

# State of California

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Gavin Newsom, Governor



OFFICE OF ENVIRONMENTAL  
HEALTH HAZARD ASSESSMENT

March 21, 2019

Aaron Yeow, M.P.H.  
Designated Federal Officer  
Docket ID No. EPA-HQ-ORD-2014-0859  
EPA Docket Center (ORD Docket, Mail Code: 28221T)  
U.S. Environmental Protection Agency,  
1200 Pennsylvania Ave., NW.  
Washington, DC 20460

Dear Mr. Yeow,

The California Air Resources Board (CARB) and Office of Environmental Health Hazard Assessment (OEHHHA) are writing today to convey our concern about the review process recently developed for the Clean Air Scientific Advisory Committee (CASAC) and the inadequate resulting Draft Report on U.S. EPA's Integrated Science Assessment (ISA) for Particulate Matter (PM) (External Review Draft – October 2018). We reiterate our broad agreement with the draft ISA document in its current form, and commend the staff of U.S. EPA for the high quality of their work in this document. The recommendations of the CASAC appear to reflect their lack of expertise in epidemiology.

The U.S. EPA administration implemented a wholesale replacement of CASAC and also dismissed the large subcommittee of subject matter experts. The result is a lack of continuity and expertise. Most strikingly, the resulting CASAC completely lacks any epidemiologists. This expertise is critical since the causality determination between PM exposure and mortality and morbidity rests on the strength of the epidemiology studies. Congress envisioned that CASAC members would be selected on the basis of their specific expertise in environmental toxicology, epidemiology and/or clinical medicine, and further expected them to provide independent review of scientific and medical data that would help determine whether a given pollutant may reasonably be anticipated to endanger public health or environment. The previous process was robust with a 20 member subcommittee of nationally known experts that included several highly regarded epidemiologists. The current expertise is inadequate to provide a sound and credible review of the draft ISA.

CARB and OEHHHA are also troubled by the decision and subsequent misuse of time in drafting a report revisiting settled science. Given the wealth of health studies, CASAC's failure to reach consensus on basic scientific issues speaks to the problem. For example, the panel failed to come to consensus on the causality determination of

mortality from PM<sub>2.5</sub> exposure despite the fact that many studies from around the world have observed PM-related mortality, with wide ranging exposures and diverse sources. Moreover, a substantial number of studies in animals have shown plausible biological mechanisms for the adverse health effects observed in exposed humans. The committee also came to a lack of consensus on the assessment of the concentration-response (C-R) functions. These C-R functions have already been reviewed and accepted by previous CASAC panels with epidemiological expertise and it was unnecessary to reopen a settled issue with no stated reasons to refute the original finding.

The PM ISA covers a broad range of scientific disciplines, and a panel composed of individuals with expertise in these diverse areas is crucial to a thorough, critical review of the scientific literature. Four members of the current seven-member CASAC panel, Drs. James Boylan, Mark Frampton, Timothy E. Lewis, and Steven Packham, agreed that additional expertise is needed to review the ISA in a comprehensive manner. Moreover, three CASAC members specifically called on the US EPA to reconstitute the larger PM review panel.

As pointed out by Dr. Mark Frampton, expert review panels have assisted CASAC over the past 30 years. Without the panels, "CASAC members by themselves do not have the breadth and depth of knowledge or expertise in many areas that are necessary to adequately advise the EPA, and to meet the statutory requirement for a thorough and accurate review" (page A-92). CARB and OEHHA strongly supports reconvening the full PM Review Panel to provide a credible review of the ISA.

Moreover, we need to raise the extraordinarily foreshortened, and inappropriate, review process offered for this document. The CASAC Draft Report was released March 8, 2019, with comments due March 21, 2019. (See 84 Fed. Reg. 8,523). This cursory public process is inadequate for a scientific product of this magnitude, which has the potential to have sweeping implications for public health. It is particularly concerning because the CASAC's findings ultimately implicate the PM National Ambient Air Quality Standards (NAAQS), for which states are required by law to plan. As you know, the federal Clean Air Act is grounded on cooperative federalism (see, e.g., 42 U.S.C. § 7401), including due regard for the states as primary regulators of air pollution. We remind you that federal actions with broad federalism implications are also subject to specific state consultation requirements under Executive Order 13132 (Federalism). This brief review process, with no direct engagement with state experts, departs from the Clean Air Act's premises and certainly does not satisfy EO 13132. We therefore would have very serious concerns with any decisions premised on this flawed process.

We look forward to continuing our participation in the PM standards review process, and are taking this opportunity to comment on the CASAC Draft Report and review process despite the inadequate review time provided. CARB and OEHHA strongly

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disagree with the CASAC Report and reiterate our commendation for the high quality draft ISA, and our broad agreement with its analysis and conclusions. We are prepared to take appropriate actions to defend the health-protective NAAQS grounded on prior analyses, and the state plans which attain those NAAQS. If you need additional information please contact Elizabeth Scheehle, Chief of the Research Division at (916) 322-7630 or [Elizabeth.Scheehle@arb.ca.gov](mailto:Elizabeth.Scheehle@arb.ca.gov)

Sincerely,

Richard W. Corey  
Executive Officer  
California Air Resources Board

Lauren Zeise, Ph.D.  
Director  
Office of Environmental Health  
Hazard Assessment

cc: Kurt Karperos  
Deputy Executive Officer  
California Air Resources Board

John Faust  
Branch Chief  
California Office of Environmental Health Hazard Assessment