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Creating a Safer and Healthier World by Advancing the Science and Increasing the Impact of Toxicology

DATE: Wednesday, April 1, 2020

TO: Andrew R. Wheeler, Administrator of the US Environmental Protection Agency

FROM: The Society of Toxicology (SOT)

RE: Strengthening Transparency in Regulatory Science
Docket ID No. EPA–HQ–OA–2018–0259

The Society of Toxicology (SOT), a professional organization representing more than 8,000 toxicologists, environmental scientists, and researchers in other allied sciences, offers the following comments on the proposed Strengthening Transparency in Regulatory Science Rule by the US Environmental Protection Agency (40 CFR Part 30) (EPA–HQ–OA–2018–0259; FRL–10004–72– ORD).

In response to public comments, the US Environmental Protection Agency (US EPA) has embraced the concept of tiered access to data that will require data repositories. The establishment of such data repositories is being actively explored by several agencies, and the US Centers for Disease Control and Prevention (US CDC) has already established such a repository with which the US EPA is conducting a pilot study. The establishment of such data repositories are consistent with and complement the different open data access policies that have been making government-generated data publicly available for the past four to five years. Further, the government agencies that sponsor extramural research are already moving to integrate those programs into their open data access policies. Similar movements to ensure open data access also are underway in Europe and elsewhere. Thus, the Strengthening Transparency in Regulatory Science Rule will create an ineffective bureaucracy that will have minimal impact on strengthening transparency in regulatory science and will only serve to curtail the Agency's ability to respond to crises such as the current COVID-19 pandemic. **As such, SOT strongly urges the US EPA to consider withdrawing the proposed rule.**

If the US EPA continues to move forward with this rule, SOT offers the following specific comments to the sections of the rule as explained in the "Supplementary Information" section of the "Supplemental Notice of Proposed Rulemaking" published in *Federal Register* Vol. 85, No. 53 on March 18, 2020.

Applicability to Data and Models

SOT is supportive of the modified rule that allows all available high-quality data to be used in rulemaking. However, the Society is concerned that the current draft of the rule may allow for greater consideration to be given to studies with data available for independent validation—a concern that is elucidated further in the comments related to "Availability of Data and Models."

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Definitions
The proposed definitions add considerable clarity to the intent of the Strengthening Transparency in Regulatory Science Rule. SOT is concerned about the intent to include "trade secrets, commercial information, materials necessary to be held confidential by a researcher until they are published, or similar information which is protected under law and personal, medical information and similar information the disclosure of which would constitute a clearly unwarranted invasion of personal privacy" in the proposed rule. Again, these concerns are further expressed in the Society's comments related to "Availability of Data and Models."

Availability of Data and Models
Although the description and proposed rules regarding the availability of data and models is greatly improved, SOT remains concerned about the failure of the revised rule to explicitly address how it intends to handle data and models from high-quality studies wherein the data or models have not been made publicly available. As explained in Section II, Availability of Data and Models, in the March 18, 2020, *Federal Register* notice, the proposed rule states that within a collection of studies that address a specific issue, a small number of studies wherein data are publicly available would be considered over a larger set of studies wherein in the data has not been made publicly available. While this language clarifies that studies without publicly available data will not be excluded automatically in regulatory decision-making, the proposed rule still may exclude the best science from being used when promulgating regulatory decisions unless an exemption is granted, which is concerning.

SOT commends the US EPA for incorporating the concept of tiered access to data in the current draft of the rule and for piloting the use of the Research Data Center of the US CDC National Center for Health Statistics. Clearly, the establishment of such data repository centers with the capability of serving as honest brokers for anonymizing protected data sets is a desired goal, is consistent with, and complements the open data access polices of major research enterprises with the US federal government. However, SOT also is aware that the annual operation of such data repositories costs several million dollars above and beyond the initial costs of establishing such centers. Based on the current status of available data repositories and these anticipated costs, the explicit inclusion of tiered access to data and models that have CBI, proprietary data, or PII that cannot be sufficiently de-identified to protect the data subjects in the proposed rule is premature. Without requiring action by the Administrator, the rule should specifically exempt such data and models until such time that the described data repositories have been established and are fully capable of providing tiered access to data.

Exemptions by the Administrator
The requirement for an exemption by the Administrator remains a high barrier, particularly when one considers the number of high-quality studies that, because of CBI, proprietary information, or PII, cannot currently make their data publicly available. When an exemption is required, at a minimum, SOT would recommend allowing this exemption to be made at the level of an Office Assistant Administrator or Deputy Assistant Administrator in consultation with Office staff scientists as well as the Office of Research and Development.

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