assessment and other selected issues. General administrative procedures for the upcoming meeting of the IPMRP are given in **Attachment D**.

The IPMRP will address general and specific charge questions developed by the EPA, as well as supplemental charge questions that address scientific issues pertaining to the draft Policy Assessment in more depth, as well as issues related to the NAAQS review process and the key scientific findings of the draft Integrated Science Assessment. The charge questions from EPA to the CASAC are given in **Attachment E**. These charge questions are incorporated and supplemented with additional charge questions for the IPMRP in **Attachment F**. Discussant and Lead Discussant assignments for the charge questions are in **Attachment G**.

ATTACHMENT A: OVERARCHING CONTEXT FOR REVIEW OF THE PARTICULATE MATTER (PM) NATIONAL AMBIENT AIR QUALITY STANDARDS (NAAQS)

This following is excerpted from the undated memorandum from Erika N. Sasser to Aaron Yeow pertaining to the CASAC review of the draft PM Policy Assessment.¹ Text in addition to that excerpted from the memorandum is *italicized*.

Two sections of the Clean Air Act (CAA) govern the establishment and revision of the NAAQS. Section 108 (42 U.S.C. 7408) directs the Administrator to identify and list certain air pollutants and then to issue air quality criteria for those pollutants.² *Additionally, Section 108 states that the criteria “shall accurately reflect the latest scientific knowledge useful in indicating the kind and extent of all identifiable effects on public health and welfare which may be expected from the presence of such pollutant in the ambient air.” The NAAQS must be based on these criteria.*

Section 109 [42 U.S.C. 7409] directs the Administrator to propose and promulgate “primary” and “secondary” NAAQS for pollutants for which air quality criteria are issued [42 U.S.C. § 7409(a)]. *Section 109 requires the EPA Administrator to “complete a thorough review” of the NAAQS at five-year intervals.* Section 109(b)(1) defines primary standards as ones “the attainment and maintenance of which in the judgment of the Administrator, based on such criteria and allowing an adequate margin of safety, are requisite to protect the public health.”³ Under section 109(b)(2), a secondary standard must “specify a level of air quality the attainment and maintenance of which, in the judgment of the Administrator, based on such criteria, is requisite to protect the public welfare from any known or anticipated adverse effects associated with the presence of [the] pollutant in the ambient air.”⁴

In setting primary and secondary standards that are “requisite” to protect public health and welfare, respectively, as provided in section 109(b), the EPA’s task is to establish standards that are neither more nor less stringent than necessary. In so doing, the EPA may not consider the costs of implementing the standards.⁵ Likewise, “[a]ttainability and technological feasibility are not relevant considerations in the promulgation of national ambient air quality standards.”⁶ At the same time, courts have clarified the EPA may consider “relative proximity to peak background ... concentrations” as a factor in deciding how to revise the NAAQS in the context of considering

¹ Sasser, E.N., CASAC Review of the document titled Policy Assessment for Review of the National Ambient Air Quality Standards for Particulate Matter – External Review Draft, Memorandum to A. Yeow, U.S. Environmental Protection Agency, Research Triangle Park, NC, undated, [https://yosemite.epa.gov/sab/sabproduct.nsf/264cb1227d55e02c85257402007446a4/64C246444C9CC319852584430045E365/\\$File/Charge+memo+and+questions+for+draft+PA.pdf](https://yosemite.epa.gov/sab/sabproduct.nsf/264cb1227d55e02c85257402007446a4/64C246444C9CC319852584430045E365/$File/Charge+memo+and+questions+for+draft+PA.pdf) (accessed September 13, 2019).

² In the current NAAQS process, the air quality criteria are represented by the Integrated Science Assessment.

³ The legislative history of section 109 indicates that a primary standard is to be set at “the maximum permissible ambient air level . . . which will protect the health of any [sensitive] group of the population,” and that for this purpose “reference should be made to a representative sample of persons comprising the sensitive group rather than to a single person in such a group.” S. Rep. No. 91-1196, 91st Cong., 2d Sess. 10 (1970).

⁴ Under CAA section 302(h) (42 U.S.C. § 7602(h)), effects on welfare include, but are not limited to, “effects on soils, water, crops, vegetation, manmade materials, animals, wildlife, weather, visibility, and climate, damage to and deterioration of property, and hazards to transportation, as well as effects on economic values and on personal comfort and well-being.”

⁵ See generally, *Whitman v. American Trucking Associations*, 531 U.S. 457, 465-472, 475-76 (2001).

⁶ *American Petroleum Institute v. Costle*, 665 F.2d 1176, 1185 (D.C. Cir. 1981).

standard levels within the range of reasonable values supported by the air quality criteria and judgments of the Administrator.⁷

Section 109(d)(2)(B) provides that the independent scientific review committee “shall complete a review of the criteria...and the national primary and secondary ambient air quality standards...and shall recommend to the Administrator any new...standards and revisions of existing criteria and standards as may be appropriate....” Since the early 1980s, this independent review function has been performed by the CASAC of the EPA’s Science Advisory Board.⁸ A number of other advisory functions are also identified for the committee by section 109(d)(2)(C), which reads:

Such committee shall also (i) advise the Administrator of areas in which additional knowledge is required to appraise the adequacy and basis of existing, new, or revised national ambient air quality standards, (ii) describe the research efforts necessary to provide the required information, (iii) advise the Administrator on the relative contribution to air pollution concentrations of natural as well as anthropogenic activity, and (iv) 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 such national ambient air quality standards.

⁷ American Trucking Associations, Inc. v. EPA, 283 F.3d 355, 379 (D.C. Cir. 2002).

⁸ *CASAC is administered by the EPA Science Advisory Board office staff, but is not part of the EPA Science Advisory Board. CASAC is chartered under the authority of the Clean Air Act. The SAB is separately chartered under the authority of the Environmental Research, Development, and Demonstration Authorization Act.*

ATTACHMENT B: BACKGROUND ON CASAC PM REVIEW PANEL AND THE INDEPENDENT PARTICULATE MATTER REVIEW PANEL (IPMRP)

The core statutory obligation of the EPA Clean Air Scientific Advisory Committee (CASAC) is incorporated into CASAC's charter with Congress.⁹ Under that charter, CASAC may be augmented with experts. Specifically, the charter states:

“EPA, or CASAC with the Agency's approval, may form subcommittees or workgroups for any purpose consistent with this charter. Such subcommittees or workgroups may not work independently of the chartered committee and must report their recommendations and advice to the chartered CASAC for full deliberation and discussion. Subcommittees or workgroups have no authority to make decisions on behalf of the chartered committee, nor can they report directly to the EPA.”

Augmentation of CASAC with additional experts for the review of criteria and standards has been a routine practice for four decades. Additional experts have been appointed to review panels that interact with members of the chartered CASAC for all reviews since the late 1970s.¹⁰ Over time, the chartered CASAC has typically been augmented with 12 or more additional experts in a given review cycle for a given criteria pollutant. The average number of experts among 20 such panels for which membership data is available is 14, and the average size of the review panels is 20 members, inclusive of participating CASAC members.

The previous four particulate matter review panels have been comprised of members of the chartered CASAC augmented with additional experts. CASAC was augmented with additional experts for the joint review of the criteria and standards for particulate matter and sulfur oxides in the early 1980s.¹¹ The CASAC Subcommittee on Health Effects of Particulate Matter and Sulfur Oxides included six experts in addition to members of the chartered CASAC. The CASAC Subcommittee on Welfare Effects of Particulate Matter and Sulfur Oxides included five additional experts in addition to members of the chartered CASAC. In total, there were 11 additional experts who augmented the chartered CASAC for this review cycle. For the 1994 to 1996 PM review, there were 6 members of the chartered CASAC and 15 additional experts on the review panel.¹² For the 2001 to 2006 scientific review, and for the 2008 to 2010 scientific

⁹ United States Environmental Protection Agency Charter, Clean Air Scientific Advisory Committee, Filed with Congress, June 5, 2019, [https://yosemite.epa.gov/sab/sabproduct.nsf/WebCASAC/2019casaccharter/\\$File/CASAC%202019%20Renewal%20Charter%203.21.19%20-%20final.pdf](https://yosemite.epa.gov/sab/sabproduct.nsf/WebCASAC/2019casaccharter/$File/CASAC%202019%20Renewal%20Charter%203.21.19%20-%20final.pdf)

¹⁰ Frey, H.C., A.V. Diez Roux, J. Balmes, J.C. Chow, D.W. Dockery, J.R. Harkema, J. Kaufman, D.M. Kenski, M. Kleinman, R.L. Poirot, J.A. Sarnat, E.A. Sheppard, B. Turpin, and S. Vedal, “CASAC Review of EPA's Integrated Science Assessment (ISA) for Particulate Matter (External Review Draft – October 2018),” 34 page letter and 100 pages of attachments submitted to Chair, Clean Air Scientific Advisory Committee, U.S. Environmental Protection Agency and to Docket EPA–HQ–ORD–2014–0859, December 10, 2018. Pages E-37 to E-39, [https://yosemite.epa.gov/sab/sabproduct.nsf/086D8B853E0B63AE8525835F004DC679/\\$File/PMRP+Letter+to+CASAC+181210+Final+181210.pdf](https://yosemite.epa.gov/sab/sabproduct.nsf/086D8B853E0B63AE8525835F004DC679/$File/PMRP+Letter+to+CASAC+181210+Final+181210.pdf)

¹¹ EPA, Air Quality Criteria for Particulate Matter and Sulfur Oxides, Volume 1, EPA-600/8-82-029a, U.S. Environmental Protection Agency, Research Triangle Park, NC, December 1982. http://ofmpub.epa.gov/eims/eimscmm.getfile?p_download_id=459608

¹² Wolff, G.T., “Closure by the Clean Air Scientific Advisory Committee (CASAC) on the Staff Paper for Particulate Matter,” Letter to Carol M. Browner, EPA-SAB-CASAC-LTR-96-008, Clean Air Scientific Advisory Committee, U.S. Environmental Protection Agency, Washington, DC, June 13, 1996. [https://yosemite.epa.gov/sab/sabproduct.nsf/C146C65BA26865A2852571AA00530007/\\$File/casl9608.pdf](https://yosemite.epa.gov/sab/sabproduct.nsf/C146C65BA26865A2852571AA00530007/$File/casl9608.pdf)

review, there were 7 members of the chartered CASAC and 15 additional experts.^{13,14} From 2015 to 2018, the CASAC Particulate Review Panel had 6 members of the chartered CASAC and 20 additional experts.¹⁵ Thus, the use of augmented review panels specifically for particulate matter dates back 37 years.

The 7-member chartered CASAC does not have the breadth, depth, and diversity of expertise required for a review of the particulate matter criteria and standards that meets the requirements of the Clean Air Act for a “thorough review” that “shall accurately reflect the latest scientific knowledge” of the “extent and kind of ... effects.”¹⁶ The only credible way to provide a “thorough review” that “shall accurately reflect the latest scientific knowledge” is to engage scientists who are active at the leading edge of scientific work in disciplines and areas related to the subject matter of a review, as described in the February 4, 2015 Federal Register request for nominations, and as illustrated by the history of CASAC Review Panels.

On February 4, 2015, the EPA Science Advisory Board (SAB) office issued a “Request for Nominations of Experts for the Clean Air Scientific Advisory Committee (CASAC) Particulate Matter Review Panel.”¹⁷ In this notice, EPA stated that it will “form a CASAC ad hoc panel to provide advice through the chartered CASAC on the scientific and technical aspects of air quality criteria and the National Ambient Air Quality Standards (NAAQS) for particulate matter (PM).” The notice further stated:

“The SAB Staff Office is seeking nominations of nationally and internationally recognized scientists with demonstrated expertise and research in the field of air pollution related to PM. Experts are sought in: air quality and climate responses, atmospheric science and chemistry, dosimetry, toxicology, controlled clinical exposure, epidemiology, biostatistics, human exposure modeling, risk assessment/modeling, characterization of PM concentrations and light extinction, and visibility impairment and related welfare effects.”

¹³ Henderson, R. “Clean Air Scientific Advisory Committee Recommendations Concerning the Proposed National Ambient Air Quality Standards for Particulate Matter,” EPA-CASAC-LTR-06-002, Letter to Stephen L. Johnson, Clean Air Scientific Advisory Committee, U.S. Environmental Protection Agency, Washington, DC, March 21, 2006, [https://yosemite.epa.gov/sab/sabproduct.nsf/CD706C976DAC62B3852571390081CC21/\\$File/casac-ltr-06-002.pdf](https://yosemite.epa.gov/sab/sabproduct.nsf/CD706C976DAC62B3852571390081CC21/$File/casac-ltr-06-002.pdf)

¹⁴ Samet, J.M., “CASAC Review of Policy Assessment for the Review of the PM NAAQS – Second External Review Draft (June 2010),” EPA-CASAC-10-015, Letter to Lisa P. Jackson, Clean Air Scientific Advisory Committee, U.S. Environmental Protection Agency, Washington, DC, September 10, 2010, [https://yosemite.epa.gov/sab/sabproduct.nsf/CCF9F4C0500C500F8525779D0073C593/\\$File/EPA-CASAC-10-015-unsigned.pdf](https://yosemite.epa.gov/sab/sabproduct.nsf/CCF9F4C0500C500F8525779D0073C593/$File/EPA-CASAC-10-015-unsigned.pdf)

¹⁵ Diez Roux, A., “CASAC Review of the EPA’s Integrated Review Plan for the National Ambient Air Quality Standards for Particulate Matter (External Review Draft – April 2016),” EPA-CASAC-16-003, Letter to Gina McCarthy, Clean Air Scientific Advisory Committee, U.S. Environmental Protection Agency, Washington, DC, August 31, 2016. [https://yosemite.epa.gov/sab/sabproduct.nsf/9920C7E70022CCF98525802000702022/\\$File/EPA-CASAC+2016-003+unsigned.pdf](https://yosemite.epa.gov/sab/sabproduct.nsf/9920C7E70022CCF98525802000702022/$File/EPA-CASAC+2016-003+unsigned.pdf)

¹⁶ Frey, H.C., A.V. Diez Roux, J. Balmes, J.C. Chow, D.W. Dockery, J.R. Harkema, J. Kaufman, D.M. Kenski, M. Kleinman, R.L. Poirot, J.A. Sarnat, E.A. Sheppard, B. Turpin, and S. Vedal, “CASAC Review of EPA’s Integrated Science Assessment (ISA) for Particulate Matter (External Review Draft – October 2018),” 34 page letter and 100 pages of attachments submitted to Chair, Clean Air Scientific Advisory Committee, U.S. Environmental Protection Agency and to Docket EPA–HQ–ORD–2014–0859, December 10, 2018. Page E-39. [https://yosemite.epa.gov/sab/sabproduct.nsf/086D8B853E0B63AE8525835F004DC679/\\$File/PMRP+Letter+to+CA+SAC+181210+Final+181210.pdf](https://yosemite.epa.gov/sab/sabproduct.nsf/086D8B853E0B63AE8525835F004DC679/$File/PMRP+Letter+to+CA+SAC+181210+Final+181210.pdf)

¹⁷ EPA, “Request for Nominations of Experts for the Clean Air Scientific Advisory Committee (CASAC) Particulate Matter Review Panel,” *Federal Register*, 80(23):6086-6089 (February 4, 2015). <https://www.govinfo.gov/content/pkg/FR-2015-02-04/pdf/2015-02265.pdf>

The notice also stated:

“Selection criteria to be used for panel membership include: (a) Scientific and/or technical expertise, knowledge, and experience (primary factors); (b) availability and willingness to serve; (c) absence of financial conflicts of interest; (d) absence of an appearance of a lack of impartiality; (e) skills working in committees, subcommittees and advisory panels; and, (f) for the panel as a whole, diversity of expertise and viewpoints.”

On November 17, 2015, a memorandum from Aaron Yeow to Chris Zarba in the EPA Science Advisory Board office established the CASAC PM Review Panel.¹⁸ The panel was formed for the following purpose:

“An ad hoc expert panel of the CASAC will provide independent advice through the chartered CASAC on EPA’s technical and policy assessments that support the Agency’s review of the National Ambient Air Quality Standard (NAAQS) for PM, including drafts of the Integrated Review Plan, Integrated Science Assessment, Risk/Exposure Assessment, and Policy Assessment.”

In the case of particulate matter, for which there are health effects data from multiple scientific disciplines, including epidemiology, toxicology, and controlled human studies, it has been common practice to have multiple experts in each of these disciplines to assure breadth and depth of expertise. The CASAC PM Review Panel was comprised of leading scientists recognized nationally and internationally for their expertise in multiple scientific disciplines, including air quality, exposure assessment, dosimetry, toxicology, epidemiology, medicine, risk assessment methodology, uncertainty analysis, and related fields.

The CASAC Particulate Matter Panel held teleconference meetings on May 23, 2016, and August 9, 2016, to peer review the EPA’s Integrated Review Plan for the National Ambient Air Quality Standards for Particulate Matter (External Review Draft – April 2016).¹⁹

On October 10, 2018, then acting EPA Administrator Wheeler eliminated the CASAC PM Review Panel by press release,²⁰ with a follow-up email from the SAB office on October 11, 2018. This was done without advance notice and without prior consultation with the panel or the CASAC. There is no precedent for disbanding a review panel in the middle of a review cycle.

¹⁸ Yeow, A., Formation of the Clean Air Scientific Advisory Committee (CASAC) Particulate Matter (PM) Review Panel, Memorandum to C. Zarba, Science Advisory Board Staff Office, U.S. Environmental Protection Agency, Washington, DC, November 17, 2015, [https://yosemite.epa.gov/sab/sabproduct.nsf/0/EB862B233FBD0CDE85257DDA004FCB8C/\\$File/Determination%20memo-CASAC%20PM.pdf](https://yosemite.epa.gov/sab/sabproduct.nsf/0/EB862B233FBD0CDE85257DDA004FCB8C/$File/Determination%20memo-CASAC%20PM.pdf)

¹⁹ Diez Roux, A., “CASAC Review of the EPA’s Integrated Review Plan for the National Ambient Air Quality Standards for Particulate Matter (External Review Draft – April 2016),” EPA-CASAC-16-003, Letter to Gina McCarthy, Clean Air Scientific Advisory Committee, U.S. Environmental Protection Agency, Washington, DC, August 31, 2016. <https://yosemite.epa.gov/sab/sabproduct.nsf/9920C7E70022CCF98525802000702022/%24File/EPA-CASAC+2016-003+unsigned.pdf>

²⁰ EPA, “Acting Administrator Wheeler Announces Science Advisors for Key Clean Air Act Committee Tasks Chartered Panel to Lead Review of Ozone & Particulate Matter Standards Under Reformed Process,” News Release, U.S. Environmental Protection Agency, Washington, DC, October 10, 2018, <https://www.epa.gov/newsreleases/acting-administrator-wheeler-announces-science-advisors-key-clean-air-act-committee>

The EPA released the external review draft of the Integrated Science Assessment (ISA) on October 15, 2018, five days after disbanding the CASAC PM Review Panel.²¹ The Federal Register notice announcing that the draft ISA was available for public review was dated October 16, 2018 and published on October 23, 2018.²²

Compared to the chartered CASAC, the PM review panel has more experts, covers more scientific disciplines, and has multiple experts who provide diversity of perspectives in many key disciplines, such as epidemiology, toxicology, and human clinical studies, among others.

Since that time, members of the disbanded CASAC PM Review Panel have formed this Independent Particulate Matter Review Panel (IPMRP). Like the disbanded CASAC PM Review Panel, the IPMRP is committed to providing “public service” “in protecting public health and safeguarding our nation’s air,” as described in the Nov 20, 2015 appointment letters from the EPA SAB office to panelists. The panel does not require affiliation with EPA to carry on its mission. Although no longer affiliated with the U.S. EPA, the IPMRP continues as a group of independent science advisors recognized for their national leadership in policy-relevant science pertaining to the particulate matter NAAQS.

The mission of this Panel is three-fold: (1) to provide independent advice regarding technical and policy assessments pertaining to the EPA’s review of the National Ambient Air Quality Standard (NAAQS); (2) objectively observe and assess modifications to the NAAQS Review Process and their implications; and (3) educate the public about the public health and public welfare objectives of the NAAQS, the NAAQS review process, and scientific issues pertaining to the NAAQS. Given the process under which this group was originally formed as the CASAC PM Review Panel, we are recognized for our expertise and our independence.

On December 10, 2018, the IPMRP submitted public comments to the CASAC pertaining to the EPA’s Integrated Science Assessment (ISA) for Particulate Matter (External Review Draft – October 2018).²³ The IPMRP subsequently submitted comments to the CASAC on March 27, 2019 with additional comments on the draft ISA.²⁴ These letters contain detail on the statutory requirements for the review of the NAAQS, history of the CASAC PM Review Panel and the

²¹ EPA, “Integrated Science Assessment for Particulate Matter (External Review Draft),” EPA/600/R-18/179, U.S. Environmental Protection Agency, Research Triangle Park, NC, October 2018. [https://yosemite.epa.gov/sab/sabproduct.nsf/0/932D1DF8C2A9043F852581000048170D/\\$File/PM-1STERD-OCT2018.PDF](https://yosemite.epa.gov/sab/sabproduct.nsf/0/932D1DF8C2A9043F852581000048170D/$File/PM-1STERD-OCT2018.PDF)

²² EPA, “Integrated Science Assessment for Particulate Matter (External Review Draft),” *Federal Register*, 83(205):53471-53472 (October 23, 2019). <https://www.govinfo.gov/content/pkg/FR-2018-10-23/pdf/2018-23125.pdf>

²³ Frey, H.C., A.V. Diez Roux, J. Balmes, J.C. Chow, D.W. Dockery, J.R. Harkema, J. Kaufman, D.M. Kenski, M. Kleinman, R.L. Poirot, J.A. Sarnat, E.A. Sheppard, B. Turpin, and S. Vedal, “CASAC Review of EPA’s Integrated Science Assessment (ISA) for Particulate Matter (External Review Draft – October 2018),” 34 page letter and 100 pages of attachments submitted to Chair, Clean Air Scientific Advisory Committee, U.S. Environmental Protection Agency and to Docket EPA–HQ–ORD–2014-0859, December 10, 2018. [https://yosemite.epa.gov/sab/sabproduct.nsf/086D8B853E0B63AE8525835F004DC679/\\$File/PMRP+Letter+to+CASAC+181210+Final+181210.pdf](https://yosemite.epa.gov/sab/sabproduct.nsf/086D8B853E0B63AE8525835F004DC679/$File/PMRP+Letter+to+CASAC+181210+Final+181210.pdf)

²⁴ Frey, H.C., A.V. Diez Roux, P. Adams, G. Allen, J. Balmes, J.C. Chow, D.W. Dockery, J.R. Harkema, J. Kaufman, D.M. Kenski, M. Kleinman, R. McConnell, R.L. Poirot, J.A. Sarnat, E.A. Sheppard, B. Turpin, and S. Vedal, “03-07-19 Draft CASAC Review of EPA’s Integrated Science Assessment (ISA) for Particulate Matter (External Review Draft – October 2018),” 19 page letter submitted to Chair, Clean Air Scientific Advisory Committee, U.S. Environmental Protection Agency, Washington, DC, March 27, 2019. [https://yosemite.epa.gov/sab/sabproduct.nsf/A491FD482BB83BEE852583CA006A2548/\\$File/Written+Comments+from+17+Members+of+the+CASAC+PM+Review+Panel+that+was+Disbanded+on+October+11+2018+rev.pdf](https://yosemite.epa.gov/sab/sabproduct.nsf/A491FD482BB83BEE852583CA006A2548/$File/Written+Comments+from+17+Members+of+the+CASAC+PM+Review+Panel+that+was+Disbanded+on+October+11+2018+rev.pdf)

IPMRP, and specific findings and recommendations related to the CASAC, NAAQS review process, and draft ISA.

In early September of 2019, EPA released an external review draft of the Policy Assessment (PA) for the PM NAAQS review.²⁵ A Federal Register notice published on September 11, 2019 indicated availability of the draft PA for public comment through November 12, 2019.²⁶ The chartered CASAC will hold a public teleconference on October 22, 2019 to receive public comments to consider in their peer review of the EPA's Policy Assessment for Particulate Matter on October 24-25, 2019.²⁷ The chartered CASAC will hold a public meeting at a location to be determined in North Carolina on October 24-25, 2019 for the purpose of conducting a peer review of EPA's Policy Assessment for the Review of the National Ambient Air Quality Standards for Particulate Matter (External Review Draft – September 2019).²⁸

The CASAC stated in its April 11, 2019 letter to the EPA Administrator that “the breadth and diversity of evidence to be considered exceeds the expertise of the statutory CASAC members, or indeed of any seven individuals.”²⁹ Furthermore, the CASAC recommended that “the EPA reappoint the previous CASAC PM panel or appoint a panel with similar expertise.” The disbanding of the PM Review Panel on October 10, 2017 deprived CASAC of the needed expertise. The EPA Administrator responded in a letter dated July 25, 2019 that disregarded CASAC's advice to reappoint the disbanded panel or form a new panel. Specifically, the Administrator stated that he would instead “create a pool of subject matter experts.”³⁰ In addition, he rejected the CASAC request for the augmented committee to review a revised draft of the ISA. On August 7, 2019, EPA issued a Federal Register notice to request nominations for consultants to support CASAC reviews of particulate matter and ozone.³¹

²⁵ EPA (2019), Policy Assessment for the Review of the National Ambient Air Quality Standards for Particulate Matter, External Review Draft, EPA-452/P-19-001, U.S. Environmental Protection Agency, Research Triangle Park, NC, September 2019. https://www.epa.gov/sites/production/files/2019-09/documents/draft_policy_assessment_for_pm_anaqs_09-05-2019.pdf

²⁶ EPA, “Release of a Draft Document Related to the Review of the National Ambient Air Quality Standards for Particulate Matter,” *Federal Register*, 84(176):47944-47945 (September 11, 2019). <https://www.govinfo.gov/content/pkg/FR-2019-09-11/pdf/2019-19627.pdf>

²⁷ Public Teleconference of the Chartered Clean Air Scientific Advisory Committee (CASAC) on Particulate Matter, 10/22/2019, 12:00 PM - 04:00 PM. <https://yosemite.epa.gov/sab/sabproduct.nsf/MeetingCalCASAC/A2DF51609E3DFC9C85258473006CF120?OpenDocument>

²⁸ Public Meeting of the Chartered Clean Air Scientific Advisory Committee (CASAC) on Particulate Matter, 10/24/2019 to 10/25/2019. <https://yosemite.epa.gov/sab/sabproduct.nsf/MeetingCalCASAC/49FAF8892AD2D38285258473006D1F4A?OpenDocument>

²⁹ Cox, L.A. (2019), “CASAC Review of the EPA's Integrated Science Assessment for Particulate Matter (External Review Draft – October 2018),” EPA-CASAC-19-002, Letter to A. Wheeler, Clean Air Scientific Advisory Committee, U.S. Environmental Protection Agency, Washington, DC, April 2019. [https://yosemite.epa.gov/sab/sabproduct.nsf/LookupWebReportsLastMonthCASAC/6CBCBBC3025E13B4852583D90047B352/\\$File/EPA-CASAC-19-002+.pdf](https://yosemite.epa.gov/sab/sabproduct.nsf/LookupWebReportsLastMonthCASAC/6CBCBBC3025E13B4852583D90047B352/$File/EPA-CASAC-19-002+.pdf)

³⁰ Wheeler, A.R. (2019), Letter to L.A. Cox, EPA Clean Air Scientific Advisory Committee, from Administrator, U.S. Environmental Protection Agency, Washington, DC, July 25, 2019, [https://yosemite.epa.gov/sab/sabproduct.nsf/0/6CBCBBC3025E13B4852583D90047B352/\\$File/EPA-CASAC-19-002_Response.pdf](https://yosemite.epa.gov/sab/sabproduct.nsf/0/6CBCBBC3025E13B4852583D90047B352/$File/EPA-CASAC-19-002_Response.pdf)

³¹ EPA, “Request for Nominations of Consultants To Support the Clean Air Scientific Advisory Committee (CASAC) for the Particulate Matter and Ozone Reviews,” *Federal Register*, 84(152):38625 (August 7, 2019). <https://www.govinfo.gov/content/pkg/FR-2019-08-07/pdf/2019-16913.pdf>

The use of a “pool of subject matter experts” rather than a review panel to augment the chartered CASAC is unprecedented. Review Panels augment and report through the chartered CASAC, working in parallel and in collaboration with the members of the chartered CASAC. Members of review panels are nominated by the public and the nominations are subject to public comment. The SAB staff office reviews, vets, and appoints members of review panels. Members of review panels participate in meetings with members of the chartered CASAC, and deliberate interactively with members of the chartered CASAC on complex subject matter. The chartered CASAC is ultimately responsible for the content of advice sent to the Administrator, but the formulation of that advice is informed based on deliberations with panelists who provide the breadth, depth, and diversity of needed scientific expertise.

In contrast, there has been no opportunity for public comment on the nominees for the pool of subject matter experts, who were named in an EPA press release on September 13, 2019.³² The decision regarding appointments of ad hoc consultants to serve as subject matter experts was made by the Administrator, not by the SAB Staff Office. All interactions between CASAC and the subject matter experts will be done solely through the Designated Federal Official (DFO) for CASAC and the CASAC chair, in writing. Subject matter experts will not be allowed to participate in deliberative meetings with CASAC. For example, subject matter experts are not allowed to, unless invited in writing by the chair, respond to all charge questions that might be of interest to the consultant. Subject matter experts will not be allowed to deliberate or interact with the CASAC other than in writing. The appointment of subject matter experts by the Administrator is not correcting the deficiencies in CASAC’s ability to conduct a thorough review that have resulted from disbanding the PM Review Panel.

Therefore, the IPMRP will continue to provide its expert advice, based on the breadth, depth, and diversity of its expertise, and based on interactive deliberation among its members. The IPMRP will submit its review and advice as a public comment to the CASAC and as a public comment to docket EPA-HQ-OAR-2015-0072 for the PM NAAQS review.

³² EPA, “Administrator Wheeler Announces New CASAC Member, Pool of NAAQS Subject Matter Experts,” News Release, U.S. Environmental Protection Agency, Washington, DC, September 13, 2019. <https://www.epa.gov/newsreleases/administrator-wheeler-announces-new-casac-member-pool-naaqs-subject-matter-experts>.

ATTACHMENT C: Eligibility for Membership in the Independent Particulate Matter Review Panel

The criteria for membership on the IPMRP are that any member of the CASAC PM Review Panel from any time during the CASAC PM Review Panel existence from 2015 until being disbanded on October 10, 2018, and any member of the chartered CASAC from any time during the CASAC PM Review Panel's existence, is eligible, with the exception of any such persons currently serving as members of the chartered CASAC. All of the members of the IPMRP were originally appointed by EPA as Special Government Employees (SGEs) and were subject to disclosure requirements and ethics review. Members of the IPMRP have submitted updates of these disclosures for review by a former EPA Deputy Ethics official in a good faith effort to meet or exceed peer review process and ethics requirements.

On October 31, 2017, EPA Administrator Scott Pruitt signed a memorandum that changed membership criteria for EPA advisory committees.³³ The memorandum states that "no member of an EPA federal advisory committee currently receive EPA grants," but that this "principle should not apply to state, tribal, or local government agency recipients of EPA grants." This is inconsistent with the Federal Advisory Committee Act and inappropriate for four reasons. One is the obvious inconsistency of implying that receiving a grant creates a conflict of interest for one but not another class of persons. The second is the longstanding recognition that receipt of a peer-reviewed scientific research grant, for which the Agency does not manage the work nor control the output, is not a conflict of interest. Per the Office of Management and Budget (OMB): "When an agency awards grants through a competitive process that includes peer review, the agency's potential to influence the scientist's research is limited. As such, when a scientist is awarded a government research grant through an investigator-initiated, peer-reviewed competition, there generally should be no question as to that scientist's ability to offer independent scientific advice to the agency on other projects."³⁴ A 2013 report by the EPA Office of Inspector General reaffirmed that receipt of an EPA research grant is not a conflict of interest.³⁵ However, there can be situations in which a member of an advisory committee should recuse themselves from discussions that might pertain to their own work. Thus, third, the CASAC has had recusal policies in place for dealing with this issue and situations in which a member's work may come up for deliberation. Fourth, the memorandum does not acknowledge that persons with financial or professional ties to regulated industries have, at the very least, the appearance of conflict of interest. With respect to members who currently hold or have recently held EPA STAR research grants, we reject Administrator Pruitt's restrictions.

³³ Pruitt, E.S., "Strengthening and Improving Membership on EPA Federal Advisory Committees," Memorandum, U.S. Environmental Protection Agency, October 31, 2017. <https://www.epa.gov/sites/production/files/2018-05/documents/image2018-05-09-173219.pdf>.

³⁴ Office of Management and Budget, "Final Information Quality Bulletin for Peer Review," *Federal Register*, 70(10):2664-2677 (January 14, 2005). <https://www.govinfo.gov/content/pkg/FR-2005-01-14/pdf/05-769.pdf>

³⁵ EPA, "EPA Can Better Document Resolution of Ethics and Partiality Concerns in Managing Clean Air Federal Advisory Committees," Report No. 13-P-0387, Office of Inspector General, U.S. Environmental Protection Agency, Washington, DC, September 11, 2013. <https://www.epa.gov/sites/production/files/2015-09/documents/20130911-13-p-0387.pdf>

ATTACHMENT D: Administrative Procedures for the Meeting

The meeting will be opened with remarks from a person filling the role of a designated official who will describe the ethics review procedure and the status of the members with respect to ethics compliance. We will have a period for public comments. Following that, the panel will deliberate on charge questions or groups of charge questions in a sequential order. A former EPA lawyer and a former EPA air science/policy expert will be available as a resource for IPMRP questions.

The goal of the deliberations is to develop “consensus” panel responses to charge questions relating to the review of the draft Policy Assessment and elicit the panel’s recommendation on the criteria and standards, as well as to consider other statements that the panel may wish to make. “Consensus” does not mean that all members of the panel must share or agree to the same viewpoints. “Consensus” means that all members of the panel agree that the written responses to charge questions and other written statements from the panel accurately reflect the views of the panel. If there are topics for which there are a diversity of viewpoints among members of the panel, the “consensus” response should accurately reflect such diversity of viewpoints. If a consensus response could not be achieved then it is acceptable for one or several panel members to express a dissenting opinion on all or part of the final report. The dissenting opinion will be captured in writing and included in the final report or the appendices.

The role of the chair is to facilitate the work of the panel. Examples of responsibilities of the chair are to monitor and guide progress on the agenda, enable panelists to have an opportunity to provide input and deliberate, assist the panel in identifying areas of consensus, and assist the panel in focusing on issues that require deliberation. The chair can also address issues regarding the scope of the panel’s work and recommend approaches to formulating and communicating advice.

The following are the most common procedural considerations for this type of meeting:

- The deliverable from the panel meeting will be a written report. The written report will include the following key elements: (1) a summary letter; (2) consensus responses to charge questions; and (3) individual member comments. The letter may additionally include consensus responses on other issues identified by the panel. The purpose of the letter is to concisely communicate the high level key findings and advice of the panel. The purpose of the consensus responses to charge questions is to provide more detail regarding the panel’s findings and advice.
- All panelists are invited and encouraged to prepare written pre-meeting comments that address charge questions relevant to each panelist’s expertise, as well as any other issues that the panelist may want to address that generally relate to the scope of issues for review of the draft Policy Assessment and of the PM NAAQS. See **Attachment G** for more details.
- The panel is in deliberation if more than half of its members are interacting in formulating a written or oral statement on an issue. Panel deliberations must occur in public. Small groups of panelists, representing up to less than one-half of the panel members, may interact offline to refine draft materials.
- For each charge question or related group of charge questions, discussants and lead discussants are assigned, as given in Attachment G. All of the discussants should prepare draft responses to the charge questions in advance of the public meeting, and may include these as part of their individual pre-meeting written comments. During deliberations at the public meeting, the lead discussant, with assistance from the other discussants, should formulate a draft consensus written response to the charge questions. Drafts of consensus

responses may be circulated among discussants for editing and revision, as long as the discussant group has fewer than 50% of panel members.

- During the course of the meeting, the lead discussant for each charge question should identify the top three to five key “bullet points” that might be included in the panel’s letter. This will enable the full panel to deliberate on key points for inclusion in the panel’s letter.
- All key points for the main letter from the panel to the Administrator and the docket, and for the consensus responses to charge questions, must be deliberated in a public meeting. No information not deliberated in a public meeting can be included in the letter or consensus responses to charge questions.
- Comments from individual members that are reported only as individual comments do not have to be deliberated in the public meeting. However, any individual comments that might inform the formulation of panel consensus on an issue will need to be deliberated with the panel. Thus, in sharing their individual comments with the full panel, individual panelists are encouraged to give priority to any points that they think should be considered by the full panel in formulating content for the letter or consensus responses to charge questions, but reserve for their own individual written comments any other content.
- Individual panelists should not engage in deliberations on studies that they authored or co-authored, or research for which they are or were a principal investigator or co-principal investigator. Panelists who are authors or leaders of such studies may respond to clarifying questions but may not otherwise interact with the panel on topics pertaining to such studies.
- Because it is unlikely that a complete draft of the letter and consensus responses to the charge questions can be completed by the end of the October 10-11, 2019 meeting, the panel will hold one (or more) follow-up teleconference(s). Prior to the follow-up teleconference(s), a draft letter will be prepared by the chair and drafts of consensus responses to charge questions will be prepared by the charge question discussant groups. The panel will deliberate in the follow-up teleconference(s) to revise, as needed, the draft letter and consensus responses to charge questions. The goal of the teleconference(s) is to, if possible, approve the final letter and consensus responses to charge questions. More details are given in Attachment G.
- Individual members of the panel may submit a final version of their individual comments up to the time of the follow-up teleconference.

The meeting is being sponsored by the Union of Concerned Scientists, a 501(c)3 nonprofit organization. UCS does not take policy positions on NAAQS criteria and standards, other than to advocate that independent science advice is followed.³⁶ UCS is funded by individual members and private foundations and accepts no money from corporations or government entities.³⁷ Panelists are compensated for travel to attend the October 10-11, 2019 meeting but are accepting no honoraria for the meeting. The content of the meeting is at the sole discretion of the Independent Particulate Matter Review Panel. The viewpoints and opinions of members of the IPMRP, and of the consensus of the IPMRP, are their own and do not represent any position of UCS.

³⁶ Goldman, G.T. 2015. Union of Concerned Scientists. Comment on EPA-HQ-OAR-2008-0699-2472: Proposed Rule: National Ambient Air Quality Standards for Ozone. <https://www.regulations.gov/document?D=EPA-HQ-OAR-2008-0699-2472>

³⁷ Union of Concerned Scientists. 2018. Internal Revenue Service Form 990. <https://www.ucsusa.org/sites/default/files/attach/2019/03/ucs-fy18-990.pdf>

ATTACHMENT E: EPA Charge Questions to the Chartered Clean Air Scientific Advisory Committee for Review of the Draft Policy Assessment for Particulate Matter

These charge questions are taken from an undated memorandum from the Office of Air Quality Planning and Standards (OAQPS) to the Science Advisory Board staff office.³⁸ The text below is reproduced verbatim from the memorandum. This text is for information only. The charge questions for the Independent Particulate Matter Review Panel are given in Attachment F.

Referencing the Clean Air Act (CAA), the May 2018 National Ambient Air Quality Standard (NAAQS) process memorandum (Pruitt, 2018) identified a set of general charge questions to be posed to the EPA Clean Air Scientific Advisory Committee (CASAC) in the NAAQS review process.³⁹ Those questions are as follows:

- What scientific evidence has been developed since the last review to indicate if the current primary and/or secondary NAAQS need to be revised or if an alternative level or form of these standards is needed to protect public health and/or public welfare? Please recommend to the Administrator any new NAAQS or revisions of existing criteria and standards as may be appropriate. In providing advice, please consider a range of options for standard setting, in terms of indicators, averaging times, form, and levels for any alternative standards, along with a description of the alternative underlying interpretations of the scientific evidence and risk/exposure information that might support such alternative standards and that could be considered by the Administrator in making NAAQS decisions.
- Do key studies, analyses, and assessments which may inform the Administrator's decision to revise the NAAQS properly address or characterize uncertainty and causality? Are there appropriate criteria to ensure transparency in the evaluation, assessment, and characterization of key scientific evidence for this review?
- Are there areas in which additional knowledge is required to appraise the adequacy and basis of existing, new, or revised NAAQS? Please describe the research efforts necessary to provide the required information.
- What is the relative contribution to air pollution concentrations of natural as well as anthropogenic activity? In providing advice on any recommended NAAQS levels, please discuss relative proximity to peak background levels.
- Please 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 such NAAQS.

The draft PA for the current PM NAAQS review is being transmitted to CASAC for review. The PA, prepared by the OAQPS,⁴⁰ is a document that provides a transparent analysis regarding the adequacy of the current standards and, as appropriate, potential alternatives for Agency

³⁸ Sasser, E.N., CASAC Review of the document titled Policy Assessment for Review of the National Ambient Air Quality Standards for Particulate Matter – External Review Draft, Memorandum to A. Yeow, U.S. Environmental Protection Agency, Research Triangle Park, NC, undated, [https://yosemite.epa.gov/sab/sabproduct.nsf/LookupWebProjectsCurrentCASAC/64C246444C9CC319852584430319E365/\\$File/Charge+memo+and+questions+for+draft+PA.pdf](https://yosemite.epa.gov/sab/sabproduct.nsf/LookupWebProjectsCurrentCASAC/64C246444C9CC319852584430319E365/$File/Charge+memo+and+questions+for+draft+PA.pdf) (accessed September 13, 2019)

³⁹ Pruitt, S.E., "Back to Basics Process for Reviewing National Ambient Air Quality Standards," Memorandum, U.S. Environmental Protection Agency, Washington, DC, May 9, 2018. <https://www.epa.gov/sites/production/files/2018-05/documents/image2018-05-09-173219.pdf>

⁴⁰ OAQPS is the Office of Air Quality Planning and Standards of the U.S. Environmental Protection Agency.

consideration prior to the issuance of proposed and final decisions. The PA integrates and interprets the information from the Integrated Science Assessment (ISA) and from any risk and exposure analyses, together with related limitations and uncertainties, to frame policy options for consideration by the Administrator. Such an evaluation of policy implications is intended to help “bridge the gap” between the Agency’s scientific assessments, presented in the ISA and quantitative analyses, and the judgments required of the EPA Administrator in determining whether it is appropriate to retain or revise the NAAQS. In so doing, the PA is also intended to facilitate CASAC advice to the Agency and recommendations to the Administrator on the adequacy of the existing standards or revisions that may be appropriate to consider, as provided for in the CAA.

In addition to the general charge questions listed above, the May 2018 NAAQS process memorandum recognized that supplemental charge questions would also be made available to provide more detailed requests as necessary (Pruitt, 2018). In order to facilitate the CASAC’s review of the draft PA and consideration of its advice to the Administrator on the PM NAAQS, the EPA has also identified the following specific charge questions. These questions focus on the approaches taken in the draft PA to evaluating the available scientific and technical information and to reaching preliminary conclusions on the PM NAAQS. The CASAC’s responses to these specific charge questions will be considered by the EPA in developing a final PA in this review.

Specific Charge Questions for Review of the Draft PA

Chapter 1 – Introduction: To what extent does the CASAC find that the information in Chapter 1 is clearly presented and that it provides useful context for the review?

Chapter 2 – PM Air Quality: To what extent does the CASAC find that the information in Chapter 2 is clearly presented and that it provides useful context for the review?

Chapter 3 – Review of the Primary PM_{2.5} Standards: What are the CASAC views on the approaches described in Chapter 3 to considering the PM_{2.5} health effects evidence and the risk assessment in order to inform preliminary conclusions on the primary PM_{2.5} standards? What are the CASAC views regarding the rationales supporting the preliminary conclusions on the current and potential alternative primary PM_{2.5} standards?

Chapter 4 – Review of the Primary PM₁₀ Standard: What are the CASAC views on the approach described in Chapter 4 to considering the PM_{10-2.5} health effects evidence in order to inform preliminary conclusions on the primary PM₁₀ standard? What are the CASAC views regarding the rationale supporting the preliminary conclusions on the current primary PM₁₀ standard?

Chapter 5 – Review of the Secondary Standards: What are the CASAC views on the approach described in Chapter 5 to considering the evidence for PM-related welfare effects in order to inform preliminary conclusions on the secondary standards? What are the CASAC views regarding the rationale supporting the preliminary conclusions on the current secondary PM standards?

Chapters 3 to 5: What are the CASAC views regarding the areas for additional research identified in Chapters 3, 4 and 5? Are there additional areas that should be highlighted?

Attachment F: Charge Questions for the Independent Particulate Matter Review Panel

The following list restates the EPA charge questions given in Attachment E, supplementing them to: (a) address additional details to be considered by the IPMRP; and (b) deal with additional process and science issues within the scope of the PM review. Thus, the complete set of charge questions on the draft Policy Assessment (PA), including EPA charge questions, and supplemental charge questions (SCGs), is given below. The original text of EPA charge questions is given in **bold**. The charge questions are labeled alphanumerically for referencing.

EPA-1. Chapter 1 – Introduction: To what extent does the CASAC find that the information in Chapter 1 is clearly presented and that it provides useful context for the review?

EPA-2. Chapter 2 – PM Air Quality: To what extent does the CASAC find that the information in Chapter 2 is clearly presented and that it provides useful context for the review?

SCQ-2.1 What are the panel's views regarding whether the draft PA accurately reflects and communicates the air quality related information most relevant to its subsequent evidence-based assessment of the health and welfare effects studies, including uncertainties, as well as the development of the risk assessment for current and alternative standards? In particular, do the following sections accurately reflect and communicate current scientific understanding, including uncertainties, for: (a) relationships between annual and daily distributions of PM; (b) the review of hybrid modelling approaches used to estimate exposure in some studies and the risk assessment; and (c) information on background levels of various PM indicators?

EPA-3. Chapter 3 – Review of the Primary PM_{2.5} Standards: What are the CASAC views on the approaches described in Chapter 3 to considering the PM_{2.5} health effects evidence and the risk assessment in order to inform preliminary conclusions on the primary PM_{2.5} standards? What are the CASAC views regarding the rationales supporting the preliminary conclusions on the current and potential alternative primary PM_{2.5} standards?

SCQ-3.1 Does the panel find that the questions posed in this chapter appropriately reflect the important policy-relevant issues for the PM_{2.5} review? Are there additional policy-relevant questions that should be addressed?

SCQ-3.2 What are the panel's views on the relative weight that the draft Policy Assessment gives to the evidence-based (i.e. draft PA, section 3.2) and risk-based (i.e. draft PA, section 3.3) approaches in reaching conclusions and recommendations regarding current and alternative PM_{2.5} standards?

SCQ 3.3 What are the panel's views on the evidence-based approach, including:

- a) The emphasis on health outcomes for which the draft ISA causality determinations are "causal" or "likely causal"?
- b) The identification of potential at-risk populations?
- c) Reliance on key multicity epidemiology studies conducted in the US and Canada for assessing the PM_{2.5} levels associated with health effects?
- d) Characterizing air quality in these key studies using two approaches: the overall mean and 25th/75th percentiles of the distribution and the "pseudo design value" reflecting a monitor with the highest levels in an area?

- e) The preference for continuing the use of an annual PM_{2.5} standard as the principle means of providing public health protection against the bulk of the distribution of short- and long-term PM_{2.5} exposures?
 - f) The draft PA conclusions on the extent to which the current scientific information strengthens or alters conclusions reached in the last review on the health effects of PM_{2.5}?
 - g) Whether the discussions of these and other issues in Chapter 3 accurately reflect and clearly communicate the currently available health effects evidence, including important uncertainties, as characterized in the ISA?
- SCQ 3.4 What are the panel's views on the quantitative risk assessment for PM_{2.5} including:
- a) The choice of health outcomes and studies selected for developing concentration-response functions for long and short-term effects?
 - b) The selection criteria for the 47 urban areas and PM_{2.5} air quality scenarios analyzed?
 - c) The hybrid modeling approach used for quantifying exposure surrogates across an area and adjusting air quality for alternative standard levels, as supplemented by interpolation/extrapolation?
 - d) The characterization of variability and uncertainty in the risk assessment?
 - e) The robustness and validity of the risk estimates?
- SCQ-3.5 What are the panel's views on the draft PA preliminary conclusion that, taken together, the available scientific evidence, air quality analyses, and the risk assessment can reasonably be viewed as calling into question the adequacy of the public health protection afforded by the current primary PM_{2.5} standards?
- SCQ-3.6 What are the panel's views on the conclusions in the draft PA regarding developing potential PM_{2.5} alternative standards with respect to:
- a) The preliminary conclusion that the available information continues to support the PM_{2.5} mass-based indicator, remains too limited to support a distinct standard for any specific PM_{2.5} component or group of components, and remains too limited to support a distinct standard for the ultrafine fraction?
 - b) The preliminary conclusion to retain the annual and 24-hour averaging times?
 - c) The preliminary conclusion that it is appropriate to consider retaining the forms of the current annual and 24-hour PM_{2.5} standards, in conjunction with revised levels?
 - d) The preliminary conclusion that the range for alternative levels for the annual PM_{2.5} standard should begin below 12 ug/m³ and extend as low as 8 u/m³?
 - e) The possible rationales for alternative annual PM_{2.5} levels of 12, 10, and 8 ug/m³?
 - f) The preliminary conclusion that, in conjunction with a lower annual standard intended to protect against both short- and long-term exposures, the evidence does not support the need for a revised level for the PM_{2.5} 24-hour standard?

- g) The discussion of an alternative approach to lower the level of the 24 hour standard to 30 ug/m³ to provide increased protection for both short- and long term exposures?

EPA-4. Chapter 4 – Review of the Primary PM₁₀ Standard: What are the CASAC views on the approach described in Chapter 4 to considering the PM_{10-2.5} health effects evidence in order to inform preliminary conclusions on the primary PM₁₀ standard? What are the CASAC views regarding the rationale supporting the preliminary conclusions on the current primary PM₁₀ standard?

- SCQ-4.1 To what extent does the panel find that the questions posed in this chapter appropriately reflect the important policy-relevant issues for the PM₁₀ NAAQS review? Are there additional policy-relevant questions that should be addressed?
- SCQ-4.2 What are the panel's views of the draft PA assessment of the currently available scientific evidence regarding the health effects associated with exposures to thoracic course particles, PM_{10-2.5}?
- SCQ-4.3 What are the panel's views on the draft PA preliminary conclusion that the available evidence does not call into question the adequacy of the public health protection afforded by the current primary PM₁₀ standard and that evidence supports consideration of retaining the current standard?

EPA-5. Chapter 5 – Review of the Secondary Standards: What are the CASAC views on the approach described in Chapter 5 to considering the evidence for PM-related welfare effects in order to inform preliminary conclusions on the secondary standards? What are the CASAC views regarding the rationale supporting the preliminary conclusions on the current secondary PM standards?

- SCQ-5.1 To what extent does the panel find that the questions posed in this chapter appropriately reflect the important policy-relevant issues for the secondary PM standards? Are there additional policy-relevant questions that should be addressed?
- SCQ-5.2 What are the panel's views of the draft PA evaluation of the currently available scientific evidence with respect to the welfare effects of PM. Does the assessment appropriately account for any new information related to factors that influence:
 - a) Quantification of visibility impairment associated with PM_{2.5} and examination of methods for characterizing visibility and its value to the public?
 - b) The effects of PM_{2.5} components on climate?
 - c) The effects of fine and coarse particles on materials?
- SCQ-5.3 What are the panel's views of the draft PA preliminary conclusion that the currently available scientific evidence does not call into question the protection afforded by the current secondary PM standards against PM welfare effects and that it is appropriate to consider retaining the current secondary PM standards without revision?

EPA-6. Chapters 3 to 5: What are the CASAC views regarding the areas for additional research identified in Chapters 3, 4 and 5? Are there additional areas that should be highlighted?

In addressing the charge questions above, the IPMRP is likely to also address four of the general charge questions given in the Pruitt (2018) process memo. For convenience of referencing, these questions are numbered as General Charge (GC) questions 1 through 4. The IPMRP should review these general questions and, to the extent these issues are not covered in the responses to the above questions, should consider formulation of comments and advice that cover the scope of these questions:

- GC-1. What scientific evidence has been developed since the last review to indicate if the current primary and/or secondary NAAQS need to be revised or if an alternative level or form of these standards is needed to protect public health and/or public welfare? Please recommend to the Administrator any new NAAQS or revisions of existing criteria and standards as may be appropriate. In providing advice, please consider a range of options for standard setting, in terms of indicators, averaging times, form, and levels for any alternative standards, along with a description of the alternative underlying interpretations of the scientific evidence and risk/exposure information that might support such alternative standards and that could be considered by the Administrator in making NAAQS decisions.**
- GC-2. Do key studies, analyses, and assessments which may inform the Administrator's decision to revise the NAAQS properly address or characterize uncertainty and causality? Are there appropriate criteria to ensure transparency in the evaluation, assessment, and characterization of key scientific evidence for this review?**
- GC-3. Are there areas in which additional knowledge is required to appraise the adequacy and basis of existing, new, or revised NAAQS? Please describe the research efforts necessary to provide the required information.**
- GC-4. What is the relative contribution to air pollution concentrations of natural as well as anthropogenic activity? In providing advice on any recommended NAAQS levels, please discuss relative proximity to peak background levels.**

Finally, the IPMRP may consider issues beyond the charge questions from EPA. For example, EPA announced in July 2019 that there will not be a second draft of the ISA, despite advice from CASAC that a second draft should be made available for external review. Therefore, the IPMRP may wish to provide comments and advice regarding the draft ISA in addition to that of its December 10, 2018 and March 27, 2019 letters to CASAC. EPA has recently made announcements or taken actions that pertain to the CASAC and the NAAQS review process, such as those described in Attachment B. Therefore, the IPMRP may wish to address questions related to process issues pertaining to CASAC and NAAQS review, such as: (a) what changes have taken place to the CASAC and the NAAQS Review Process?; (b) in what ways have these changes improved or degraded the quality, credibility, and integrity of the NAAQS review process?; and (c) does the panel have recommendations regarding how the NAAQS review process can be improved?

Attachment G: Discussant Assignments for Charge Questions

Assignments are given below for discussants and lead discussants of the charge questions detailed in **Attachment F**. This attachment explains the purpose of engaging discussants, how discussants were selected, responsibilities of panel members and discussants, key milestones and deliverables related to individual and panel written materials, and the timing of panel activities culminating in closure on a final letter and consensus responses to charge questions.

Charge Question Assignments

Charge Question Identifier ^a or Topic Description	Lead Discussant	Discussants
EPA-1 (Chapter 1)	Sheppard	Adgate, Dockery, Wyzga
EPA-2 (Chapter 2)	Allen	Adams, Chow, Poirot, Felton, Turpin
EPA-3 (Chapter 3): SCQ-3.1	Wyzga	Adgate, Balmes, Sheppard
EPA-3 (Chapter 3): SCQ-3.2	Dockery	Gordon, Kaufman, Kinney, McConnell
EPA-3 (Chapter 3): SCQ-3.3 (and subparts)	Sarnat	Balmes, Dockery, Gordon, Harkema, Kaufman, Kinney, McConnell
EPA-3 (Chapter 3): SCQ-3.4 (and subparts)	Sheppard	Adgate, Kinney, Poirot, Sarnat, Turpin
EPA-3 (Chapter 3): SCQ-3.5	Sheppard	Adgate, Balmes, Dockery, Felton, Harkema,
EPA-3 (Chapter 3): SCQ-3.6 (and subparts)	Allen	Adams, Felton, Harkema, Poirot, Sarnat
EPA-4 (Chapter 4): SCQ-4.1 to SCQ-4.3, inclusive of subparts.	Chow	Balmes, Gordon, Harkema, Kaufman, Kinney, Kleinman, McConnell
EPA-5 (Chapter 5): SCQ-5.1 to SCQ-5.3	Poirot	Adams, Allen, Chow, Kinney, Turpin, Wyzga
EPA-6 (Additional Research)	Wyzga	Dockery, Gordon, Sheppard, McConnell
Residual Issues for the Draft ISA	Frey to facilitate	All
NAAQS review process	Frey to facilitate	All
General Charge Questions (GC-1 to GC-4)	Frey to facilitate	All

^a See Attachment F for the charge questions.

The purpose of the discussant assignments is to assure that a critical mass of panel members are responding to each charge question in depth. These assignments are not exclusive. Thus, if you would like to respond to more charge questions than those to which you are assigned, you are welcome and encouraged to do so. All members of the IPMRP may respond to all charge questions.

Lead discussants were selected based on relevant scientific expertise and prior experience with CASAC or CASAC review panels. Lead discussants were also assigned based on expectations of in-person attendance of the October 10-11, 2019 meeting, to facilitate the logistics of executing the responsibilities of a lead discussant.

Discussants were assigned based on the areas of scientific expertise indicated in biographical sketches posted on the archived EPA website for the CASAC Particulate Matter Review Panel

(2015-2018)⁴¹ and the subject matter of the charge questions. The discussant assignments are also distributed among policy-relevant questions for which integration of scientific knowledge across disciplines and subject areas is required.

The table on page G-1 lists several discussion items that are not specifically assigned to discussant groups. The chair will lead panel discussions related to whether there are residual issues with respect to EPA's draft Integrated Science Assessment and the NAAQS review process in addition to those already covered in the panel's December 10, 2018 and March 27, 2019 comments to CASAC, and will lead a discussion to address, if needed, issues pertaining to EPA's general charge questions that may not have been covered in responses to the EPA and supplemental charge questions regarding the draft Policy Assessment. All members of the panel are invited to contribute to these topics in their pre-meeting written comments as well as during the panel deliberations.

The responsibilities associated with the roles of panel member, discussant, and lead discussant are briefly described.

All Members of the Panel: Please prepare pre-meeting written comments on any charge question relevant to your expertise and interests. Furthermore, any member of the panel may offer pre-meeting written comments on any additional topics or issues that they deem relevant to the review of the NAAQS for particulate matter.

Discussants: Please prepare pre-meeting written comments that specifically address the charge question(s) to which you are assigned as a discussant. For the charge questions with multiple subparts (e.g., SCQ-3.3(a)-(g)), it is not expected that each discussant should respond to every subpart. However, it is expected that, as a group, the discussants collectively will address each of the subparts. Based on your pre-meeting written comments, it is recommended that you identify the key points that you believe should be shared with the full panel in public deliberations for possible inclusion in consensus responses to the charge questions. The chair will call upon each of the discussants to contribute to panel deliberations. Minor points that do not require inclusion in the consensus response to charge questions can remain in your individual comments without further elaboration. To assist the lead discussant, it will be helpful if, when making your oral comments during panel deliberations, you indicate which of your comments are recommended for consideration for the consensus response. Throughout the course of the meeting, please assist the lead discussant in identifying key points for inclusion in the consensus response based on your comments as well as those of fellow discussants and based on deliberations of the panel.

Lead Discussants: The lead discussant should integrate and synthesize the pre-meeting written comments and the oral comments of the discussants, and the content of the panel deliberation, to formulate a draft of the consensus response to each assigned charge question. The lead discussant may seek help from the discussants in so doing, and discussants are encouraged to provide assistance to the lead discussant.

⁴¹ CASAC Particulate Matter Review Panel (2015-2018), Clean Air Scientific Advisory Committee, U.S. Environmental Protection Agency, [https://web.archive.org/web/20170126175127/https://yosemite.epa.gov/sab/sabpeople.nsf/WebCommitteesSubWebCommitt/CASAC%20Particulate%20Matter%20Review%20Panel%20\(2015-2018\)](https://web.archive.org/web/20170126175127/https://yosemite.epa.gov/sab/sabpeople.nsf/WebCommitteesSubWebCommitt/CASAC%20Particulate%20Matter%20Review%20Panel%20(2015-2018)) (accessed September 19, 2019).

Pre-Meeting Written Individual Comments: Target Date of October 7, 2019

With regard to the first expected deliverable, all discussants and lead discussants should address their assigned charge questions in their pre-meeting written comments, and all members may address any charge questions and other relevant matters. Pre-meeting written comments should be submitted by a target date of **Monday, October 7, 2019** to the panel chair, H. Christopher Frey at frey@ncsu.edu and to the acting designated official, Chris Zarba at chriszarba@yahoo.com. The pre-meeting written comments will be compiled and posted publicly on the meeting website. Thus, all panelists will have access to the pre-meeting written comments, as available, from other panelists. It is helpful to your lead discussant and fellow discussants to share your pre-meeting written comments in advance of the meeting to allow time for identification and formulation of key points for panel deliberation.

At the Meeting

The bulk of the meeting will be spent discussing charge questions. For each charge question, the lead discussant will be asked to summarize not just their individual comments, but the key findings, comments, and advice on behalf of all discussants. The latter will be informed by the written pre-meeting written comments. Each discussant will then be asked in turn for their comments and responses to the charge question. If a point has already been well-covered in an agreeable manner, it is appropriate to briefly state agreement and use time to address other issues that may merit attention. Each discussant should introduce for panel consideration and deliberation any candidate points for inclusion in the consensus response that have not already been covered. As noted earlier (see Attachment D), no content can be included in the final written consensus responses or in the letter unless it has been deliberated in a public meeting of the panel.

Charge question groups, including the lead discussant and discussant, may have and are encouraged to have “off-line” conversations and interactions to refine the draft consensus response to charge questions, as long as such interactions do not involve 50% or more of panel members. None of the charge question groups as currently assigned have more than 50% of panel membership. Any new points that may emerge as a result of such interactions must be brought to the full panel for deliberation to be eligible for possible inclusion in the final consensus response or in the letter.

In the latter part of the public meeting on October 11, the chair will likely ask lead discussants to summarize possible key points for the letter that emerge from the formulation of consensus responses. Thus, it is helpful if all discussants on a charge question identify and suggest which key points may merit inclusion in the letter and assist the lead discussant in this regard.

Post-Meeting Written Comments: Target Date to be determined.

All panel members may revise, add to, or replace their pre-meeting written comments. Final individual written comments should be submitted by a date to be determined. The timing of this deadline will depend on the timing of the follow-up teleconference. The final individual written comments should be submitted to H. Christopher Frey and Chris Zarba at the emails given above.

Follow-Up Teleconference and Closure

Because it is unlikely that the final content and wording of consensus responses to charge questions and the letter can be completed during the October 10-11, 2019 meeting, the panel

will have a follow-up teleconference at a time to be announced. The interval between the October 10-11, 2019 meeting and the follow-up teleconference will allow time for discussant groups to complete the draft of consensus responses to charge questions and for the chair to draft the letter and compile the consensus responses. A draft of the letter and consensus responses will be shared with the panel prior to the follow-up teleconference. At the follow-up teleconference, the panel will deliberate on any unresolved or otherwise remaining issues related to content. Panel members will be asked to indicate approval or disapproval of the content of the draft letter and consensus responses, with revisions to be made as discussed. The writing needed to complete revisions to finalize the letter will be supervised by the chair.

The final individual written comments are attached to the final letter and final consensus responses. The individual written comments do not require approval by the full panel. However, as appropriate, the consensus response to a charge question, or the letter, may reference additional details that are found in the attached individual comments of one or more members of the panel.