Comments by Christina Franz at the Public SAB-EPA Consultation on Proposed Rulemaking on Strengthening Transparency in Regulatory Science

August 27, 2019

- Good afternoon. I'm Christina Franz. I am a Senior Director of Regulatory & Technical Affairs at the American Chemistry Council.
- Thank you for the opportunity to provide comments at this consultation between the SAB and EPA regarding the 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."
- ACC provided written comments on this consultation and I understand those have been made available to the participants. I won't reiterate all those comments here, but will simply highlight a few key points, which were also included in ACC's comments to EPA on the proposed rulemaking.

First, EPA Should Incorporate Stronger Data and Model Access Requirements into its Cooperative Agreements and Grants while Complying with Privacy and Confidentiality Requirements and Laws

- EPA had requested comment on its proposed rulemaking regarding how it 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.

Second, Methodologies and Technologies Exist that Provide 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.

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

- 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.
- When protecting data while also promoting data access, NIH guidelines should be consulted.[2] 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 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 of NIH's Office of Research Integrity to adjudicate any issues that may arise in the administration of its practices under this rule.[3]

Third, 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.

Thank you for the opportunity to comment.

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[2] https://www.niaid.nih.gov/research/data-sharing-and-release-guidelinesand https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5302472/

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