August 20, 2019

Dr. Thomas Armitage
Designated Federal Officer
EPA Science Advisory Board (1400R)
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20460

Via email armitage.thomas@epa.gov

Re: Science Advisory Board Consultation on Strengthening Transparency in Regulatory Science, August 27, 2019.

Dear Dr. Armitage:

The American Chemistry Council (ACC) is pleased to submit these comments for consideration by the Science Advisory Board (SAB) as it prepares to conduct a consultation with EPA on mechanisms for secure access to personally identifying information (PII) and confidential business information (CBI) as discussed in EPA's proposed rulemaking, "Strengthening Transparency in Regulatory Science." (83 Fed. Reg. 18768, April 30, 2018).

ACC provided comments to EPA in support of its proposed rulemaking, and offered a number of specific recommendations to help improve and strengthen the rulemaking. ACC reiterates below comments made previously on this rulemaking that are relevant to the consultation on PII and CBI.

I. EPA Should Incorporate Stronger Data and Model Access Requirements into Cooperative Agreements and Grants while Complying with Privacy and Confidentiality Requirements and Laws

EPA requested comment in its proposed rulemaking on how EPA can incorporate stronger data and model access requirements into the terms and conditions of Cooperative Agreements and Grants. ACC believes EPA can accomplish this by implementing requirements that all models and results developed under EPA Cooperative Agreements and Grants be open access and not proprietary. EPA should also require all grant proposal applicants to include as part of any grant proposal a data management plan, similar to those required by the National Institutes of Health (NIH).[1] EPA may elect to exclude from these requirements grants/agreements of some specified annual amount, but that annual amount should be reasonable and ensure that the vast majority of models and results developed under grants/agreements is shared.

[1] https://grants.nih.gov/grants/policy/data_sharing/data_sharing_guidance.htm

EPA should adopt model evaluation criteria to apply the greatest weight and credibility to models that are open access, describe the endpoint predicted clearly, are based on unambiguous open access computer algorithms, have a defined domain of applicability, have been transparently verified with publicly available datasets, and are shown to be robust and scientifically sound for the intended use.

In addition, EPA should develop common data templates and digital platforms for the most common types of research studies to be used by entities subject to Cooperative Agreements and Grants to facilitate public use and validation.

II. Methodologies and Technologies Providing Protected Access to Sensitive or Confidential Data

In circumstances where company CBI and other intellectual property may be implicated, EPA should confer with the CBI data owner to determine how to make that data available to the greatest extent possible without disclosing the CBI within that data, study, or model. How this is handled will likely be impacted by the type of regulatory decision and the specific requirements of the statute involved.

For example, under TSCA, while the summarized study results, analysis, and final report may be publicly available, the underlying data in a health and safety study may qualify as CBI when the underlying data are not in the public domain and that data provides a commercial value to its owner.[2] In such circumstance, it is the availability of the underlying data that determines whether or not an unpublished study can be used by a competitor to support its notification or registration of a substance overseas without obtaining ownership or citation rights to use such data, depriving the data owner of the value of its investment in the underlying data. Current EPA regulations require chemical manufacturers to submit health and safety studies under some circumstances. However, it is noteworthy that none of these regulations routinely require study submitters to submit underlying data along with a final report summarizing the results and analysis. This indicates that the final report likely communicates sufficient information about the potential health and environmental effects to the public when a company has submitted health and safety studies in which it has a commercial interest in protecting.[3]

ACC believes that making a final study report publicly available where the underlying data are CBI would, in most circumstances, be an effective way to make public the relevant information EPA has relied on in reaching a decision. In these situations, EPA can access the underlying data to confirm the methods, models, and approaches are based on validated procedures, accessible data, etc. If necessary, when specialized expertise is needed, EPA could contract with an independent third-party science reviewer to confirm those findings, although we believe this would likely only be necessary in unusual circumstances. In addition, EPA might also consider an approach followed under FIFRA where Data

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[2] See, e.g., *Cohen v. Kessler*, No. 95-6140 (D.N.J. Nov. 25, 1996).

[3] 40 C.F.R. §720.50(a)(3)(i) requires that if data do not appear in the open scientific literature, the submitter must provide a full study report, including the experimental methods and materials, results, discussion and data analysis, conclusions, references, and the name and address of the laboratory that developed the data.

Evaluation Records of studies are made publicly available, but not full studies.[4] Another approach is that of the European Union's REACH program, which makes Robust Study Summaries (RSS) publicly available, while protecting from disclosure the competitively sensitive underlying data of health and safety studies.

When protecting data while also promoting data access, NIH guidelines should be consulted.[5] ACC believes many of these guidelines could be applied in EPA's implementation of this proposed policy under each of the statutory programs EPA administers to ensure the guidelines adopted suit the specific needs of each statute.

EPA should ensure that it implements its final rule in a manner that enables it to use confidential health records that may exist with certain kinds of studies, such as long-term air pollution and workplace exposure studies that involve confidential health records. Several agencies and organizations have successfully addressed the issue of data access while maintaining confidentiality that should be considered by EPA. For example:

- The existing rule requiring federally funded research to be made available to other researchers. This standard could be adopted and applied to third-party funded research that is relied upon or used in support of regulatory decision-making. [6,7]
- Health care claims and related data are now being made available to researchers in de-identified form by some health insurance companies, such as Optum, which offers a "proprietary research database of health care and administrative data that links patient, physician, and treatment attributes from millions of geographically diverse individuals in the U.S." Optum appears to have developed methods and procedures to appropriately address confidentiality concerns.[8]
- Medicare claims data are already available to researchers in de-identified form. Algorithms and methods developed by the Center for Medical Services should be examined by the EPA.[9]
- Several professional societies have guidance on the protection of health data and de-identification, such as the Institute of Electrical and Electronic Engineers and the International Association of Privacy Professionals. [10]

EPA should develop clear guidance on protecting privacy, de-identifying data, and settling disputes should a breach occur. It may also want to consider establishing an office similar to that

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[4] See, e.g., https://archive.epa.gov/pesticides/chemicalsearch/chemical/foia/web/pdf/010501/010501-050.pdf
[5] https://www.niaid.nih.gov/research/data-sharing-and-release-guidelinesand https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5302472/
[6] https://fas.org/sgp/crs/misc/R44774.pdf
[7] Subject to CBI constraints and/or completing non-disclosure agreements.
[8] https://cdn-aem.optum.com/content/dam/optum3/optum/en/resources/articles-blog-posts/WF219537_LS_Amplify_Revised_2017_v3.pdf
[9] https://www.hhs.gov/hipaa/for-professionals/privacy/special-topics/de-identification/index.html
[10] http://www.ehealthinformation.ca/wp-content/uploads/2014/08/2010-Risk-based-de-identification-of-health-data.pdf and https://iapp.org/media/pdf/knowledge_center/Perspectives_on_Health_Data_De-Identification_final.pdf

of NIH's Office of Research Integrity to adjudicate any issues that may arise in the administration of its practices under this rule.[11]

III. EPA Should Work with Entities Where Scientific Data are not Publicly Available in a Manner Sufficient for Independent Evaluation

In exceptional circumstances, where data may not available in a manner sufficient for independent evaluation, EPA should attempt to work with data owners to reach an agreement to make the information available to the public to the greatest extent practicable without jeopardizing the privacy, confidentiality, or the proprietary interests that deserve protection. In circumstances where there is significant difficulty making data available in a meaningful way, EPA should consider contracting with external experts in the scientific discipline at issue, have them sign confidentiality agreements, analyze the data, and prepare a confidential report with a non-confidential summary for EPA to share publicly.

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Sincerely,

Christina Franz
Senior Director, Regulatory & Technical Affairs

[11] https://ori.hhs.gov/