

**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 30**

**[EPA-HQ-OA-2018-0259; FRL-10024-32-ORD]**

**[RIN 2080-AA15]**

**Strengthening Transparency in Pivotal Science Underlying Significant Regulatory Actions and Influential Scientific Information; Implementation of Vacatur**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** The Environmental Protection Agency (EPA) is removing the regulatory provisions associated with the final rule Strengthening Transparency in Pivotal Science Underlying Significant Regulatory Actions and Influential Scientific Information. This action effectuates the vacatur of the final rule ordered by the United States District Court for the District of Montana. It is also responsive to the Executive order entitled “Protecting Public Health and the Environment and Restoring Science to Tackle the Climate Crisis,” signed on January 20, 2021.

**DATES:** This final rule is effective **[INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

**ADDRESSES:** The EPA has established a docket for this action under Docket ID No. **EPA-HQ-OA--2018-0259**. All documents in the docket are listed on the <http://www.regulations.gov> web site. Although listed in the index, some information may not be publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available electronically through <http://www.regulations.gov>.

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**SUPPLEMENTARY INFORMATION:**

**I. General Information**

*A. Does this action apply to me?*

This action removes requirements for how the EPA considers the availability of dose-response data underlying its pivotal science used in its significant regulatory actions and influential scientific information. The EPA recognizes any entity interested in submitting studies to EPA or how EPA evaluates and considers science in EPA regulations may be interested in this final rule.

*B. Why is EPA issuing this action?*

The EPA is removing the regulatory provisions associated with the final rule “Strengthening Transparency in Pivotal Science Underlying Significant Regulatory Actions and Influential Scientific Information” (86 FR 469, January 6, 2021), herein referred to as the “2021

final rule” (Ref. 1). This action effectuates the vacatur of the final rule ordered by the United States District Court for the District of Montana in *Environmental Defense Fund et al. v. EPA*, No. 21-cv-00003 (D. Mon. Feb. 1, 2021) (*EDF v. EPA*).

Section 553 of the Administrative Procedure Act, 5 U.S.C. 553(b)(B), provides that, when an agency for good cause finds that notice and public procedure are impracticable, unnecessary or contrary to the public interest, the agency may issue a rule without providing notice and an opportunity for public comment. EPA has determined that there is good cause under section 553(b)(B) to issue this final rule without prior proposal and opportunity for comment because this action undertakes the ministerial tasks of removing regulatory provisions vacated by the court in *EDF v. EPA* (Ref. 2).

As a matter of law, the order issued by the court in *EDF v. EPA* on February 1, 2021 vacated the 2021 final rule. It is, therefore, unnecessary to provide notice and an opportunity for comment on this action, which carries out the court’s orders by removing the 2021 final rule from 40 CFR part 30.

In addition, EPA finds that it has good cause to make these revisions immediately effective upon publication under section 553(d) of the Administrative Procedure Act, 5 U.S.C. 553(d). Section 553(d) provides that final rules shall not become effective until 30 days after publication in the Federal Register “except . . . as otherwise provided by the agency for good cause.” The purpose of this provision is to “give affected parties a reasonable time to adjust their behavior before the final rule takes effect.” *Omnipoint Corp. v. Fed. Comm’n Comm’n*, 78 F.3d 620, 630 (D.C. Cir. 1996); *see also United States v. Gavrilovic*, 551 F.2d 1099, 1104 (8th Cir. 1977) (quoting legislative history). Thus, in determining whether good cause exists to waive the 30-day delay, an agency should, “balance the necessity for immediate implementation against

principles of fundamental fairness which require that all affected persons be afforded a reasonable amount of time to prepare for the effective date of its ruling.” *Gavrilovic*, 551 F.2d at 1105. EPA has determined that there is good cause under section 553(d) for making this final rule effective immediately because this action merely implements the court order vacating the 2021 final rule. Delaying the effectiveness of this rule further would prolong the period of time between the change in the law (i.e., the court’s vacatur) and the corresponding update to the regulations, without providing the corresponding benefit underlying the 30-day delay. Minimizing that time period would reduce the possibility of confusion for the public. Accordingly, EPA is making this rule effective immediately upon publication.

*C. What is the Agency’s authority for taking this action?*

EPA promulgated the 2021 final rule pursuant to its housekeeping authority, which EPA gained through the Reorganization Plan No. 3 of 1970, 84 Stat. 2086 (July 9, 1970), which created the EPA. The Reorganization Plan established the Administrator as “head of the agency,” transferred functions and authorities of various agencies and Executive departments to the EPA, including the authority to promulgate regulations to carry out the transferred functions. including a housekeeping authority to promulgate procedural, but not substantive, rules. However, the rule was vacated and remanded in light of the court’s conclusion that the 2021 final rule constituted a substantive rule, and therefore the EPA lacked authorization to promulgate the 2021 final rule pursuant to its housekeeping authority. This action to implement the vacatur is being taken pursuant to the court’s order (Ref. 2).

## **II. Background of the Vacated 2021 Final Rule**

*A. Summary of the Key Requirements in the 2021 Final Rule*

The 2021 final rule established how the EPA would have considered the availability of

dose-response data underlying pivotal science used in its significant regulatory actions and influential scientific information (Ref. 1). When promulgating significant regulatory actions or developing influential scientific information for which the conclusions are driven by the quantitative relationship between the amount of dose or exposure to a pollutant, contaminant, or substance and an effect, the 2021 final rule would have required that the EPA give greater consideration to studies where the underlying dose-response data are available in a manner sufficient for independent validation. The 2021 final rule also would have required the EPA to identify and make publicly available the science that serves as the basis for informing a significant regulatory action at the proposed rule stage to the extent practicable; included additional requirements for the peer review of pivotal science; and provided criteria for the Administrator to exempt certain studies from the requirements of the rule.

*B. Litigation, Vacatur and Court Mandate*

On January 11, 2021 the plaintiffs Environmental Defense Fund and others (EDF) filed a complaint in the U.S. District Court for the District of Montana (Ref. 3). Among other allegations, EDF contended that the 2021 final rule was substantive and therefore unlawful to promulgate under the EPA's housekeeping authority, which only permits promulgation of procedural rules. The plaintiffs further argued that the EPA lacked good cause to make the rule effective immediately. On January 27, 2021, the court issued a partial summary judgment ruling that the 2021 final rule was substantive because it failed to provide the EPA with procedural direction but instead narrowly limited the agency's discretion to consider certain scientific research when conducting future rulemakings. The court reasoned that by determining how the Agency weighs particular scientific evidence, the 2021 final rule determined outcomes rather than process. The court further ruled that EPA did not have good cause to make the 2021 final

rule effective immediately and held that the effective date for the rule was 30 days after publication, or February 5, 2021 (Ref. 4). Based on the district court's conclusion that the final rule constituted a substantive rather than a procedural rule, EPA lacked authority to promulgate the final rule under its housekeeping authority. Given the court's decision, the EPA filed an unopposed motion to vacate and remand the rule (Ref. 5). On February 1, 2021, the court granted the motion vacating the 2021 final rule and remanding it to the EPA (Ref. 2). This action effectuates the court order vacating the 2021 final rule.

### **III. Effective Date**

This final rule will become effective upon publication in the Federal Register.

### **IV. References**

1. U.S. EPA. Strengthening Transparency in Pivotal Science Underlying Significant Regulatory Actions and Influential Scientific Information; Rule, 86 FR 469 (January 6, 2021) (FRL-10019-07-ORD), *available at* <https://www.federalregister.gov/documents/2021/01/06/2020-29179/strengthening-transparency-in-pivotal-science-underlying-significant-regulatory-actions-and>.
2. *EDF vs. EPA*, Case No. 4:21-cv-00003-BMM, United States District Court for the District of Montana, Order (February 1, 2021), *available at* [https://www.epa.gov/sites/production/files/2021-02/documents/vacatur\\_and\\_remand\\_final\\_order\\_case\\_421-cv-00003-bmm.pdf](https://www.epa.gov/sites/production/files/2021-02/documents/vacatur_and_remand_final_order_case_421-cv-00003-bmm.pdf).
3. *EDF vs. EPA*, Case No. 4:21-cv-00003-BMM, United States District Court for the District of Montana, Complaint (January 11, 2021).
4. *EDF vs. EPA*, Case No. 4:21-cv-00003-BMM, United States District Court for the District of Montana, Order on Partial Motion (January 27, 2021).

5. *EDF vs. EPA*, Case No. 4:21-cv-00003-BMM-JTJ, United States District Court for the District of Montana, Defendants’ Unopposed Motion for Vacatur and Remand (January 31, 2021).

## **V. Statutory and Executive Orders Reviews**

### *A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review*

This action is a significant regulatory action that was submitted to the Office of Management and Budget (OMB) for review. Any changes made in response to OMB recommendations have been documented in the docket. The EPA does not anticipate that this rulemaking will have an economic impact on regulated entities.

### *B. Paperwork Reduction Act (PRA)*

This action does not contain any information collection activities and therefore does not impose an information collection burden under the PRA.

### *C. Regulatory Flexibility Act (RFA)*

This action is not subject to the RFA. The RFA applies only to rules subject to notice and comment rulemaking requirements under the Administrative Procedure Act (APA), 5 U.S.C. 553, or any other statute. This rule is not subject to notice and comment requirements because the Agency has invoked the APA “good cause” exemption under 5 U.S.C. 553(b).

### *D. Unfunded Mandates Reform Act (UMRA)*

This action does not contain any unfunded mandate as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. The action imposes no enforceable duty on any state, local or tribal governments or the private sector.

### *E. Executive Order 13132: Federalism*

This action does not have federalism implications. It will not have substantial direct effects on the states, on the relationship between the National Government and the states, or on the distribution of power and responsibilities among the various levels of government.

*F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments*

This action does not have tribal implications as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this action.

*G. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks*

The EPA interprets Executive Order 13045 as applying only to those regulatory actions that concern environmental health or safety risks that the EPA has reason to believe may disproportionately affect children, per the definition of “covered regulatory action” in section 2–202 of the Executive order. This action is not subject to Executive Order 13045 because it does not concern an environmental health risk or safety risk.

*H. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution or Use*

This action is not a “significant energy action” within the meaning of Executive Order 13211. It is not likely to have a significant adverse effect on the supply, distribution or use of energy, and it has not otherwise been designated as a significant energy action by the Administrator of the Office of Information and Regulatory Affairs (OIRA).

*I. National Technology Transfer and Advancement Act (NTTAA)*

This rulemaking does not involve technical standards.

*J. Executive Order 12898: Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations*



The EPA believes that this action is not subject to Executive Order 12898 (59 FR 7629, February 16, 1994) because it does not establish an environmental health or safety standard.

*K. Congressional Review Act (CRA)*

This action is subject to the CRA, and the EPA will submit a rule report to each House of the Congress and to the Comptroller General of the United States. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

## **List of Subjects in 40 CFR Part 30**

Environmental protection, Administrative practice and procedure, Reporting and recordkeeping requirements.

Michael S. Regan, *Administrator*

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**PART 30 [REMOVED AND RESERVED]**

For the reasons set forth in the preamble and under the authority of the court order in Environmental Defense Fund et al. v. EPA, No. 21-cv-00003 (D. Mon. Feb. 1, 2021) (EDF v. EPA), the EPA removes and reserves 40 CFR part 30.