EPA Releases Strengthening Transparency in Regulatory Science Proposed Rule

Saturday, April 28, 2018

On April 30, 2018, the U.S. Environmental Protection Agency (EPA) will publish in the Federal Register a proposed rule entitled "Strengthening Transparency in Regulatory Science" (Science Rule) that EPA states is intended to “strengthen the transparency of EPA regulatory science.” EPA states in the preamble that “[t]he proposed regulation provides that when EPA develops regulations, including regulations for which the public is likely to bear the cost of compliance, with regard to those scientific studies that are pivotal to the action being taken, EPA should ensure that the data underlying those are publicly available in a manner sufficient for independent validation.” EPA further states that “EPA is proposing to establish a clear policy for the transparency of the scientific information used for significant regulations: specifically, the dose response data and models that underlie what we are calling ‘pivotal regulatory science.’ ‘Pivotal regulatory science’ is the studies, models, and analyses that drive the magnitude of the benefit-cost calculation, the level of a standard, or point-of-departure from which a reference value is calculated.”

EPA intends the rule to provide this transparency “in a manner consistent with statutory requirements for protection of privacy and confidentiality of research participants, protection of proprietary data and confidential business information, and other compelling interests.” EPA “will use peer-reviewed information, standardized test methods, consistent data evaluation procedures, and good laboratory practices to ensure transparent, understandable, and reproducible scientific assessments.” EPA states that its “regulatory science” should be “consistent with the Office Management and Budget’s Final Information Quality Bulletin for Peer Review,” and that “[r]obust peer review plays a critical role in independently validating key findings and ensuring that the quality of published information meets the standards of the scientific and technical community.” In addition, EPA states, the proposed rule “is designed to increase transparency of the assumptions underlying dose response models,” noting that “[t]he use of default models, without consideration of alternatives or model uncertainty, can obscure the scientific justification for EPA actions.”

EPA states: “Across EPA programs much of the science that informs regulatory actions is developed outside the Agency. It is the charge of regulators to ensure that key findings are valid and credible, as required by OMB’s Guidelines.” EPA “believes that concerns about access to confidential or private information can, in many cases, be addressed through the application of solutions commonly in use across some parts of the Federal government,” and “[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.”

The rule as proposed has ten subparts:

1. **Section 30.1** states the purpose of the rule: “This subpart directs EPA to ensure that the regulatory science underlying its actions is publicly available in a manner sufficient for independent validation.”

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2. **Section 30.2** sets forth definitions of the following five terms: “dose response data and models”; “pivotal regulatory science”; “regulatory decisions”; “regulatory science”; and “research data.”

3. **Section 30.3** addresses what and what is not subject to the rule.

4. **Section 30.4** provides: “EPA shall clearly identify all studies (or other regulatory science) relied upon when it takes any final agency action. EPA should make all such studies available to the public to the extent practicable.”

5. **Sections 30.5** and **30.6** establish requirements applicable to EPA’s use of dose response data and models underlying pivotal regulatory science, as those terms are defined elsewhere in the proposed rule.

6. **Section 30.7** requires EPA to conduct independent peer review on all pivotal regulatory science used to justify regulatory decisions, as those terms are defined, and to ask peer reviewers to “articulate the strengths and weaknesses of EPA’s justification for the assumptions applied and the implications of those assumptions for the results.”

7. **Section 30.8** addresses how EPA is to account for cost under the rule.

8. **Section 30.9** provides that EPA may grant an exemption to the rule on a case-by-case basis if EPA “determines that compliance is impracticable” because either: it is not feasible to ensure that all dose response data and models underlying pivotal regulatory science is publicly available in a manner sufficient for independent validation, in a fashion that is consistent with law, protects privacy, confidentiality, confidential business information, and is sensitive to national and homeland security; or it is not feasible to conduct independent peer review on all pivotal regulatory science used to justify regulatory decisions for reasons outlined in OMB Final Information Quality Bulletin for Peer Review Section IX.

9. **Section 30.10** addresses other requirements applicable under the rule.

EPA is soliciting comments on the proposed rule and “how it can best be promulgated and implemented in light of existing law and prior Federal policies that already require increasing public access to data and influential scientific information used to inform federal regulation.” Among the issues EPA asks for comment are the following:

1. All aspects of the proposed regulation and the bases articulated for it.
2. Whether alternative or additional regulatory or other policy vehicles are appropriate to establish and implement these policies, and whether further regulatory or other policy vehicles at the programmatic or statutory level would be appropriate as alternative or additional steps the Agency may take to further the policies articulated.
3. Effects of the proposed rule on individual EPA programs, including whether certain activities are appropriate to be excepted or if other requirements would affect implementation.
4. Which criteria the Agency should use to base any exceptions, including whether case-by-case exceptions may be appropriate.
5. Whether and to what extent the rule requirements, or other provisions and policies, should apply to other stages of the rulemaking process, including proposed rules, as well as to other types of Agency actions and promulgations, such as guidance.
6. Whether a narrower scope of coverage would be appropriate, such as only final regulations that are determined to be “major” under the Congressional Review Act, or “economically significant “under EO 12866.

7. Whether certain categories of regulations should be excluded from coverage, such as those that merely reaffirm an existing standard, or some other category, including whether the rule should apply to individual party adjudications, enforcement activities, or permit proceedings when EPA determines that these provisions are practical and appropriate and that the actions are scientifically or technical novel or likely to have precedent-setting influence on future actions, and whether the Agency should apply the provisions of the proposed rule to these actions or to specific types of actions within these categories.

8. Whether other agency actions, beyond significant final regulatory actions under EO 12866, should be included, such as site-specific permitting actions or non-binding regulatory determinations.

9. The definitions of “pivotal regulatory science,” and “dose response data and models” and how to implement such definitions.

10. How to incorporate stronger data and model access requirements into the terms and conditions of cooperative agreements and grants.

11. How EPA can build up on other federal agencies’ policies regarding grantee and cooperator requirements for data access and data sharing.

12. Methodologies and technologies designed to provide protected access to identifiable and sensitive data, such as individual health data, and on commenters’ experience with the use of such methodologies and technologies and their strengths and limitations.

13. How to balance appropriate protection for copyrighted or confidential business information, including where protected by law, with requirements for increased transparency of pivotal regulatory science.

14. Whether there are other compelling interests besides privacy, confidentiality, national and homeland security that may require special consideration when data are being released.

15. Implementation of the proposed regulation, including which parts of the Agency should be responsible for
carrying out these requirements.

16. The effective date of the rule and whether there should be a phase-in, as well as the manner in which the rule should apply to previous records.
17. Whether and how the proposed rule should apply to dose response data and models underlying pivotal regulatory science if those data and models were developed prior to the effective date.
18. How the prospective or retrospective application of the provisions for dose response data and models or pivotal regulatory science could inadvertently introduce bias regarding the timeliness and quality of the scientific information available.
19. How to address a circumstance in which EPA has a statutory requirement to make a determination for which scientific information publicly available in a manner sufficient for independent validation does not exist.
20. Additional implementation challenges not discussed in the notice.
21. Whether proposed exemptions are appropriate.
22. Whether disclosure requirements applicable to dose response data and models in the proposed rule should be expanded to cover other types of data and information, such as economic and environmental impact data and models that are designed to predict the costs, benefits, market impacts and/or environmental effects of specific regulatory interventions on complex economic or environmental systems.

On April 26, 2018, EPA Administrator Scott Pruitt was a witness in a hearing before the U.S. House Committee on Energy and Commerce, Subcommittee on Environment entitled The Fiscal Year (FY) 2019 U.S. Environmental Protection Agency (EPA) Budget. Administrator Pruitt discussed the forthcoming proposed rule at this hearing, stating that the rule is an effort to make the data and methodology that underlie scientific studies, oftentimes done by third parties, more accessible and more transparent -- especially to those interested stakeholders commenting on the determinations that the studies support. Many of the Committee members were supportive of the Science Rule, stating that the transparency is long overdue. Others expressed concerns with the proposed rule, including concerns about a potential for EPA to handpick certain “public” studies and to discount other valid studies only because they did not divulge all of their confidential data; and concerns regarding the inability to protect important confidential information, such as identities of patients.

Commentary

The proposed rule is controversial and will likely be the subject of significant comment. Similar to when legislative proposals offer new terminology, the establishment and use of terms such as “pivotal regulatory science” suggest some distinction between it and “not so pivotal science” not subject to the new procedures and requirements. How such distinctions will be made and what the impact may be could be significant for companies that submit “routine” data under existing Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) regulations concerning registration data requirements. Interest in the subject has been reported to focus especially on questions some have raised about the way EPA has utilized studies and scientific data to support initiatives and rules issued by the air program. What that raises is a fear that addressing some concerns about how air regulations are justified might have unintended consequences in other EPA media programs.

In brief, for pesticide registrants, the rule poses significant potential issues. For example, registrants spending millions of dollars on studies necessary to register products that are proprietary and protected from release to those who might use them to register their own products without compensating the owners; issues with regard to EPA's reliance under the proposed rule on these registrant generated and FIFRA required studies will need to be carefully considered carefully. As another example, EPA's review of epidemiology data underlying its conclusions regarding chlorpyrifos and other organophosphate pesticide requirements potentially may be subject to more stringent requirements than they previously were. Registrants should review the proposed rule carefully and monitor closely developments relating to it.

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