ACS
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EPA Docket Center
Environmental Protection Agency
Mail Code 28221T
1200 Pennsylvania Avenue NW
Washington, DC 20460

Re: Docket ID No. EPA-HQ-OA-2018-0259

The American Chemical Society (ACS or "the Society"), the world's largest scientific society, is comprised of more than 150,000 chemists, chemical engineers, and related professionals from across academia, government, and the private sector. Upon reviewing the docket listed above, ACS is concerned that the proposed rule, if implemented in its current form, could needlessly limit the use of insightful, comprehensive scientific information in the policy process and complicate the U.S. Environmental Protection Agency's (EPA's, or "the Agency's") ability to comply with applicable laws. Such limitations might negatively impact the EPA's ability to safeguard human and environmental health.

While ACS agrees that government agencies should have clear policies and procedures for providing access to scientific data, the Society firmly believes that the goal of transparency should not unduly limit the use of the best available science in agency decision-making. ACS urges EPA to include all relevant scientific studies—regardless of the ability to release complete datasets to the public—when making any regulatory decisions.

Given the potentially serious impact of the proposed rule, ACS respectfully requests that the Agency allow more time to solicit stakeholder input. This could be done either by extending the comment period to 90 days or by withdrawing the proposed rule. In either instance, ACS requests EPA to initiate a comprehensive discussion with all stakeholders of potential options to maintain the integrity of the Agency's use of scientific information

while satisfying concerns about the availability of data, models, and methods incorporated into regulatory actions. Toward this end, ACS requests that EPA hold public hearings or workshops and consult with members of the scientific community, including the National Academy of Sciences (NAS), regarding this issue.

While ACS believes that a more comprehensive feedback process is warranted, the Society nevertheless offers the following comments and suggestions on the proposed rule as published in Docket No. EPA-HQ-OA-2018-0259.

1. Pivotal regulatory science

In the proposed rule, EPA variably defines *pivotal regulatory science* as "the studies, models, and analyses that drive the magnitude of the benefit-cost calculation, the level of a standard, or point-of-departure from which a reference value is calculated," and "the specific scientific studies or analyses that drive the requirements and/or quantitative analysis of EPA final significant regulatory decisions." These designations are vague and without further guidance for what constitutes *pivotal regulatory science*, EPA will introduce uncertainty into its decision-making process. Moreover, it is unclear why EPA is choosing to create a new class of scientific information and holding it to a standard of data access that the rulemaking does not require for "non-pivotal" regulatory science.

ACS does not interpret the proposed rule's classification of *pivotal regulatory science* as a change to the current understanding of what constitutes "best available science," and the Society urges EPA to continue to use the best available science when building the foundation for regulatory actions. Ideally, the studies used by EPA should adhere to good laboratory and field practices, with results being peer-reviewed and any associated methods, models, and data made available for further review and analysis. However, these ideal conditions are not always possible to achieve. In cases where patient confidentiality or other circumstances prevents the dissemination of data, ACS asks EPA to continue to follow the guidelines set forth in the Office of Management and Budget's *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies*. These guidelines appropriately state that the worthwhile goal of allowing public access to data and methods "does not override other compelling interests such as privacy, trade secrets, intellectual property, and other confidentiality protections."

If any aspect of the proposed rule is intended to alter EPA's definition and use of the best available science, ACS asks that the Agency issue further guidance clarifying these changes and allow for public comment and consultation with the scientific community prior to implementation.

2. Administrator-granted exemptions from the proposed rule

ACS is concerned by the mechanism in the proposed rule that would allow the Administrator to exempt scientific studies from the proposed data disclosure requirements on a case-by-case basis. While such exemptions could rightly facilitate the use of scientific research not able to be fully in compliance with the proposed data transparency rule, uneven application of standards by EPA could have distorting effects on the scientific foundations of regulatory actions.

ACS asks EPA to develop a clear, consistent, and systematic process for determining which studies warrant exemption from the transparency standard set forth in this proposed rule. This process should require formal consultation with EPA career scientists and/or the Science Advisory Board (SAB) and other relevant Agency advisory committees. This process also should adhere to the standards for scientific objectivity found in *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies*. Finally, any process to exempt certain scientific studies from the proposed transparency requirements should err toward inclusion of the best available science in EPA deliberations.

3. Protection of sensitive personal and business information

In the course of its deliberations, EPA often encounters data that are shielded from public dissemination due to their confidential nature. This is done to uphold privacy agreements with individuals who have participated in scientific studies or to prevent the release of confidential business information. The scope of public release of data mandated by the proposed rule for *pivotal regulatory science* may prevent the proper shielding of these data or prevent the use of important studies in agency deliberations. ACS does not believe this is necessary for proper assessment by EPA of relevant scientific studies. The Food and Drug Administration (FDA) routinely relies on aggregated data to evaluate the safety and efficacy of drugs with no issue; EPA has similarly used aggregated data throughout its history. ACS believes that this standard is acceptable and expresses concern that it may be impossible to both publicly share all raw data from scientific studies without inadvertently exposing private medical records or confidential business information.

As EPA seeks to increase the amount of data made publicly available, the Agency should consult with data privacy experts and the NAS to assess methodologies, technologies, and institutional arrangements for making data available. As stated above, EPA should avoid insisting on complete release of data—even as methods to anonymize data or decouple them from other confidential information sources improve— if the security of the data would remain in doubt or if the failure to comply with the proposed transparency standard would prohibit EPA's use of the best available science.

4. Statutory cases where “transparent data” is not available

ACS believes that the proposed rule would create unnecessary difficulties for EPA and its ability to comply with statutes that rely upon the assessment of the best scientific data currently available. This includes the Frank R. Lautenberg Chemical Safety for the 21st Century Act, which updates the Toxic Substances Control Act (TSCA) and requires the Administrator to use “scientific information, technical procedures, measures, methods, protocols, methodologies, or models, employed in a manner consistent with the best available science.” EPA should reconsider this proposed rule to ensure that any new guidelines comply with applicable laws and encourage the use of all relevant scientific information, even if the underlying data cannot be made public.

5. Recurring regulatory processes and retroactive application of this proposed rule

ACS agrees with EPA’s stated intention that the proposed rule apply “prospectively” to future regulations. Because it may not be possible for EPA to acquire and release, in a manner consistent with the proposed rule, the data generated from studies previously incorporated into the administrative record, EPA should refrain from retroactively applying this proposed rule. This would ensure that critical results stemming from sensitive personal information or confidential business information barred from release and/or the study of unique events, longitudinal populations, or other circumstances that would be impossible to recreate are not excluded from EPA’s decision-making process. Omitting these data from the administrative record would unnecessarily weaken the body of evidence EPA can consider in its regulatory actions.

ACS does not believe that the absence of publicly available data alone justifies review of data currently part of the administrative record, and EPA should avoid reviewing data previously incorporated into the administrative record unless new scientific data necessitates the review or EPA is periodically required to do so by law. While ACS does not interpret the proposed rule as a means to reconsider the scientific basis of existing rules and regulations, the Society asks EPA to clearly identify how it will apply data transparency standards when considering regulatory programs that base future standards on existing standards that may have been developed with data not in compliance with the standards set forth in the proposed rule.

6. Other types of data and information

In general, EPA should provide access to economic and environmental impact data and models that are designed to predict the costs, benefits, market impacts and/or environmental effects of specific regulatory interventions on complex economic or environmental systems, so long as confidential business information, private personal information, and other potentially sensitive data sources are not made public in a manner that could violate confidentiality (i.e., EPA should aim to make aggregated data available).

However, EPA must be cognizant of the increased burden any such requirement would place on researchers, and the agency should avoid making extensive or repetitive requests for information and explanation.

7. Grants and cooperative agreements

When EPA funds research activities through grants or cooperative agreements, the agency should seek to minimize administrative burdens on researchers. If the agency requires that data be made publicly accessible, it should make all reasonable attempts to provide the infrastructure necessary and appropriate for the specific data type or provide researchers guidance regarding proper channels for data dissemination. Further, EPA should provide sufficient funding to cover the indirect costs associated with preparing and disseminating data generated by researchers funded through grants or cooperative agreements.

8. Models

ACS supports EPA's consideration of different models when assessing toxicity and agrees that the scientific basis for model assumptions should be clearly explained. Changes in the use of underlying models should be further explored through appropriate guidelines that allow for appropriate input from the scientific community and NAS prior to implementation.

9. Conclusion

ACS appreciates the opportunity to provide comments on this proposal. As stated at the outset, ACS has concerns with this proposal and believes that given complexities of this topic the public comment period should be extended to allow more time to solicit stakeholder input and also for EPA to hold public hearings or workshops and consult with members of the scientific community, including the National Academy of Sciences (NAS). If there are any questions on the material provided herein, or if further information or clarification is needed, please contact Mr. Glenn Ruskin, Director, ACS External Affairs & Communications, Office of the Secretary and General Counsel at g_ruskin@acs.org.

Very truly yours,

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