ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 30

[EPA-HQ-OA-2018-0259; FRL-XXXX-XX]

RIN 2080-AA14

Strengthening Transparency in Regulatory Science

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: This document proposes a regulation intended to strengthen the transparency of EPA regulatory science. The proposed regulation provides that when EPA develops regulations, including regulations for which the public is likely to bear the cost of compliance, with regard to those scientific studies that are pivotal to the action being taken, EPA should ensure that the data underlying those are publicly available in a manner sufficient for independent validation. In this notice, EPA solicits comment on this proposal and how it can best be promulgated and implemented in light of existing law and prior Federal policies that already require increasing public access to data and influential scientific information used to inform federal regulation.

DATES: Comments must be received on or before **[insert date 30 days after date of publication in the Federal Register]**.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–HQ–OA-2018-0259, at *https:// www.regulations.gov*. Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov*. EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a

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written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.*, on the web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *https://www.epa.gov/dockets/ commenting-epa-dockets.*

FOR FURTHER INFORMATION, CONTACT: Tom Sinks, Office of the Science Advisor, Environmental Protection Agency, 1200 Pennsylvania Avenue NW, Washington, DC 20460; (202) 564-0221; email address: *staff_osa@epa.gov*.

SUPPLEMENTARY INFORMATION:

Submitting CBI. Do not submit information that you consider to be CBI electronically through *https://www.regulations.gov* or email. Send or deliver information identified as CBI to only the following address using U.S Postal Service: U.S. Environmental Protection Agency, EPA Docket Center, EPA–HQ–OA-2018-0259, Mail Code 28221T, 1200 Pennsylvania Avenue, NW, Washington, DC 20460. For other methods of delivery, see https://www.epa.gov/dockets/where-send-comments-epa-dockets.

Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD-ROM that you mail to EPA, mark the outside of the disk or CD-ROM as CBI and then identify electronically within the disk or CD-ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that

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includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. If you submit a CD-ROM or disk that does not contain CBI, mark the outside of the disk or CD-ROM clearly that it does not contain CBI. Information marked as CBI will not be disclosed except in accordance with procedures set forth in 40 Code of Federal Regulations (CFR) part 2.

Organization of This Document. The following outline is provided to aid in locating information in this preamble.

I. General Information

A. Does this Action Apply to Me?

B. What action is the Agency taking?

C. What is the Agency's Authority for taking this action?

II. Background

III. Request for Comment

IV. Statutory and Executive Orders

I. General Information

A. Does this action apply to me?

This proposed regulation does not directly regulate any entity outside the federal government. However, any entity interested in EPA's regulations may be interested in this proposal. This proposal may be of particular interest to entities that conduct research and other scientific activity that is likely to be relevant to EPA's regulatory activity.

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B. What action is the agency taking?

This notice solicits information and comment from the public on a proposed regulation intended to strengthen the transparency of EPA regulatory science. The proposed regulation provides that, for the science pivotal to its significant regulatory actions, EPA will ensure that the data and models underlying the science is publicly available in a manner sufficient for validation and analysis. In this notice, EPA solicits comment on this proposal and how it can best be implemented in light of existing law and prior statements of policy that have called for increasing public access to data and influential scientific information used to inform federal regulation. EPA has not previously implemented these policies and guidance in a robust and consistent manner. This proposal will help ensure that EPA is pursuing its mission of protecting public health and the environment in a manner that the public can trust and understand.

C. What is the agency's authority for taking this action?

The Agency proposes to take this action under authority of the statutes it administers, including provisions providing general authority to promulgate regulations necessary to carry out the Agency's functions under these statutes and provisions specifically addressing the Agency's conducting of and reliance on scientific activity to inform those functions, including Clean Air Act sections 103, 301(a), 42 U.S.C. 7403, 7601(a); Clean Water Act sections 104, 501, 33 U.S.C. 1254, 1361; Safe Drinking Water Act sections 1442, 1450(a)(1), 42 U.S.C. 300j-1, 300j-9(a)(1); Resource Conservation and Recovery Act sections 2002(a)(1), 7009, 42 U.S.C. 6912(a)(1), 6979; Comprehensive Environmental Response, Compensation, and Liability Act (as delegated to the Administrator via Executive Order 12580) sections 115, 311, 42 U.S.C. 9616, 9660; Emergency Planning and Community Right-To-Know Act section 328, 42 U.S.C. 11048;

ED_002389_00000573-00004

Federal Insecticide, Fungicide, and Rodenticide Act sections 25(a)(1), 136r(a), 7 U.S.C. 136r(a), 136w; and Toxic Substances Control Act, as amended, section 10, 15 U.S.C. 2609. This action is also consistent with requirements in the Administrative Procedure Act to ensure public participation in the rulemaking process. As noted in Section III below, EPA solicits comment on whether additional or alternative sources of authority are appropriate bases for this proposed regulation.

II. Background

The best available science must serve as the foundation of EPA's regulatory actions.[1] Enhancing the transparency and validity of the scientific information relied upon by EPA strengthens the integrity of EPA's regulatory actions and its obligation to ensure the Agency is not arbitrary in its conclusions. By better informing the public, the Agency in enhancing the public's ability to understand and meaningfully participate in the regulatory process.[2] In applying the best available science to its regulatory decision-making, EPA must comply with federal transparency and data integrity laws, and must also ensure=that its decision-making is marked by independence, objectivity, transparency, clarity, and reproducibility. Although these standards are important in all scientific endeavors, they are of paramount importance when the government relies on science to inform its significant regulatory decisions that will affect the public. When EPA develops significant regulations using public resources, including regulations for which the public is likely to bear the cost of compliance, EPA should ensure that the data and models

[1] See Exec. Order No. 13563, 76 Fed. Reg. 3821 (Jan. 21, 2011). "Our regulatory system must protect public health, welfare, safety, and our environment while promoting economic growth, innovation, competitiveness, and job creation. It must be based on the best available science."

[2] See Memorandum for the Heads of Executive Department and Agencies on Scientific Integrity (Mar. 9, 2009). "If scientific and technological information is developed and used by the Federal Government, it should ordinarily be made available to the public. To the extent permitted by law, there should be transparency in the preparation, identification, and use of scientific and technological information in policymaking."

ED_002389_00000573-00005

underlying scientific studies that are pivotal to the regulatory action are available to the public. This proposed rule is designed to increase transparency in the preparation, identification, and use of science in policymaking.

This proposed rule is consistent with the principles underlying the Administrative Procedure Act and programmatic statutes that EPA administers to disclose to the public the bases for agency rules and to rationally execute and adequately explain agency actions.[3] This proposed rule is also consistent with Executive Orders 13777[4] and 13783,[5] and the focus on transparency in OMB's *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility and Integrity of Information Disseminated by Federal Agencies*[6] (the Guidelines) and OMB *Memorandum 13-13: Open Data Policy – Managing Information as an Asset.*[7] It builds upon prior EPA actions[8] in response to government-wide data access and sharing policies, as well as the experience of other

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[3] EPA has the authority to establish policies governing its reliance on science in the administration of its regulatory functions. Historically, EPA has not consistently observed the policies underlying this proposal, and courts have at times upheld EPA's use non-public data in support of its regulatory actions. *See Coalition of Battery Recyclers Ass'n v. EPA*, 604 F.3d 613, 623 (D.C. Cir. 2010); *American Trucking Ass'ns v. EPA*, 283 F.3d 355, 372 (D.C. Cir. 2002). EPA is proposing to exercise its discretionary authority to establish a policy that would preclude it from using such data in future regulatory actions.

[4] Exec. Order No. 13777, 82 Fed. Reg. 12285 (Mar. 1, 2017). Regulatory reform efforts shall attempt to identify "those regulations that rely in whole or in part on data, information, or methods that are not publicly available or that are insufficiently transparent to meet the standard for reproducibility."

[5] Exec. Order No. 13783, 82 Fed. Reg. 16093 (Mar. 31, 2017). "It is also the policy of the United States that necessary and appropriate environmental regulations comply with the law, are of greater benefit than cost, when permissible, achieve environmental improvements for the American people, and are developed through transparent processes that employ the best available peer-reviewed science and economics."

[6] February 22, 2002 (67 F.R 8453) *OMB's Guidelines Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information* (2002) https://www.federalregister.gov/documents/2002/02/22/R2-59/guidelines-for-ensuring-and-maximizing-the-quality-objectivity-utility-and-integrity-of-information.

[7] *Memorandum for the Heads of Executive Departments and Agencies on Open Data Policy—Managing Information as an Asset* (https://project-open-data.cio.gov/policy-memo/). "Specifically, this Memorandum requires agencies to collect or create information in a way that supports downstream information processing and dissemination activities. This includes using machine-readable and open formats, data standards, and common core and extensible metadata for all new information creation and collection efforts. It also includes agencies ensuring information stewardship through the use of open licenses and review of information for privacy, confidentiality, security, or other restrictions to release."

[8] Plan to Increase Access to Results of EPA-Funded Scientific Research; EPA Open Government Plan 4.0; Open Data Implementation Plan; EPA's Scientific Integrity Policy; Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency; ;

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federal agencies in this space.[9] In particular, this proposal applies concepts and lessons learned from its ongoing implementation of the 2016 Plan to Increase Access to Results of EPA-Funded Scientific Research to significant regulatory decisions. The proposed rule takes into consideration the policies or recommendations of third party organizations who advocated for open science.[10] These policies are informed by the policies recently adopted by some major scientific journals,[11] spurred in some part by the "replication crisis." [12]

Today, EPA is proposing to establish a clear policy for the transparency of the scientific information used for significant regulations: specifically, the dose response data and models that underlie what we are calling "pivotal regulatory science." "Pivotal regulatory science" is the studies, models, and analyses that drive the magnitude of the benefit-cost calculation, the level of a standard, or point-of-departure from which a reference value is calculated. In other words, they are critical to the calculation of a final regulatory standard or level, or to the quantified costs, benefits, risks and other impacts on which a final regulation is based.

With this notice, EPA is soliciting public comment on a proposed regulation designed to provide a mechanism to increase access to dose response data and models underlying pivotal regulatory

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[9] For example, see related policies from the National Science Foundation, National Institute of Science and Technology, the National Institutes of Health; and the US Census Bureau, which provides secure access to data from several agencies in an environment that protects against unauthorized disclosure (https://www.census.gov/fsrdc).

[10] These include policies and recommendations from: the Administrative Conference of the United States' Science in the Administrative Process Project; National Academies' reports on *Improving Access to and Confidentiality of Research Data*, *Expanding Access to Research Data*, and *Access to Research Data in the 21st Century*; the Health Effects Institute; Center for Open Science; members of the Risk Assessment Specialty Section of the Society of Toxicology, the Dose Response Section of the Society for Risk Analysis, and the International Society for Regulatory Toxicology and Pharmacology; and the Bipartisan Policy Center's Science for Policy Project.

[11] For example, see related policies from the *Proceedings of the National Academy of Sciences*, *PLOS ONE*, *Science*, and *Nature*.

[12] See: https://www.nature.com/articles/s41562-016-0021; http://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.0020124; http://science.sciencemag.org/content/343/6168/229.long; https://www.economist.com/news/leaders/21588069-scientific-research-has-changed-world-now-it-needs-change-itself-how-science-goes-wrong.; http://stm.sciencemag.org/content/8/341/341ps12.full

ED_002389_00000573-00007

science in a manner consistent with statutory requirements for protection of privacy and confidentiality of research participants, protection of proprietary data and confidential business information, and other compelling interests. The proposal takes comment on how to ensure that, over time, more of the data and models underlying the science that informs regulatory decisions (over and above the dose response data and models underlying "pivotal regulatory science") is available to the public for validation[13] in a manner that honors legal and ethical obligations to reduce the risks of unauthorized disclosure and re-identification. As such this proposed regulation is designed to change agency culture and practices regarding data access so that the scientific justification for regulatory actions is truly available for validation and analysis. Regulatory determinations based on science should describe and document any assumptions and methods used, and should address variability and uncertainty. Where available and appropriate, EPA will use peer-reviewed information, standardized test methods, consistent data evaluation procedures, and good laboratory practices to ensure transparent, understandable, and reproducible scientific assessments. EPA's regulatory science should be consistent with the Office of Management and Budget's *Final Information Quality Bulletin for Peer Review*.[14] Robust peer review plays a critical role in independently validating key findings and ensuring that the quality of published information meets the standards of the scientific and technical community.

In addition, this proposed regulation is designed to increase transparency of the assumptions underlying dose response models. As a case in point, there is growing empirical evidence of non-

[13] EPA has not consistently followed previous EPA policy (e.g, EPA's Scientific Integrity Guidance, referenced above) that encouraged the use of non-proprietary data and models.
[14] https://www.whitehouse.gov/wp-content/uploads/2017/11/2005-M-05-03-Issuance-of-OMBs-Final-Information-Quality-Bulletin-for-Peer-Review-December-16-2004.pdf

ED_002389_00000573-00008

linearity in the concentration-response function for specific pollutants and health effects. The use of default models, without consideration of alternatives or model uncertainty, can obscure the scientific justification for EPA actions. To be even more transparent about these complex relationships, EPA should give appropriate consideration to high quality studies that explore: a broad class of parametric concentration-response models with a robust set of potential confounding variables; nonparametric models that incorporate fewer assumptions; various threshold models across the exposure range; and spatial heterogeneity. EPA should also incorporate the concept of model uncertainty when needed as a default to optimize low dose risk estimation based on major competing models, including linear, threshold, and U-shaped, J-shaped, and bell-shaped models.

Across EPA programs, much of the science that informs regulatory actions is developed outside the Agency. It is the charge of regulators to ensure that key findings are valid and credible, as required by OMB's Guidelines[15] (which apply to "third party" information - e.g., non-government scientific research – if the agency use of that information provides the appearance of representing agency views). Using scientific information that can be independently validated will lead to better outcomes, and strengthen public confidence in the health and environmental protections underpinning EPA's regulatory actions.

EPA believes that concerns about access to confidential or private information can, in many cases, be addressed through the application of solutions commonly in use across some parts of

[15] February 22, 2002 (67 F.R 8453) *OMB's Guidelines Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information* (2002) https://www.federalregister.gov/documents/2002/02/22/R2-59/guidelines-for-ensuring-and-maximizing-the-quality-objectivity-utility-and-integrity-of-information

ED_002389_00000573-00009

the Federal government.[16] Nothing in the proposed rule compels the disclosure of any confidential or private information in a manner that violates applicable legal and ethical protections. Other federal agencies have developed tools and methods to de-identify private information for a variety of disciplines.[17] The National Academies have noted that simple data masking, coding, and de-identification techniques have been developed over the last half century and that "Nothing in the past suggests that increasing access to research data without damage to privacy and confidentiality rights is beyond scientific reach."[18] More recently, both the National Academies and the Bipartisan Commission on Evidence Based Policy[19] have discussed the challenges and opportunities for facilitating to secure access to confidential data for non-government analysts.

Considering the breadth of dose response data and models used in the development of significant EPA regulations, the requirements for availability may differ. These mechanisms may range from deposition in public data repositories, consistent with requirements for many scientific journals,[20] to, for certain types of information, controlled access in federal research data centers that facilitate secondary research use by the public.[21] EPA should collaborate with other federal agencies to identify strategies to protect confidential and private information in any circumstance in which it is making information publicly available. These strategies should be cost-effective

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[16] See examples from the U.S. Department of Health and Human Services, National Institute of Standards and Technology, U.S. Department of Education, and the U.S. Census Bureau.

[17] https://www.hhs.gov/hipaa/for-professionals/privacy/special-topics/de-identification/index.html.

[18] https://www.nap.edu/catalog/11434/expanding-access-to-research-data-reconciling-risks-and-opportunities.

[19] https://www.cep.gov/content/dam/cep/report/cep-final-report.pdf; https://www.nap.edu/catalog/24652/innovations-in-federal-statistics-combining-data-sources-while-protecting-privacy; https://www.nap.edu/catalog/24893/federal-statistics-multiple-data-sources-and-privacy-protection-next-steps.

[20] For example, see policies or recommendations of publishers Taylor & Francis, Elsevier, PLOS, and Springer Nature.

[21] For example: https://osp.od.nih.gov/scientific-sharing/requesting-access-to-controlled-access-data-maintained-in-nih-designated-data-repositories-e-g-dbgap/; https://www.census.gov/fsrdc.

ED_002389_00000573-00010

and may also include: requiring applications for access; restricting access to data for the purposes of replication, validation, and sensitivity evaluation; establishing physical controls on data storage; online training for researchers; and nondisclosure agreements.[22]

Implementation of this proposed rule will be consistent with the definition of "research data" in Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards, exemptions in P.L. 89-487, and other applicable federal laws.

This proposed regulation is intended to apply prospectively to final regulations that are determined to be "significant regulatory actions" pursuant to E.O. 12866. The Agency's offices should be guided by this policy to the maximum extent practicable during ongoing regulatory action, even where such research has already been generated, solicited, or obtained.

III. Request for Comment

EPA solicits comment on all aspects of the proposed regulation and the bases articulated for it above. Specifically, EPA believes that it has identified appropriate sources of statutory authority for this proposed regulation in Section I(c) above, and solicits public comment on whether additional or alternative sources of authority are appropriate bases for this proposed regulation.

EPA further believes that a generally applicable regulatory provision of the type proposed here is the appropriate vehicle to establish and implement the policies articulated in Section II above, in the interests of consistency, predictability, and transparency across the functions that EPA performs.

EPA solicits comment on whether alternative or additional regulatory or other policy vehicles are appropriate to establish and implement these policies, and whether further regulatory or other

[22]These recommendations are consistent with those of Lutter and Zorn (2016). https://www.mercatus.org/system/files/Mercatus-Lutter-Public-Access-Data-v3.pdf.we re

ED_002389_00000573-00011

policy vehicles at the programmatic or statutory level would be appropriate as alternative or additional steps the agency may take to further the policies articulated in Section II above. EPA solicits comment on the effects of this proposed rule on individual EPA programs, including whether certain activities are appropriate to be excepted or if other requirements would affect implementation. EPA also seeks comments on which criteria the Agency should use to base any exceptions, including whether case-by-case exceptions may be appropriate. Although the proposed regulatory text would impose requirements specifically on final regulations determined to be "significant regulatory actions" under E.O. 12866, EPA solicits comment on whether and to what extent these requirements, or other provisions and policies, should apply to other stages of the rulemaking process, including proposed rules, as well as to other types of agency actions and promulgations, such as guidance. EPA also solicits comment on whether a narrower scope of coverage would be appropriate, such as only final regulations that are determined to be "major" under the Congressional Review Act, or "economically significant" under EO 12866. EPA also requests comment on whether certain categories of regulations should be excluded from coverage, such as those that merely reaffirm an existing standard, or some other category. For instance, we request comment on whether the provisions of the proposed rule should apply to individual party adjudications, enforcement activities, or permit proceedings when EPA determines that these provisions are practical and appropriate and that the actions are scientifically or technically novel or likely to have precedent-setting influence on future actions. EPA seeks comment on whether the Agency should apply the provisions of the proposed rule to these actions or to specific types of actions within these categories. The Agency also seeks comment on whether other agency actions, beyond significant

ED_002389_00000573-00012

final regulatory actions under EO 12866, should be included, such as site-specific permitting actions or non-binding regulatory determinations.

EPA solicits comment on the definitions of "*pivotal regulatory science*," and "*dose response data and models*" and how to implement such definitions.

EPA also solicits comment on how to incorporate stronger data and model access requirements into the terms and conditions of cooperative agreements and grants. EPA solicits comments on how it can build upon other federal agencies' policies regarding grantee and cooperator requirements for data access and data sharing. EPA also solicits suggestions for a platform that would enable the Agency to implement the provisions of this proposal related to increasing public access to EPA-funded data. EPA also seeks comment on methodologies and technologies designed to provide protected access to identifiable and sensitive data, such as individual health data, and on commenters experience with the use of such methodologies and technologies and their strengths and limitations. Similarly, EPA seeks comment on how to balance appropriate protection for copyrighted or confidential business information, including where protected by law, with requirements for increased transparency of pivotal regulatory science. EPA also requests comment on whether there are other compelling interests besides privacy, confidentiality, national and homeland security that may require special consideration when data is being released.

EPA solicits comment on implementation of the proposed regulation, including which parts of the Agency should be responsible for carrying out these requirements. EPA seeks comment on the effective date of a rule as well as on whether the Agency should seek to phase-in the requirements for certain significant regulatory actions or seek to prioritize specific actions. For regulatory programs, like the National Ambient Air Quality Standards program, in which future

ED_002389_00000573-00013

significant regulatory actions may be based on the administrative record from previous reviews - particularly where the governing statute requires repeated review on a fixed, date-certain cycle - EPA seeks comment on the manner in which this proposed rule should apply to that previous record. EPA also solicits comments on whether and how the proposed rule should apply to dose response data and models underlying pivotal regulatory science if those data and models were developed prior to the effective date. In addition, EPA seeks comment on how the prospective or retrospective application of the provisions for dose response data and models or pivotal regulatory science could inadvertently introduce bias regarding the timeliness and quality of the scientific information available. EPA seeks comment on how to address a circumstance in which EPA has a statutory requirement to make a determination for which scientific information publicly available in a manner sufficient for independent validation does not exist. EPA also seeks comment on any additional implementation challenges not discussed in this notice that commenters may be aware of as well as suggestions for addressing them.

The proposed rule includes a provision allowing the Administrator to exempt significant regulatory decisions on a case-by-case basis if he or she determines that compliance is impracticable because it is not feasible to ensure that all dose response data and models underlying pivotal regulatory science are publicly available in a fashion that is consistent with law, protects privacy and confidentiality, and is sensitive to national and homeland security, or in instances where OMB's Information Quality Bulletin for Peer Review provides for an exemption (Section IX). The agency requests comment on whether these exemptions are appropriate, and on whether there are other situations in which specific significant regulatory actions, or specific categories of significant regulatory actions should be exempted.

ED_002389_00000573-00014

EPA also requests comment on whether the disclosure requirements applicable to dose response data and models in the proposed rule should be expanded to cover other types of data and information, such as for example economic and environmental impact data and models that are designed to predict the costs, benefits, market impacts and/or environmental effects of specific regulatory interventions on complex economic or environmental systems.

IV. 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.

EPA believes the benefits of this proposed rule justify the costs. The benefits of EPA ensuring that dose response data and models underlying pivotal regulatory science are publicly available in a manner sufficient for independent validation are that it will improve the data and scientific quality of the Agency's actions and facilitate expanded data sharing and exploration of key data sets; this is consistent with the conclusions of the National Academies[23] This action should be implemented in a cost-effective way and is consistent with recent activities of the scientific community and other federal agencies, which will help to lower costs of implementation. The proposed rule directs EPA to make all reasonable efforts to explore methodologies, technologies, and institutional arrangements for making dose response models and data underlying pivotal regulatory science used in significant regulatory decisions available to the public in a manner sufficient for independent validation, consistent with law and protection of privacy,

[23] https://www.nap.edu/catalog/11434/expanding-access-to-research-data-reconciling-risks-and-opportunities.

confidentiality, and national and homeland security. However, it does not compel the Agency to make that information available where it concludes after all such reasonable efforts that doing so in way that complies with the law and appropriate protections is not possible.

By limiting the proposed rule to pivotal regulatory science for final significant regulatory actions pursuant to EO 12866, the proposed rule ensures that this standard for transparency affects a smaller subset of regulations which are economically significant, create inconsistency for other federal agencies, alter budgetary impacts, or raise novel legal or policy issues. One recent analysis found that: "Improvements in reproducibility can be thought of as increasing the net benefits of regulation because they would avoid situations in which costs or benefits are wrongly estimated to occur or in which regulatory costs are imposed without corresponding benefits. …" They concluded that "an increase in existing net benefits from greater reproducibility, which, if it occurred, would cover the costs of obtaining the data and making the data available."[24]

B. Executive Order 13771: Reducing Regulations and Controlling Regulatory Costs

This action is not expected to be an Executive Order 13771 regulatory action because it relates to "agency organization, management or personnel."

C. 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.

D. Regulatory Flexibility Act (RFA)

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA. This action will not impose any requirements on small entities.

[24] https://www.mercatus.org/system/files/Mercatus-Lutter-Public-Access-Data-v3.pdf.

ED_002389_00000573-00016

E. 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.

F. 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.

G. 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.

H. 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.

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

This action is not a "significant energy action" because it is not likely to have a significant adverse effect on the supply, distribution or use of energy.

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J. National Technology Transfer and Advancement Act (NTTAA)

This rulemaking does not involve technical standards.

K. 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.

ED_002389_00000573-00018

List of Subjects in 40 CFR Part 30

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

Dated: APR 24 2018.

E. Scott Pruitt,

Administrator

For the reasons set forth in the preamble, EPA proposes to add 40 CFR part 30 as follows:

PART 30—Transparency in Regulatory Decisionmaking

1. Add part 30 to read as follows:

PART 30—Transparency in Regulatory Decisionmaking

Sec.

30.1 What is the purpose of this subpart?

30.2 What definitions apply to this subpart?

30.3 How do the provisions of this subpart apply?

30.4 What requirements apply to EPA's use of studies in taking final action?

30.5 What requirements apply to EPA's use of dose response data and models underlying pivotal regulatory science?

30.6 What additional requirements pertain to the use of dose response data and models underlying pivotal regulatory science?

30.7 What role does independent peer review play in this section?

30.8 How is EPA to account for cost under this subpart?

30.9 May the EPA Administrator grant exemptions to this subpart?

30.10 What other requirements apply under this subpart?

ED_002389_00000573-00020

Authority: Clean Air Act §§ 103, 301(a), 42 U.S.C. §§ 7403, 7601(a); Clean Water Act §§ 104, 501, 33 U.S.C. §§ 1254, 1361; Safe Drinking Water Act §§ 1442, 1450(a)(1), 42 U.S.C. §§ 300j-1, 300j-9(a)(1); Resource Conservation and Recovery Act §§ 2002(a)(1), 7009, 42 U.S.C. §§ 6912(a)(1), 6979; Comprehensive Environmental Response, Compensation, and Liability Act (as delegated to the Administrator via Executive Order 12580) §§ 115, 311, 42 U.S.C. §§ 9616, 9660; Emergency Planning and Community Right-To-Know Act § 328, 42 U.S.C. § 11048; Federal Insecticide, Fungicide, and Rodenticide Act §§ 25(a)(1), 136r(a), 7 U.S.C. §§ 136r(a), 136w; and Toxic Substances Control Act, as amended, § 10, 15 U.S.C. § 2609.

§30.1 What is the purpose of this subpart?

This subpart directs EPA to ensure that the regulatory science underlying its actions is publicly available in a manner sufficient for independent validation.

§30.2 What definitions apply to this subpart?

As used in this subpart, all terms not defined herein shall have the meaning given them in the Act or in subpart A; and the following terms shall have the specific meanings given them.

Dose response data and models means the data and models used to characterize the quantitative relationship between the amount of dose or exposure to a pollutant, contaminant, or substance and the magnitude of a predicted health or environmental impact. Such functions

ED_002389_00000573-00021

typically underlie pivotal regulatory science that drives the size of benefit-cost calculations, the level of a standard, and/or the points of departure from which reference values (reference doses or reference concentrations) are calculated.

Pivotal regulatory science means the specific scientific studies or analyses that drive the requirements and/or quantitative analysis of EPA final significant regulatory decisions.

Regulatory decisions mean final regulations determined to be "significant regulatory actions" by the Office of Management and Budget pursuant to Executive Order 12866.

Regulatory science means scientific information, including assessments, models, criteria documents, and regulatory impact analyses, that provide the basis for EPA final significant regulatory decisions.

Research data means "research data" as that term is defined in Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards.

§30.3 How do the provisions of this subpart apply?

The provisions of this subpart apply to *dose response data and models* underlying *pivotal regulatory science* that are used to justify significant *regulatory decisions* regardless of the source of funding or identity of the party conducting the regulatory science. The provisions of

ED_002389_00000573-00022

this section do not apply to physical objects (like laboratory samples), drafts, and preliminary analyses. Except where explicitly stated otherwise, the provisions of this subpart do not apply to any other type of agency action, including individual party adjudications, enforcement activities, or permit proceedings.

§30.4 What requirements apply to EPA's use of studies in taking final action?

EPA shall clearly identify all studies (or other regulatory science) relied upon when it takes any final agency action. EPA should make all such studies available to the public to the extent practicable.

§30.5 What requirements apply to EPA's use of dose response data and models underlying pivotal regulatory science?

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. This may include, for example:

ED_002389_00000573-00023

(a) Data (where necessary, data would be made available subject to access and use restrictions).

(b) Associated protocols necessary to understand, assess, and extend conclusions;

(c) Computer codes and models involved in the creation and analysis of such information;

(d) Recorded factual materials; and

(e) Detailed descriptions of how to access and use such information.

The provisions of this section apply to dose response data and models underlying pivotal regulatory science regardless of who funded or conducted the underlying data, models, or other regulatory science. The agency shall make all reasonable efforts to explore methodologies, technologies, and institutional arrangements for making such data available before it concludes that doing so in a manner consistent with law and protection of privacy, confidentiality, national and homeland security is not possible. Where data is controlled by third parties, EPA shall work with those parties to endeavor to make the data available in a manner that complies with this section.

§30.6 What additional requirements pertain to the use of dose response data and models underlying pivotal regulatory science?

EPA shall describe and document any assumptions and methods used, and should describe variability and uncertainty. EPA shall evaluate the appropriateness of using default

ED_002389_00000573-00024

assumptions, including assumptions of a linear, no-threshold dose response, on a case-by-case basis. EPA shall clearly explain the scientific basis for each model assumption used and present analyses showing the sensitivity of the modeled results to alternative assumptions. When available, EPA shall give explicit consideration to high quality studies that explore: a broad class of parametric dose-response or concentration-response models; a robust set of potential confounding variables; nonparametric models that incorporate fewer assumptions; various threshold models across the dose or exposure range; and models that investigate factors that might account for spatial heterogeneity.

§30.7 What role does independent peer review in this section?

EPA shall conduct independent peer review on all *pivotal regulatory science* used to justify *regulatory decisions,* consistent with the requirements of the OMB Final Information Quality Bulletin for Peer Review (70 FR 2664) and the exemptions described therein.

Because transparency in regulatory science includes addressing issues associated with assumptions used in models, EPA shall ask peer reviewers to articulate the strengths and weaknesses of EPA's justification for the assumptions applied and the implications of those assumptions for the results.

§30.8 How is EPA to account for cost under this subpart?

ED_002389_00000573-00025

EPA shall implement the provisions of this subpart in a manner that minimizes costs.

§30.9 May the EPA Administrator grant exemptions to this subpart?

Yes. The Administrator may grant an exemption to this subpart on a case-by-case basis if he or she determines that compliance is impracticable because:

(a) It is not feasible to ensure that all dose response data and models underlying pivotal regulatory science is publicly available in a manner sufficient for independent validation, in a fashion that is consistent with law, protects privacy, confidentiality, confidential business information, and is sensitive to national and homeland security; or

(b) It is not feasible to conduct independent peer review on all pivotal regulatory science used to justify regulatory decisions for reasons outlined in OMB Final Information Quality Bulletin for Peer Review (70 FR 2664), Section IX.

§30.10 What other requirements apply under this subpart?

EPA shall implement the provisions of this section consistent with the definition of "research data" in Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards, exemptions in P.L. 89-487, and other applicable federal laws.

ED_002389_00000573-00026

Where appropriate, data sharing agreements and state-of-the-art data-masking techniques may be employed to facilitate access to information.

ED_002389_00000573-00027