UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

April 19, 2019

THE ADMINISTRATOR

Dr. Michael Honeycutt
Chair, Science Advisory Board
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, D.C. 20460

RE: SAB Discussions about EPA Planned Actions in the Fall 2017 Unified Agenda, Spring 2017 Unified Agenda, "Strengthening Transparency in Regulatory Science" and its Supporting Science; and Review of EPA's report titled *Screening Methodologies to Support Risk and Technology Review (RTR): A Case Study Approach* and *Framework for Assessing Biogenic CO2 Emissions from Stationary Sources* (2014)

Dear Dr. Honeycutt and Members of the Board:

The U.S. Environmental Protection Agency recognizes the important role the Science Advisory Board plays in helping the EPA fulfill its mission to protect human health and the environment. This letter responds to several communications from the SAB during the past several months. I understand that following public meetings in 2018, the board expressed an interest in reviewing several recent, pending and future regulations from the EPA.[1]

I welcome your interest in these matters and appreciate your desire to advise me in this regard. This letter is intended to provide further information regarding the regulatory matters in which you have expressed interest (including updates as to their respective status), important context regarding the role of the SAB and the EPA in regulatory matters and questions with regard to which I would appreciate your scientific advice and comments.

The Board has expressed an interest in six critical regulatory matters, five of which were selected from the Spring 2017 and Fall 2017 Unified Agendas of Federal Regulatory and

[1] These include five regulatory matters in the Office of Air and Radiation: Reconsideration of Final Determination: Mid-Term Evaluation of Greenhouse Gas Emissions Standards for Model Year 2022–2025 Light Duty Vehicles; Repeal of Emission Requirements for Glider Vehicles, Glider Engines and Glider Kits; Review of the 2016 Oil and Gas New Source Performance Standards for New, Reconstructed and Modified Sources; Review of the Clean Power Plan; and Review of the Standards of Performance for Greenhouse Gas Emissions from New, Modified and Reconstructed Stationary Sources: Electric Generating Units. The sixth regulatory matter, Strengthening Transparency in Regulatory Science, was proposed by the Office of the Administrator.

Recycled/Recyclable • Printed with Vegetable Oil Based Inks on 100% Recycled Paper (40% Postconsumer)

Deregulatory Actions, published in July and December 2017, respectively. These agendas are issued by the Office of Information and Regulatory Affairs based on information provided by the EPA semiannually, and they provide a snapshot of the agency's intended actions. Understandably, the descriptions and status of these matters as provided in the 2017 agendas are no longer current.

This letter includes updated information on the corresponding regulatory matters as detailed in the more recent 2018 Unified Agendas of Federal Regulatory and Deregulatory Action, as well as important context about the status of these rulemakings and whether they include influential scientific information or highly influential scientific assessments appropriate for peer review by the SAB. As you know, the EPA has provided much of this information to the SAB Work Group on EPA Planned Actions for SAB Considerations of the Underlying Sciene, including in mid-September 2018 for the Spring 2018 agenda and in late 2018 and early 2019 for the Fall 2018 agenda.

The current process for prioritizing regulatory topics for scientific advice has been conducted through engagement among EPA programs, the SAB Staff Office and the SAB Work Group and has focused on previously issued semiannual regulatory agendas. This process is based on the 2012 EPA memorandum, *Identifying EPA Planned Actions for Science Advisory Board (SAB) Consideration of the Underlying Science - Semi-annual Process* and the Office of Policy's 2015 guide, *Process and Best Practices for EPA Engagement with the Science Advisory Board in SAB Screening of the Scientific Basis for Major Agency Planned Actions*. However, several deficiencies in this process, including many raised by SAB members, have come to my attention.

To address these issues, the EPA will update the process by which we engage with the SAB on regulatory science matters. I am asking the Office of Policy, in consultation with the Office of General Counsel, to strengthen the following principles inside the EPA's regulatory development process:

- **Timeliness and Early Notification.** Moving forward, the EPA will ensure that there is early engagement between the EPA and the full Science Advisory Board, including more rapid and frequent briefings to the SAB on major proposed regulations shortly after their release. This will also include other opportunities to regularly keep the board apprised of other ways in which the EPA tracks peer review of influential regulatory science, including the agency's Peer Review Agenda.

- **Transparency and Consistency.** It also seems evident that a more transparent and productive process would entail more early engagement on key regulatory science issues with both the public and the full SAB. In addition, the more detailed templates prepared for a subset of SAB members on the work group duplicate other agency efforts to provide information on the status of major regulations and increase the likelihood of inconsistency. Therefore, we will now offer a briefing to the full SAB following the publication of proposed criteria documents, standards, limitations or regulations that have undergone interagency review pursuant to Executive Order

12866 (including relevant scientific and technical information available to the public on which the proposed action is based).

- **Inter-Committee Coordination.** I am also asking the various EPA program offices and the SAB to work to ensure that the process for seeking scientific advice, and for establishing the scope of that advice on particular regulatory actions, properly takes account of the full suite of important EPA advisory committees. For example, the EPA Clean Air Act Advisory Committee has been chartered to provide advice and recommendations on: approaches for new and expanded programs, including those using innovative technologies and policy mechanisms to achieve environmental improvements; the potential health, environmental and economic effects of Clean Air Act programs on the public, the regulated community, state and local governments and other federal agencies; the policy and technical contents of proposed major EPA rulemaking and guidance required by the act to help effectively incorporate appropriate outside advice and information; and the integration of existing policies, regulations, standards, guidelines and procedures into programs for implementing requirements of the act. To that end, several of the proposed regulatory actions from the Spring and Fall 2017 agendas identified as being of interest to the SAB have already been the subject of briefings during the most recent CAAAC meetings.

Incorporating these principles into the process is consistent with and provides greater support to the vital role the SAB is expected to play in providing scientific advice to the agency. The SAB provides advice as requested by the EPA Administrator, and I believe it is critical for the EPA to clearly establish the scope and timing for such scientific advice. Further, ensuring that reviews are coordinated through the proper committees also helps to provide an important delineation between scientific advice and policy judgment. The SAB Staff Office Handbook acknowledges this, noting that "[t]he SAB may comment on the policy implications of scientific analyses but should not 'cross the line' into policy recommendations."[2] The policy decisions that I and other EPA officials are responsible for making are *informed* by scientific considerations, including, where appropriate, advice from the SAB and other advisory bodies.[3] But, ultimately, in exercising the authority given to us by Congress, the EPA must take account of a wide range of considerations if the judgments we make and the actions we take within the proper range of that authority are to be reasonable, defensible and consistent with our responsibilities to the American people.

---

[2] *Serving on the EPA Science Advisory Board: A Handbook for Members and Consultants* (March 2012), at 10.

[3] This emphasis on the SAB's scientific advice, as well as its role as an input in the regulatory development process, has also been noted by federal courts. *See American Petroleum Institute v. Costle*, 665 F.2d 1176, 1187-88 (D.C. Cir. 1981) ("SAB approval is not required before proceeding to the final stage of rulemaking. . . . 'The Science Advisory Board is intended to be advisory only. The Administrator will still have the responsibility for making the decisions required of him by law. The reviews and comments of the Board are to be provided to the Administrator for his use . . . .'") (quoting Conference Report, H.R. Rep. No. 95–722, 95th Cong., 1st Sess. 16 (1977), *reprinted at* 1977 U.S.C.C.A.N. 3283, 3295. It goes without saying that "SAB approval is not required before proceeding to the final stage of rulemaking." *Id.*

As for the aforementioned topics of interest identified by the SAB, provided below is an update on the status of these actions, along with requests for engagement in 2019:

- The proposed regulation, *Strengthening Transparency in Regulatory Science*, 83 Fed. Reg. 18,768 (Apr. 30, 2018), provides that the EPA will ensure that the regulatory science underlying its actions is publicly available in a manner sufficient for independent validation. The comment period for the proposed rule was open from April 30, 2018, to August 16, 2018. A public hearing for the proposed rule was held on July 17, 2018, in Washington, D.C.

  The proposal notes the "challenges and opportunities for facilitating secure access to confidential data for non-government analysts," and that "mechanisms [for such access] may range from deposition in public data repositories, consistent with requirements for many scientific journals, to, for certain types of information, controlled access in federal research data centers that facilitate secondary research use by the public." *Id.* at 18,771 (footnotes omitted). The proposal contemplates that the "EPA should collaborate with other federal agencies to identify strategies to protect confidential and private information in any circumstance in which it is making information publicly available." The EPA would benefit from an SAB consultation on existing mechanisms for secure access to confidential business information and personally identifiable information as discussed in the proposal.

- In its recent communications to the Office of the Administrator, the SAB expressed interest in assessing whether methodologies and assumptions in the EPA's regulatory impact analyses warrant further review. As the board noted, the EPA sought comment on an Advanced Notice of Proposed Rulemaking on *Increasing Consistency, Reliability and Transparency in the Rulemaking Process* (RIN 2010-AA12) through August 13, 2018. The EPA is in the process of reviewing the public comments received. Subsequent actions as well as updates to the EPA's Guidelines for Preparing Economic Analysis and the development of a Computable General Equilibrium model for evaluating costs, benefits and economic impacts in regulatory analyses may provide better opportunities for the board to review the technical aspects of these analyses and methodologies. Regulatory impact analyses or regulatory flexibility analyses subject to interagency review under Executive Order 12866 are exempted from peer review requirements under the Office of Management and Budget's Peer Review Bulletin and the EPA's Peer Review Handbook.[4]

- The Board also nominated the *Review of the 2016 Oil and Gas New Source Performance Standards for New, Reconstructed and Modified Sources* (RIN 2060-AT54) as a rulemaking potentially meriting further review. The EPA believes that neither *Review of the 2016 Oil and Gas New Source Performance Standards for New, Reconstructed and Modified Sources* (RIN 2060-AT90), nor *Oil and Natural Gas Sector: Emission Standards for New, Reconstructed and Modified Sources Reconsideration* (RIN 2060-AT54) warrant review by the SAB. As noted in the April 4, 2017, notice announcing review of the 2016 action, the agency "will reevaluate whether this Rule or alternative approaches are appropriately grounded in EPA's statutory authority and consistent with the rule of law." On September 11, 2018, the EPA proposed

[4] https://www.epa.gov/sites/production/files/2016-03/documents/epa_peer_review_handbook_4th_edition.pdf.

targeted improvements to the 2016 New Source Performance Standards for the oil and gas industry to streamline implementation, reduce duplicative EPA and state requirements and significantly decrease unnecessary burdens on domestic energy producers. The EPA held a public hearing on the proposed rule on November 14, 2018, in Denver, Colorado. The public comment period on this proposal closed December 17, 2018. Consistent with CAAAC's chartered objective to provide advice, information and recommendations on policy and technical issues associated with implementation of the Clean Air Act, the EPA Office of Air and Radiation provided a briefing on these actions and responded to questions during the September 2018 CAAAC meeting.

The EPA continues to consider broad policy issues in the 2016 rule, including the regulation of greenhouse gases in the oil and natural gas sector. These issues will be addressed in a separate proposal at a later date. OAR is available to brief the board on the upcoming timeline for this regulatory action and address any questions on its review of information.

- The SAB also expressed an interest in the *Review of the Clean Power Plan* (RIN 2060-AT55) being submitted for further review. The EPA has taken a number of regulatory steps related to repealing or replacing the Clean Power Plan, and forthcoming final actions would not benefit from SAB review. To the extent that the agency is also considering a final action, the EPA does not anticipate using any information that would be considered influential scientific information or highly influential scientific assessments. Consistent with CAAAC's chartered objective to provide advice, information and recommendations on policy and technical issues associated with implementation of the Clean Air Act, OAR provided a briefing on these actions and responded to questions during the September 2018 CAAAC meeting.

  In October 2017, the EPA proposed to repeal the Clean Power Plan because it exceeded the EPA's authority. The comment period closed April 26, 2018. The EPA held a public hearing from November 28-29, 2017, in Charleston, West Virginia, and listening sessions in Kansas City, Missouri, San Francisco, California, and Gillette, Wyoming.

  In December 2017, the EPA issued an Advance Notice of Proposed Rulemaking to solicit information from the public about a potential future rulemaking to limit greenhouse gas emissions from existing electric utility generating units. The comment period ended February 26, 2018.

  On August 21, 2018, the EPA proposed the Affordable Clean Energy rule, which would establish emission guidelines for states to develop plans to address greenhouse gas emissions from existing coal-fired power plants. The ACE rule would replace the 2015 Clean Power Plan, which the EPA has proposed to repeal because it exceeded the EPA's authority. The Clean Power Plan was stayed by the U.S. Supreme Court and has never gone into effect. The comment period for the ACE proposal ended on October 31, 2018. The EPA received approximately 500,000 comments on the proposal. The EPA intends to take final action in the second quarter of 2019.

- The Board also suggested reviewing *Review of the Standards of Performance for Greenhouse Gas Emissions from New, Modified and Reconstructed Stationary Sources: Electric Generating Units* (RIN 2060-AT56) from the Spring 2017 Unified Agenda. On December 6, 2018, the EPA proposed to revise the New Source Performance Standards for greenhouse gas emissions from new, modified and reconstructed fossil fuel-fired power plants. After further analysis and review, the EPA proposes to determine that the best system of emission reduction for newly constructed coal-fired units is the most efficient demonstrated steam cycle in combination with the best operating practices. The EPA held a public hearing on the proposal on February 14, 2019, and the public comment period on the proposal will be open through March 18, 2019. OAR could brief the SAB on this action and its relationship to RIN 2060 AT-55 along with the timeline for rulemaking scheduled for these actions. Consistent with CAAAC's chartered objective to provide advice, information and recommendations on policy and technical issues associated with implementation of the Clean Air Act, OAR intends to engage with CAAAC on this action.

- In its letter on the Fall 2017 regulatory agenda, the SAB recommended that the *Reconsideration of Final Determination: Mid Term Evaluation of Greenhouse Gas Emissions Standards for Model Year 2022-2025 Light Duty Vehicles* (RIN 2060-AT77) be submitted for further review. This reconsideration was completed and published in the *Federal Register* on April 13, 2018 (83 FR 16077). In August 2018, the EPA and the National Highway Traffic Safety Administration proposed the Safer Affordable Fuel-Efficient Vehicles Rule for Model Years 2021-2026 Passenger Cars and Light Trucks. The comment period ended on October 26, 2018, and theEPA and NHTSA held public hearings in Fresno, California, Dearborn, Michigan, and Pittsburgh, Pennsylvania.

  OAR has been engaging with the SAB Work Group on this regulatory action. OAR presented to the CAAAC at its September 2018 meeting on the proposed SAFE rule consistent with CAAAC's chartered objective to provide advice, information and recommendations on policy and technical issues associated with implementation of the Clean Air Act. OAR answered CAAAC member questions and provided further clarification on this action. The EPA believes that CAAAC and its Mobile Sources Technical Review Subcommittee would be more appropriate venues for any future necessary advice on these actions.

- The Board also recommended for review the proposed *Repeal of Emission Requirements for Glider Vehicles, Glider Engines and Glider Kits* (RIN 2060-AT79). In November 2017, the EPA published a proposal to repeal application of the 2016 Heavy-Duty Phase 2 Rule to gliders, glider engines and glider kits. The proposed repeal is premised on an interpretation of the Clean Air Act under which gliders would be found not to constitute "new motor vehicles" or "new motor vehicle engines" under the CAA. The comment period on the proposal ended on January 5, 2018. On July 6, 2018, the EPA issued a "Conditional No Action Assurance" for certain small manufacturers and their suppliers on the basis of avoiding profound disruptions to small manufacturers in the glider industry while the EPA completes a rulemaking on gliders, with a duration of no longer than one year. On July 26, 2018, the EPA withdrew the no action assurance and explained that the EPA will continue to pursue a rulemaking for gliders. The EPA is in the process of evaluating options to revise requirements applicable to glider vehicles

in a manner that ensures consistency with statutory requirements. The agency expects that any action it may choose to take with respect to this matter would be based on legal and policy grounds and that the CAAAC and its Mobile Sources Technical Review Subcommittee would be more appropriate venues for advice.

- I would also to thank you and all the members of the SAB Risk and Technology Review Methods Review Panel for your comments on the U.S. Environmental Protection Agency''s draft document titled, *Screening Methodologies to Support Risk and Technology Reviews (RTR): A Case Study Analysis (May 2017).* My staff and I appreciate the detailed review and advice provided by the SAB during the public meeting on June 29 and 30, 2017, the public teleconference on December 5, 2017, the public meeting on May 31, 2018, and in your final report dated September 13, 2018. We will review the report and consider each of the recommendations as we continue to update and enhance our risk assessment methods for risk and technology rulemakings.

- The EPA is also appreciative of the efforts of the Board and the Biogenic Carbon Emissions Panel following completion of its second peer review of the EPA's 2014 draft *Framework for Assessing Biogenic Carbon Dioxide for Stationary* Sources with final recommendations communicated on March 6, 2019. As the EPA reviews the SAB's final recommendations, we will consider them in light of the FY2018 Consolidated Appropriations Act, the agency's April 2018 statement regarding the treatment of biogenic carbon dioxide emissions from the use of biomass from managed forests, as well as the November 2018 interagency letter to Congress from the EPA, the U.S. Department of Agriculture and the U.S. Department of Energy, which describes the agencies' work to ensure consistent federal policy on biomass energy. We acknowledge the hard work and dedication of the Biogenic Carbon Emissions Panel and the Chartered SAB and thank them for their recommendations supporting the EPA's technical work on this important topic.

Finally, the EPA will soon be initiating feedback from the SAB on a number of issues not raised in the SAB's letters. Besides our need for recommendations on existing mechanisms for data access as necessary to implement the *Strengthening Transparency in Regulatory Science* rule, the agency anticipates asking for SAB advice regarding upcoming actions related to an update to the 2005 EPA *Guidelines for Carcinogen Risk Assessment*, creation of a guidelines for non-cancer risk assessment and specific advice on improving agency risk communication.[5] These opportunities are in addition to ongoing and recent advisory activities by the SAB related to the All-Ages Lead Model, efforts to update Environmental Radiation Protection Standards for Nuclear Power Operations (40 CFR part 190), IRIS Assessments for Ethyl Tertiary Butyl Ether and tert-Butyl Alcohol, Scientific and Technological Achievement Awards and Guidelines for Devising Numerical Water Quality Criteria to Protect Aquatic Life.

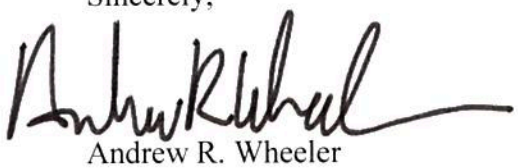
As projects are developed and ready for review, the SAB Staff Office, in conjunction with the appropriate program offices, will develop a project description and list of charge questions for

[5] EPA recently formed an agency-wide Risk Communications Work Group in order to elevate and clarify how EPA communicates about risk. This is a top priority for the Administrator, and this effort may present opportunities for additional engagement with the Board.

delivery to the SAB. The first of these requests will be provided to the SAB prior to its next face-to-face meeting.

I appreciate the Board's work in support of the EPA's activities. As always, we would be pleased to work with the SAB Staff Office to schedule an informational briefing on any of these topics. I look forward to continuing to work with you and the board to achieve our shared goals of maintaining transparency, scientific integrity and certainty in the EPA's work.

Sincerely,



Andrew R. Wheeler