Insight

EPA Transparency at the End of the Tunnel

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EXECUTIVE SUMMARY

- The Environmental Protection Agency (EPA) has finalized a rule that has drawn both praise for attempting to make the data underlying EPA regulations more transparent and derision as some believe it will unduly constrain the EPA in making regulatory decisions.
- The rulemaking has had one of the more complicated paths to finalization, but the changes made to it along the way present an interesting case study in how public input can significantly refine a rule from its earlier stages to its final form.
- Since it is a procedural rule that governs how EPA conducts its regulatory development, it occupies a unique space that has some unusual ramifications for its implementation going forward.

INTRODUCTION

On January 5, the Environmental Protection Agency (EPA) released the final version of its rule on "Strengthening Transparency in Pivotal Science Underlying Significant Regulatory Actions and Influential Scientific Information" (Transparency Rule). The rulemaking has taken a long and winding road: beginning as a proposed rule in 2018, adding a "supplemental proposed rule" early last year, and now becoming final in the waning weeks of the Trump Administration. The Transparency Rule has proven quite contentious over the course of its development with nearly one million comments filed both for and against it. Supporters contend that it will bring needed clarity to the underlying data EPA bases its rulemaking activities upon, while opponents argue that the rule's new requirements will

effectively impede EPA's ability to address certain health and safety concerns. An examination of the rule's meandering development, however, reveals a more nuanced situation.

PROPOSED RULE

The original proposed version of the Transparency Rule was published on April 30, 2018. Spurred on by various administration initiatives to further open up the data behind agency decisions, the proposal focuses primarily on "dose response data and models" (essentially what effect a particular level of pollutant can have on a population) used in determining the "pivotal regulatory science" (the scientific data EPA uses determine costs and benefits) behind a potential rulemaking. The core proposed regulatory text (40 CFR 30.5) states that:

> *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. 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. 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.*

EPA's primary motivation in establishing this requirement was "to change agency culture and practices regarding data access so that the scientific justification for regulatory actions is truly available for validation and analysis." The primary concern of the proposal's opponents was that in setting this requirement certain studies and models could not feasibly meet this standard, and thus the findings therein would be excluded from EPA's regulatory decision-making. Enter the supplemental proposed rule.

SUPPLEMENTAL PROPOSED RULE

In an uncommon, but hardly novel, move, EPA published a supplemental proposed rule on the issue on March 18, 2020. This additional version was driven largely by "extensive comment" received on the first iteration. Broadly, this supplemental proposal makes the following changes to the original version:

- Expands the rulemaking's scope to include "data and models, not only dose-response data and dose-response models," and to EPA's development of "influential scientific

information" (defined as "scientific information the agency reasonably can determine will have or does have a clear and substantial impact on important public policies or private sector decisions") on top of purely regulatory decisions.

- Redefines a series of terms used in the proposed regulatory text in order to further clarify the rule's structure.
- Amends the aforementioned 40 CFR 30.5 section to allow some consideration of data that did not exactly meet the original proposal's standard but would still require EPA to give "greater consideration" to data that did meet such criteria.
- Changes the reasons for whether or not the EPA Administrator can exempt certain data or studies from these new requirements.

FINAL RULE

The final rule released this week makes further changes that pull back both the scope and restrictiveness of the rulemaking's requirements from the proposed versions. Crucially, it constrains the scope of 40 CFR 30.5 to "those studies that describe the quantitative relationship between the dose or exposure of a pollutant, contaminant, or substance and an effect," or in other words, studies or data that directly apply to a specific, measurable issue. This represents a smaller universe of studies and data since the proposed versions' criteria could have also encompassed other studies and data that indirectly support the more direct studies and data in question. Additionally, due to concerns raised in comments about EPA applying this retrospectively, the agency can only apply it to future considerations.

The final rule is maintaining – and expanding upon – the supplemental's allowance of consideration of materials that do not fully meet the criteria. Specifically, 40 CFR 30.5(d) provides EPA with a series of instructions on how to determine "the degree of consideration to afford pivotal science for which the dose response data are not available for independent validation." Another aspect that makes it more flexible than the proposed versions is the further widening of rationales an Administrator can cite in exempting certain materials from this process (seen under section 40 CFR 30.7).

THE RULE'S STATUS

EPA states that this is a "rulemaking of agency organization, procedure, or practice." This status affects its implementation and potential in important ways. First, given this designation, EPA claims the ability to skip the "effective date" window (typically 30 to 60 days, depending upon other designations) and it becomes effective upon publication on

January 6. Thus, for roughly two weeks in the final days of the Trump Administration, the EPA led by Administrator Wheeler would implement its provisions. Its implementation under a Biden Administration will likely be quite different.

This designation also confers it a stated exemption from Congressional Review Act (CRA) scrutiny. This is important since the timing of its final publication, the potential ensuing legislative and executive balance, and the rule's contentious nature all would otherwise make it a likely candidate for CRA scrutiny. Specifically, EPA notes: "This rule is exempt from the CRA because it is a rule of agency organization, procedure or practice that does not substantially affect the rights or obligations of non-agency parties." Although, as this 2019 Congressional Research Service report explains (see pg. 16-17), the true applicability of this exemption is still something of an open question given the incongruence between the relevant exemption clauses in the CRA and the Administrative Procedure Act.

CONCLUSION

The Trump Administration is down to its final days, but it was able to get this rule across the finish line. The level of public discourse surrounding this rulemaking highlights its contentiousness. That input, however, may have also been instrumental in further refining the rule's proposed requirements into a more flexible final framework. Despite this shift, it remains a hotly contested regulatory process issue and its exact fate in the coming weeks, months, and years under a new administration remains unclear.