EPA Proposes Increased Transparency For Scientific Studies

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EPA has proposed a major change in how it uses and relies upon scientific data and analysis for its rulemakings. The proposed rule would increase the transparency and availability of such data and analysis "pivotal to [EPA's] significant regulatory actions," so that third parties may independently validate the agency's scientific support for such actions. EPA states that this increased transparency will help EPA fulfill its core mission with better scientific analysis and increased public trust in its regulatory actions. While EPA's objectives seem laudable in several respects, the agency will need to balance transparency with legal protections that may apply to disclosure of the information.

More specifically, the proposed rule targets "*dose response data and models* underlying *pivotal regulatory science* that are used to justify significant *regulatory decisions* regardless of the source of funding or identity of the party conducting the regulatory science." The net effect of these defined terms is that the proposed rule would apply to the data and modeling used in support of "significant regulatory actions" as defined by Executive Order 12866 (issued by President Clinton in 1993) to establish standards for allowable exposure to pollutants or contaminants. These standards are in turn used to set or otherwise influence emission and discharge limits, chemical and waste management criteria, and cleanup risk standards. Therefore, this standard-setting process affects pollution control requirements and costs for facility compliance and site remediation under many federal environmental statutes and regulatory programs. The proposed rule would not apply to other agency actions, such as enforcement or permitting matters.

The proposed rule would impose certain duties on EPA to fulfill the proposed rule's objectives. First and foremost, EPA would have to provide the public with access to covered "dose response data and models," whether generated by EPA or third parties, so they can be independently validated. To this end, the data and model information must be sufficient "for the public to understand, assess, and replicate findings." EPA's regulatory actions would be required to include descriptions of "any assumptions and methods used" and any "variability and uncertainty" associated with the underlying dose response data and modeling. In addition, EPA would ensure independent peer-review of the "pivotal regulatory science" underpinning its regulatory decisions, including "information, standardized test methods, consistent data evaluation procedures, and good laboratory practices to ensure transparent, understandable, and reproducible scientific assessments." EPA is looking to "open

science" advocates for recommendations on how to proceed in these respects. If adopted as currently drafted, the proposed rule would apply prospectively to final rulemakings relying on such data and modeling. However, EPA states in the proposed rule's preamble that the agency "should be guided by [the policy set forth in the proposed rule] to the maximum extent practicable during ongoing regulatory action, even where such research has already been generated, solicited, or obtained." This suggests that the proposed rule is being considered as guidance for pending or planned EPA rulemaking efforts before the proposed rule is finalized.

To address potentially conflicting laws and other concerns about revealing confidential or sensitive information, the proposed rule would require that such public access occur "in a fashion that is consistent with law, protects privacy, confidentiality, confidential business information, and is sensitive to national and homeland security." The preamble notes that "[n]othing in the proposed rule compels the disclosure of any confidential or private information in a manner that violates applicable legal and ethical protections," and EPA is examining how other agencies have handled and protected such sensitive information. The proposed rule also allows for certain case-by-case exceptions to the proposed public accessibility and peer-review obligations. Despite these stated considerations, some argue that reliance only on publicly available data may effectively block use of otherwise suitable peer-reviewed data and related studies, given their reliance on confidential personal health information for study subjects. Others have concerns about whether the proposed rule's approach is too narrowly focused - why is it limited to just dose response data and models? – and whether EPA will offer more specific guidance for implementation. Still, the regulated community and some environmental groups would likely gain greater insights into how EPA relied upon scientific data and modeling when developing its regulations if the proposed rule is adopted as a final rule.

EPA requests comment on a number of aspects of its proposal, including: (i) the sufficiency of or alternatives for legal authority for this proposal; (ii) whether the proposal's principles and duties for increasing transparency and reliability of data should be incorporated into contracts that EPA has with researchers and others who provide scientific data to EPA in support of its regulatory functions; (iii) to what degree other means, laws or compelling reasons, such as privacy or national security, exist for protection of confidential information for business and individuals; (iv) phasing in of the increased obligations for transparency and data rigor; (v) how this proposal should apply to past data reviews and analyses (such as periodic reviews of the National Ambient Air Quality Standards under the Clean Air Act); and (vi) how to address previously developed dose response data and models lacking the level or transparency or third-party validation contemplated under the proposed rule.

Based on the initial strong interest by a variety of stakeholders, EPA has extended the public comment period for the proposed rule to August 16, 2018 and will hold a public hearing on July 17, 2018. The proposed rule's emphasis on greater transparency and validation of scientific analysis and the related confidentiality concerns can be expected to generate many comments from all quarters.

***Strengthening Transparency in Regulatory Science*, 83 Fed. Reg. 18768-18774 (April 30, 2018); *Strengthening Transparency in Regulatory Science; Extension of Comments Period and Notice of Public Hearing*, 83 Fed. Reg. 24255-24256 (May 25, 2018).**

Exec. Order No. 12,866, 58 Fed. Reg. 51735 (October 4, 1993).

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