MEMORANDUM

TO: Members of the Chartered SAB and SAB Liaisons

FROM: Alison Cullen, Chair, SAB Work Group on EPA Planned Actions for SAB Consideration of the Underlying Science */signed/*

DATE: May 12, 2018

SUBJECT: Preparations for Chartered Science Advisory Board (SAB) Discussions of Proposed Rule: Strengthening Transparency in Regulatory Science RIN (2080-AA14)

The Chartered Science Advisory Board convened Work Groups to discuss whether to review the adequacy of the science supporting planned regulatory actions identified by the EPA as major actions in the Spring and Fall 2017 semi-annual regulatory agenda at its May 31, 2018 meeting. To support this discussion a SAB Work Group was charged with identifying actions for further consideration by the Chartered SAB.

The Environmental Protection Agency announced the proposed rulemaking entitled Strengthening Transparency in Regulatory Science RIN (2080-AA14) on April 25, 2018 at a press event and published a *Federal Register* notice on April 30, 2018 with a 30-day public comments period. The Work Group notes that this planned action was not identified as a major action in either of the Spring 2017 nor Fall 2017 semi-annual Regulatory Agendas.

This memorandum summarizes the charge to the Work Group, their discussion regarding the planned action and issues and questions for the SAB to discuss at its May 31, 2018 meeting.

Background

The Environmental Research, Development, and Demonstration Authorization Act of 1978 (ERDDAA) requires the EPA to make available to the SAB proposed criteria documents, standards, limitations, or regulations provided to any other Federal agency for formal review and comment, together with relevant scientific and technical information on which the proposed action is based. The SAB may then make available to the Administrator, within the time specified by the Administrator, its advice and comments on the adequacy of the scientific and technical basis of the proposed action.

EPA's current process is to provide the SAB with information about the publication of the semi-annual regulatory agenda and to provide descriptions of major planned actions that are not yet proposed but appear in the semi-annual regulatory agenda. These descriptions provide available information regarding the science informing agency actions. This process for engaging the SAB supplements the EPA's process for program and regional offices to request science advice from the SAB.

The SAB Work Group then follows a process adopted by the Chartered SAB in 2013[1] to initiate its review of major planned actions identified in the Unified Regulatory Agenda by EPA. This semi-annual regulatory agenda is available at https://www.reginfo.gov/public/do/eAgendaMain. The current SAB

[1] Available at http://yosemite.epa.gov/sab/sabproduct.nsf/WebSABSO/ProcScreen2017/$File/SABProtocol2017.pdf

Work Group was formed in December 2017 to review the Fall 20017 semi-annual Regulatory Agenda and includes SAB members with broad expertise in scientific and technological issues related to the proposed actions.

The Work Group met by teleconference on May 3, 2018 to discuss its recommendations on considered actions in the Fall 2017 semi-annual regulatory agenda and included the proposed rule: Strengthening Transparency in Regulatory Science RIN (2080-AA14)[2] as part of the discussions. Members were made aware of the proposed rule via the *Federal Register* and news articles. The EPA did not provide a description of the planned action. SAB members on the Work Group teleconference include Drs. Alison Cullen (Work Group chair), Robert Blanz, Otto Doering, H. Christopher Frey, John Graham, Michael Honeycutt (SAB chair) Merl Lindstrom, Jay Turner, and Messers. Richard Poirot and Robert Merritt.

Work Group Discussions Regarding Strengthening Transparency in Regulatory Science RIN (2080-AA14)

Table 1: Summary of Proposed Actions that the SAB Work Group Considered for Additional SAB Comment on the Supporting Science		
RIN	**Planned Action Title**	**Workgroup Recommendation**
2080-AA14	Proposed Rule: Strengthening Transparency in Regulatory Science RIN	Merits review by the SAB.
[1]There is no additional information available on the planned action provided in the Unified Regulatory Agenda on the OMB website http://www.reginfo.gov/. The OMB review was completed on April 23, 2018. The hyperlink is to the FR notice for the proposed rule.		

Recommendation: This action merits further review by the SAB. The proposed rule deals with issues of scientific practice and proposes constraints that the agency may apply to the use of scientific studies in particular contexts. As such, this rule deals with a myriad of scientific issues for which the Agency should seek expert advice from the Science Advisory Board.

Rationale: In reviewing the Federal Register, Work Group members noted that EPA published a proposed rule that would limit the use of science based on human subject data and would impose requirements for the analysis of dose-response relationships widely used in risk assessments across a wide range of agency programs.

The Work Group recognizes that the long-term trend in most scientific fields is for authors to supply public access to data and analytic methods after scientific findings are published. Such transparency may help to detect and discourage scientific fraud, facilitate various forms of robustness analysis, and allow supplementary lines of knowledge to be developed from the same data. Some fields of science are moving faster than others in the direction of transparency.

[2] Available at: https://www.federalregister.gov/documents/2018/04/30/2018-09078/strengthening-transparency-in-regulatory-science

For studies published many years ago, it may not be feasible to deliver public access to data and analytic methods. There are also sensitive situations where public access may infringe on legitimate confidentiality and privacy interests, and where exceptions from complete public access may be appropriate. In addition, there are considerations associated with the cost and effort that would be involved in making large and complex existing datasets available within Institutional Review Board requirements, including the issue of who would be responsible for shouldering this burden. Thus, the development of guidelines and rules in this arena requires careful collaboration between the government and the scientific community.

Although the proposed rule cites several valuable publications that support enhanced transparency, the precise design of the rule appears to have been developed without a public process for soliciting input from the scientific community. Nor does the preamble to the rule describe precisely how the proposal builds on previous efforts to promote transparency such as the Information Quality Act and EPA's Information Quality Guidelines.

The proposed rule does not include any assessment of the impact of data restrictions on existing or future regulatory programs. Without access to the restricted data, regulatory programs could become more or less stringent than they otherwise would be, with consequences for both regulatory costs and benefits. The Work Group also found that the rule is highly controversial (indeed a similar legislative effort in the House has been stalled in Congress for several years) and could have long-term implications. Furthermore, the rule could have the effect of removing legal, ethical, and peer-reviewed studies of health effects as sources to support the agency's regulatory efforts. The proposed rule does not acknowledge that the epidemiologic science community, for example, has been making significant efforts to make data available where possible and to develop studies based on publicly available data where appropriate. On the other hand, the rule might stimulate researchers to make stronger efforts toward transparency so that their work may be considered in regulatory deliberations. It might be easier to accomplish the rule's objectives if the focus were on future studies rather than on studies that are already designed and published with terms that make complete transparency difficult or impossible to accomplish. It might also be easier if the rule took into account reasonable areas for accommodation or exception in situations for which it is not possible to release a dataset publicly either entirely, or without revision, for legitimate reasons pertaining to the use, for example, of human subject data.

Among the key science issues that the rule touches upon are the following:

- Restrictions on the use of epidemiologic studies that are based on confidential human subject data. Although the epidemiologic community recognizes the need to make data public to the extent possible, in some cases it is not possible to make public full datasets. These include, but are not limited to, cases in which studies are subject to prior Institutional Review Board (IRB) conditions or in which prospective cohort studies include extensive personal data from which it would be possible to identify individual persons.

- The proposed rule fails to mention that there are various ways to assess the validity of prior epidemiologic studies without public access to data and analytic methods. For example, the Health Effects Institute (HEI) conducted a re-analysis of the influential Harvard Six Cities and American Cancer Society (ACS) epidemiologic studies and was able to replicate its findings and to assess the robustness of the findings via sensitivity analysis[3]. HEI did uncover some sensitivities in the original ACS cohort findings associated with multiple pollutants and with interactions of pollution with socio-economic status (SES) variables such as educational attainment. Furthermore, over time, additional studies have confirmed the basic findings. Thus, in this particular case, an unusually rigorous form of peer review and independent reanalysis, coupled with many follow-up studies, has accomplished a measure of confidence in findings without public access to data and analytic methods. And we note that some of the recent confirmation studies have used publicly available data.
- The proposed rule oversimplifies the argument that "concerns about access to confidential or private information can, in many case, be addressed through the application of solutions commonly in use across some parts of the Federal government." For studies already completed or underway, the participation of human subjects is undertaken according to terms approved by the cognizant IRB. These terms can vary from study to study. In some cases, the data cannot be released simply by redacting portions of it. For example, data may have been collected with an assurance to the participating individuals that their data would be kept confidential[4]..
- The requirement of the consideration of multiple dose-response models should explicitly state that this consideration is based on information relevant to the selection of the most scientifically-appropriate model(s) such as biological plausibility, mode of action, or mechanism of action. Deviations from the use of default models should be evaluated on a case-by-case basis and have adequate scientific justification for use of an alternative model better supported by the chemical-specific data. Concepts such as "replication" and "validation", although they are surely crucial in sound science, are not clearly defined in the rule.
- The proposed rule fails to mention that EPA has mechanisms for vetting science through several expert panels, including the EPA Science Advisory Board, the EPA Clean Air Scientific Advisory Committee, and the EPA FIFRA Scientific Advisory Panel (FIFRA is the Federal Insecticide, Fungicide, and Rodenticide Act). For example, the EPA CASAC routinely reviews and evaluates epidemiologic and toxicological studies that are the basis for dose-response relationships used in risk and exposure assessments for air pollutants regulated under the National Ambient Air Quality Standards. Although such mechanisms do not typically engage in reanalysis of original data using the same methods as the original investigators, they do entail a rigorous review process that goes beyond the typical journal peer review procedures.

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[3] Health Effects Institute, 2000. Reanalysis of the Harvard Six Cities Study and the American Cancer Society Study of Particulate Air Pollution and Mortality. Daniel Krewski, Richard T. Burnett, Mark S. Goldberg, Kristin Hoover, Jack Siemiatycki, Michael Jerrett, Michal Abrahamowicz, and Warren H. White. https://www.healtheffects.org/publication/reanalysis-harvard-six-cities-study-and-american-cancer-society-study-particulate-air

[4] Ibid.

Work Group Recommendations Regarding Improvements to the Process for Identifying EPA Planned Actions for SAB Consideration

The Work Group notes that the Proposed Rule on Strengthening Transparency in Regulatory Science was not included in previous semi-annual regulatory agendas, is not available on the OMB website www.reginfo.gov and that the EPA did not provide a description of the action. The Work Group continues to urge the EPA to improve the process for future review of the semi-annual regulatory agenda and strongly recommends that EPA enhance descriptions of future planned actions by providing specific information on the peer review associated with the scientific basis for actions and more description of the scientific and technological bases for actions. EPA should provide such information in the initial descriptions provided to the work group.

Effective SAB evaluation of planned actions requires the agency to characterize the following.

- All relevant key information associated with the planned action.
- The science supporting the regulatory action. If there is new science to be used, provide a description of what is being developed. If the agency is relying on existing science, provide a short description.
- The nature of the planned or completed peer review. To the extent possible, provide information about the type of peer review, the charge questions provided to the reviewers, how relevant peer review comments are/were integrated into the planned action, and information about the qualifications of the reviewer(s).

This SAB made several of these recommendations in previous reviews[5]. We request that the chartered SAB highlight to the Administrator the need for the Agency to provide more complete information to support future SAB decisions about the adequacy of the science supporting actions in future regulatory agendas.

References: Proposed Rule: Strengthening Transparency in Regulatory Science (RIN 2080-AA14) FR Vol 83, Num. 83, pages 18768-18774. Available at: https://www.federalregister.gov/documents/2018/04/30/2018-09078/strengthening-transparency-in-regulatory-science

[5] SAB Discussions about EPA Planned Actions in the Fall 2012 Unified (Regulatory) Agenda and their Supporting Science (see page 5 of the Work Group memorandum)
SAB Discussions about EPA Planned Actions in the Spring 2013 Unified Agenda and their Supporting Science (Letter to the Administrator and Work Group memorandum [see page 5])
SAB Discussions about EPA Planned Actions in the Spring 2017 Unified Agenda and their Supporting Science (see page 7)