

Strengthening Transparency in Regulatory Science Proposed Rule Charge Questions for the SAB

Summary

EPA's proposed rule "Strengthening Transparency in Regulatory Science" states:

"When promulgating significant regulatory actions, the Agency shall ensure that *dose response data and models* underlying *pivotal regulatory science* are publicly available in a manner sufficient for independent validation."

"Information is considered 'publicly available in a manner sufficient for independent validation' when it includes the 'information necessary for the public to understand, assess, and replicate findings.'"

"Where the Agency is making data or models publicly available, it shall do so in a fashion that is consistent with law, protects privacy, confidentiality, confidential business information, and is sensitive to national and homeland security."

Therefore, EPA seeks consultation with its Science Advisory Board on existing mechanisms for secure access to personally identifying information (PII) and confidential business information (CBI) as discussed in the proposed rule consistent with existing laws and policies that protect PII and CBI.

Charge Questions

1. Other agencies (e.g., NIH and HHS) use a tiered approach for access to PII data. Please comment on whether such an approach would be a good model for EPA to apply.
2. Given the laws protecting CBI and PII, as well as the proposed requirements for data availability in the Strengthening Transparency in Regulatory Science proposed rule, please comment on how EPA could use studies involving CBI and/or PII to make regulatory decisions.

Background

1. Background on existing mechanisms to protect PII

To date, EPA has not issued guidance for de-identifying PII, and intramural researchers either code such datasets as "non-public" or follow the guidance issued by Health and Human Services (HHS, see <https://www.hhs.gov/hipaa/for-professionals/privacy/special-topics/de-identification/index.html#zip>). This guidance provides two ways to de-identify information – the "safe harbor" method and the "expert determination" method. [In the "safe harbor" method, a proscribed

list of identifiers of the individual who is part of a study or of relatives, employers, or household member of the individual are removed. In the “expert determination” method protected health information is de-identified by “[a] person with appropriate knowledge of and experience with generally accepted statistical and scientific principles and methods for rendering information not individually identifiable:

- (i) Applying such principles and methods, determines that the risk is very small that the information could be used, alone or in combination with other reasonably available information, by an anticipated recipient to identify an individual who is a subject of the information; and
- (ii) [Documenting] the methods and results of the analysis that justify such determination.”]

EPA is currently gathering information for managing public access to human subjects research datasets, including the use of a tiered approach with secure data enclave(s)¹ and comparing the benefits of a centralized or distributed approach to protecting PII.

A tiered approach provides access to research data using different strategies based upon disclosure risk. Access to information and data varies by tier. The greatest amount of information is available when access to data are most restricted. Replicating findings requiring PII information (e.g., residence) may not be possible with unrestricted public access. The amount of information available for analysis is dictated by the tier chosen.

2. Background on existing mechanisms to protect CBI

Regulations at 40 CFR § 2 Subpart B govern the use of confidential business information. These regulations establish basic rules governing business confidentiality claims, the handling by EPA of business information which is or may be entitled to confidential treatment, and determinations by EPA of whether information is entitled to confidential treatment for reasons of business confidentiality. Various statutes under which EPA operates contain special provisions concerning the entitlement to confidential treatment of information gathered under such statutes. The regulations prescribe rules for treatment of certain categories of business information obtained under the various statutory provisions. In the event of a conflict between the provisions of the basic rules and those of a special rule which is applicable to the particular information in question, the provision of the special rule shall govern. See <https://www.ecfr.gov/cgi-bin/text-idx?SID=505006343d266e51c03f18fc82f41cc1&mc=true&node=sp40.1.2.b&rgn=div6>]

¹ A tiering approach was recommended in the recent update to OMB’s Information Quality Bulletin [OMB-19-15, April 24, 2019].