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Excerpt: "The Environmental Protection Agency has finalized a rule to limit what research it can use to craft public health protections, a move opponents argue is aimed at crippling the agency's ability to more aggressively regulate the nation's air and water."



Andrew Wheeler. (photo: Al Drago/NYT)

## **EPA Finalizes Rule to Limit Science Behind Public Health Safeguards**

By Juliet Eilperin and Brady Dennis, The Washington Post

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***The Trump administration's 'transparency' rule requires researchers to disclose their raw data. Opponents argue that the goal is to exclude important research on human health.***

**T**he Environmental Protection Agency has finalized a rule to limit what research it can use to craft public health protections, a move opponents argue is aimed at crippling the agency's ability to more aggressively regulate the nation's air and water.

The "Strengthening Transparency in Pivotal Science Underlying Significant Regulatory Actions and Influential Scientific Information" rule, which the administration began pursuing early in President Trump's term, would require researchers to disclose the raw data involved in their public health studies before the agency could rely upon their conclusions. It will apply this new set of standards to "dose-response studies," which evaluate how much a person's exposure to a substance increases the risk of harm.

In an opinion piece posted Monday night in the Wall Street Journal, EPA Administrator Andrew Wheeler said the rule "will prioritize transparency and increase opportunities for the public to access the 'dose-response' data that underlie significant regulations and influential scientific information."

"Dose-response data explain the relationship between the amount of a chemical or a pollutant and its effect on human health and the environment — and are at the foundation of EPA's regulations," he continued. "If the American people are to be regulated by interpretation of these scientific studies, they deserve to scrutinize the data as part of the scientific process and American self-government."

Many of the nation's leading researchers and academic organizations, however, argue that the criteria will actually restrict the EPA from using some of the most consequential research on human subjects because it often includes confidential medical records and other proprietary data that cannot be released due to privacy concerns.

"The people pushing it are claiming it's in the interest of science, but the entire independent science world says it's not," said Chris Zarba, a former director of the EPA's Science Advisory Board who retired in

2018 after nearly four decades at the agency. “It sounds good on the surface. But this is a bold attempt to get science out of the way so special interests can do what they want.”

The new standards affect not just “significant regulatory actions,” according to the new rule, but also “influential scientific information” that the EPA shares with the public.

Details of the rule, which Wheeler has already signed but has yet to make public, were first reported by the New York Times on Monday evening.

Wheeler plans to announce the final rule at a virtual session hosted Tuesday by the Competitive Enterprise Institute, a think tank that advocates for fewer federal regulations and disputes the idea that climate change poses a major threat to the United States.

The rule reflects the Trump administration’s dogged push to lock in as many policies as possible before President-elect Joe Biden takes office on Jan. 20. Although the new administration will probably seek to overturn it, such an effort will take months, if not longer. The EPA administrator is allowed to waive the requirement on a case-by-case basis, but it is possible that outside groups could challenge those waivers in court.

Forcing researchers to disclose their raw data has for years been a top priority for conservative Republicans — including some now working in the EPA’s upper ranks. The new rule was modeled on a bill championed by former House Science Committee chairman Lamar Smith (R-Tex.). One of the panel’s former staffers, Richard Yamada, helped write an early version of the regulation while serving at the EPA. Conservatives have been particularly critical of two studies that have spurred increased regulation: a 1993 Harvard University project that linked air pollution to premature deaths and a Columbia University analysis of a widely used pesticide, chlorpyrifos, that suggested the chemical causes neurological damage in babies.

According to a document obtained under the Freedom of Information Act, Trump officials discussed how to block such research in a Jan. 25, 2018, briefing on the proposed rule. Referring to Harvard’s Six Cities study and another pollution study conducted by the American Cancer Society, the notes read, “The scientific community has identified major shortcomings in the methodologies and findings of these studies, all of

which could be addressed if EPA provided the underlying data for independent review.”

In the wake of protests from public health experts and congressional Democrats, the EPA revised the proposal so that it would not apply retroactively to past assessments of studies like the ones cited in the 2018 meeting.

But Environmental Defense Fund General Counsel Vickie Patton, whose group obtained the document, said in an email that it “reveals the Trump EPA is focused on attacking the peer-reviewed health science that has saved tens of thousands of lives each year from deadly air pollution and protected America’s children from pesticides.”

Andrew Rosenberg, who directs the Union of Concerned Scientists’ Center for Science and Democracy and regularly reviews scientific studies before they are published in academic journals, said that the agency’s emphasis on the need for raw data is misplaced.

“As a well-experienced peer reviewer, I very rarely scrutinize raw data,” he said. “Rather, I look at data collection and analysis methods, summary and other statistics and graphics and results and conclusions to determine the validity of a study and the strength of its scientific evidence.”

The EPA has not published estimates on how much it will cost to implement the rule and what effect it will have on public health. Because researchers are particularly reluctant to release individual medical records used in human studies, Rosenberg said, the rule disproportionately affects “epidemiological studies, which is ironic in the midst of a pandemic. Because these data can’t be made public, EPA will ignore epidemiological evidence of population-level effects of contaminants, pollution and other environmental threats.”

In his opinion piece, Wheeler said critics of the rule had distorted both its intent and its impact.

“This rule is not a stick for forcing scientists to choose between respecting the privacy and rights of their study participants and submitting their work for consideration,” he said. “It won’t categorically exclude any scientific work from EPA use. We don’t seek to limit anyone’s ability to conduct sound science.”

Thomas Sinks, who previously led the Office of the Science Advisor at the EPA and oversaw its rules on research involving human subjects, is

among numerous scientists who note that the EPA already has a robust scientific integrity policy and a long-standing peer-review process for any data upon which it relies.

“It is based on a conspiracy theory, which is that EPA practices secret science,” Sinks, who wrote a forceful rebuke of the new rule before his retirement last September, said of the effort. “But there’s no evidence EPA practices secret science. I’m unaware of an example where EPA hasn’t clearly stated what science it is using in its rulemaking.”

Sinks said he also worries that Tuesday’s final rule deepens the broader attack on science by the Trump administration, and that it could have a lasting impact that goes beyond any single regulation.

“I’m mostly concerned about the fact this rule and other actions like this rule are diminishing the efforts and the importance of science and scientists within the federal government,” he said. “That is a dangerous precedent.”