

Fact Sheet: Strengthening Transparency in Pivotal Science Underlying Significant Regulatory Actions and Influential Scientific Information Rule

On December 30, 2020, the U.S. Environmental Protection Agency (EPA) finalized the rule, Strengthening Transparency in Pivotal Science Underlying Significant Regulatory Actions and Influential Scientific Information. This final rule establishes how EPA will consider the availability of dose-response data underlying pivotal science used in its significant regulatory actions and influential scientific information. With the implementation of this rule, EPA shall give greater consideration to pivotal science where the underlying dose-response data are available in a manner sufficient for independent validation.

Requirements of the Final Rule

EPA is issuing this final rule to help strengthen the transparency of the dose-response data underlying certain EPA actions. The requirements of the final rule are summarized below.

Determining Which Studies Constitute Pivotal Science

- When proposing significant regulatory actions or developing influential scientific information, this rule requires EPA to determine which studies constitute pivotal science and give greater consideration to studies where the underlying dose-response data are available in a manner sufficient for independent validation.
- EPA will identify specific dose-response studies or analyses as pivotal science if they drive the requirements, quantitative analyses or both of an EPA significant regulatory action or influential scientific information.
- For studies that are determined pivotal science where the underlying dose-response data are not publicly available, EPA will consider additional factors when determining the level of consideration to give those studies.
- EPA intends to identify the studies considered pivotal science in the documentation at the proposed rule stage for significant regulatory actions and when influential scientific information is disseminated for peer review

Identifying All Science Informing Significant Regulatory Actions

- This rule requires EPA to clearly identify and make available all science that serves as the basis for informing a significant regulatory action to the extent permitted by law.
- This requirement is consistent with the EPA's existing practice of making science that serves as the basis for informing a significant regulatory action available in the public docket as part of the rulemaking.

Requirements for Independent Peer Review of Pivotal Science

- The rule establishes requirements for the independent peer review of pivotal science.
- If the individual studies identified as pivotal science have already undergone journal peer review, EPA is not required to conduct a second review. However, the Agency can evaluate whether or not to initiate additional peer review, consistent with the OMB Bulletin for Peer Review and EPA Peer Review Manual.

- If the Agency conducts peer review on pivotal science, EPA will ask peer reviewers to state the strengths and weaknesses of the justification for the assumptions applied in analyzing dose-response data and the implications of those assumptions for the results.

Administrator Exemptions to Rule

- The final rule includes criteria for the Administrator to consider when granting case-by-case exemptions to the requirements of this rule.
- If an exemption is granted, EPA is required to document the rationale for granting the exemption.

Definitions

- Finally, this rule defines the following terms: “data,” “dose-response data,” “independent validation,” “influential scientific information,” “pivotal science,” “publicly available,” “reanalyze,” “science that serves as the basis for informing a significant regulatory action,” and “significant regulatory actions.”

Effects of the Final Rule

- This rule pertains to the internal practices of EPA. It does not direct or require any outside entity or EPA to establish data sharing mechanisms. Further, the final rule does not require EPA to collect, store, or publicly disseminate dose-response data underlying pivotal science.
- If there is a conflict between this rule and the environmental statutes that the EPA administers, and their implementing regulations, the statutes and regulations will take precedence.
- The final rule becomes effective immediately upon publication in the Federal Register and applies prospectively to new significant regulatory actions proposed after the effective date of this rule and influential scientific information submitted for peer review after the effective date of this rule.
- For future significant regulatory actions and influential scientific information, the final rule applies equally to all dose-response data underlying studies used as pivotal science, regardless of when the study or the data was created.

Key Changes from Proposal in Response to Comments

- Affirmed that the EPA will continue to evaluate the quality of all relevant studies and will not categorically exclude any scientific studies on the basis of data availability.
- Refined the focus of the rule from the 2020 supplemental notice of proposed rulemaking (SNPRM) to increase transparency on dose-response data, as the dose-response data are discrete, and the dose-response assessment is a well-defined and impactful step in the quantitative assessment of risk.
- Further clarified how the Agency will determine the consideration to afford to pivotal science in either significant regulatory actions or influential scientific information.

- Clarified that this final rule sets the overarching structure and principles for transparency in significant regulatory actions and influential scientific information. EPA plans to promulgate either statute-specific transparency regulations or programmatic actions implementing this procedural rule, as appropriate, to clarify how the Agency will implement the provisions from this final rule for specific programs authorized under the statutes the EPA administers.

For More Information

Information on this final rule is available on EPA's website here: <https://www.epa.gov/osa/final-rule-strengthening-transparency-pivotal-science-underlying-significant-regulatory-actions>