

January 11, 2021

Rule to increase transparency in EPA's regulatory actions hits federal register

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EPA published the final rule (<https://www.epa.gov/newsreleases/epa-finalizes-rule-strengthening-transparency-pivotal-science-underlying-significant>), Transparency in Significant Regulatory Actions and Influential Scientific Information, in the January 6 Federal Register (<https://www.govinfo.gov/content/pkg/FR-2021-01-06/pdf/2020-29179.pdf>). The rule has been in development since 2018 and is meant to strengthen the transparency of EPA's significant regulatory actions and the data used to support those actions. AMWA had most recently submitted comments (<https://www.amwa.net/article/amwa-provides-epa-comment-transparency-regulatory-science-proposal-second-time>) to EPA in May of last year addressing the agency's (<https://www.amwa.net/article/supplemental-notice-seeks-provide-clarity-proposed-epa-rule-increase-transparency-regulatory>) supplemental notice (<https://www.amwa.net/article/supplemental-notice-seeks-provide-clarity-proposed-epa-rule-increase-transparency>) of proposed rulemaking, which was meant to clarify points from the initial 2018 proposal (<https://www.amwa.net/article/epa-seeks-public-comment-transparency-proposal>). AMWA's comments applauded and supported EPA's goal to strengthen transparency but emphasized the need to do so "in concert with the development of regulations, health advisories, and guidance that protect public health and the environment."

Within the final rule, EPA has narrowed the scope to apply only to dose-response data underlying pivotal science and will not apply retroactively to any previous regulatory actions. In place of the original proposal to exclude studies entirely if the underlying data could not be made available publicly, the agency has instead implemented a proposed alternative that gives greater consideration to studies that can make dose-response data publicly available but not exclude those studies which cannot completely. AMWA's 2020 comments supported

this approach stating, “this alternative approach will give EPA appropriate flexibility when implementing this new policy.”

The final rule maintains a provision that allows EPA’s administrator to make exemptions for studies based on considerations such as technological barriers rendering sharing of data infeasible or if making the relevant data available would conflict with laws governing privacy or confidentiality. The rule is effective immediately, and EPA intends to issue guidelines to ensure the rule is implemented consistently across programs.

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