## 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.<sup>1</sup> 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.<sup>2</sup> 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.<sup>3</sup> 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.<sup>4</sup> For the 2001 to 2006 scientific review, and for the 2008 to 2010 scientific

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

<sup>&</sup>lt;sup>2</sup> 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+CA SAC+181210+Final+181210.pdf

<sup>&</sup>lt;sup>3</sup> 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/eimscomm.getfile?p\_download\_id=459608

<sup>&</sup>lt;sup>4</sup> 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

review, there were 7 members of the chartered CASAC and 15 additional experts.<sup>5,6</sup> From 2015 to 2018, the CASAC Particulate Review Panel had 6 members of the chartered CASAC and 20 additional experts.<sup>7</sup> 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." 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." 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."

## The notice also stated:

<sup>5</sup> 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

<sup>&</sup>lt;sup>6</sup> 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

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

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

<sup>&</sup>lt;sup>9</sup> 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

"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.<sup>10</sup> 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).<sup>11</sup>

On October 10, 2018, then acting EPA Administrator Wheeler eliminated the CASAC PM Review Panel by press release, <sup>12</sup> 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.

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%2 Omemo-CASAC%20PM.pdf

<sup>&</sup>lt;sup>11</sup> 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

<sup>&</sup>lt;sup>12</sup> 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.<sup>13</sup> 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.<sup>14</sup>

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). The IPMRP subsequently submitted comments to the CASAC on March 27, 2019 with additional comments on the draft ISA. These letters contain detail on the statutory requirements for the review of the NAAQS, history of the CASAC PM Review Panel and the

<sup>&</sup>lt;sup>13</sup> 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

<sup>&</sup>lt;sup>14</sup> 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

<sup>&</sup>lt;sup>15</sup> 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. <a href="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</a>

<sup>&</sup>lt;sup>16</sup> 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. <a href="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</a>

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.<sup>17</sup> A Federal Register notice published on September 11, 2019 indicated availability of the draft PA for public comment through November 12, 2019.<sup>18</sup> 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.<sup>19</sup> 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).<sup>20</sup>

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." 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." 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.<sup>23</sup>

<sup>&</sup>lt;sup>17</sup> 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. <a href="https://www.epa.gov/sites/production/files/2019-09/documents/draft\_policy\_assessment\_for\_pm\_naaqs\_09-05-2019.pdf">https://www.epa.gov/sites/production/files/2019-09/documents/draft\_policy\_assessment\_for\_pm\_naaqs\_09-05-2019.pdf</a>

<sup>&</sup>lt;sup>18</sup> 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

<sup>&</sup>lt;sup>19</sup> 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?Open Document

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?Open Document

<sup>&</sup>lt;sup>21</sup> 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/6CBCBBC3025E13B4852583 D90047B352/\$File/EPA-CASAC-19-002+.pdf

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

<sup>&</sup>lt;sup>23</sup> 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.<sup>24</sup> 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.

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<sup>&</sup>lt;sup>24</sup> 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.