approach, or would be ineffective or unacceptable without a change. A comment is adverse and significant if:

(1) The comment opposes the rule and provides a reason sufficient to require a substantive response in a notice-and-comment process. For example, a substantive response is required when:

(a) The comment causes the NRC to reevaluate (or reconsider) its position or conduct additional analysis;

(b) The comment raises an issue serious enough to warrant a substantive response to clarify or complete the record; or

(c) The comment raises a relevant issue that was not previously addressed or considered by the NRC.

(2) The comment proposes a change or an addition to the rule, and it is apparent that the rule would be ineffective or unacceptable without incorporation of the change or addition.

(3) The comment causes the NRC to make a change (other than editorial) to the rule.

For procedural information and the regulatory analysis, see the direct final rule published in the Rules and Regulations section of this issue of the **Federal Register**.

III. Background

The regulations in part 34 of title 10 of the *Code of Federal Regulations* (10 CFR), ''Licenses for Industrial Radiography and Radiation Safety Requirements for Industrial Radiographic Operations''; 10 CFR part 36, ''Licenses and Radiation Safety Requirements for Irradiators''; and 10 CFR part 39, ''Licenses and Radiation Safety Requirements for Well Logging,'' require the use of personnel dosimetry that is processed and evaluated by an accredited National Voluntary Laboratory Accreditation Program (NVLAP) processor. These regulations restrict the types of personnel dosimeters that can be used and prohibit the use of newer dosimetry technologies that do not require processing by an accredited NVLAP facility.

On July 14, 2016, the NRC received a petition for rulemaking (PRM) from the American Society for Nondestructive Testing and the Nondestructive Testing Management Association (the petitioners) (ADAMS Accession No. ML16228A045). The petition was docketed by the NRC on August 12, 2016, and assigned Docket No. PRM–34–7. The NRC published a notice of docketing of PRM–34–7 in the **Federal Register** (81 FR 78732) on November 9, 2016. The petitioners requested that the NRC amend its regulations and associated guidance to authorize the use of improved individual monitoring devices for industrial radiographic personnel. Specifically, the petitioners requested that the NRC amend its regulations to authorize the use of digital output personnel dosimeters to satisfy the personnel dosimetry requirements in § 34.47(a). The petitioners interchangeably used the terms ''improved individual monitoring devices,'' ''electronic personnel monitoring dosimeters,'' ''electronic dosimeters,'' and ''digital personnel dosimeters'' to describe digital output personnel dosimetry. In this proposed rule, the NRC uses the term ''digital output personnel dosimetry'' in place of these terms. A digital output personnel dosimeter is a specific type of personnel dosimetry that currently cannot be used to meet the requirements in 10 CFR parts 34, 36, and 39 to demonstrate compliance with the occupational dose limits in § 20.1201. The NRC published a notice of docketing of PRM–34–7 in the **Federal Register** (81 FR 78732) on November 9, 2016.

On February 11, 2019, the NRC published a document in the **Federal Register** (84 FR 3116) informing the public that it would consider PRM–34–7 in the rulemaking process. In the **Federal Register** notice, the NRC accepted the petitioners' request that the NRC amend its regulations to authorize the use of digital output personnel dosimeters for industrial radiographic personnel and expanded the scope of the rulemaking to include the use of digital output personnel dosimeters in irradiator and well logging operations.

IV. Plain Writing

The Plain Writing Act of 2010 (Pub. L. 111–274) requires Federal agencies to write documents in a clear, concise, well-organized manner. The NRC has written this document to be consistent with the Plain Writing Act as well as the Presidential Memorandum, ''Plain Language in Government Writing,'' published June 10, 1998 (63 FR 31885). The NRC requests comment on the proposed rule with respect to clarity and effectiveness of the language used.

V. Paperwork Reduction Act

This proposed rule does not contain any new or amended collections of information subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). Existing collections of information were approved by the Office of Management and Budget, approval numbers 3150–0007, 3150–0130, and 3150–0158.

Public Protection Notification

The NRC may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the document requesting or requiring the collection displays a currently valid OMB control number.

List of Subjects

10 CFR Part 34

Criminal penalties, Manpower training programs, Occupational safety and health, Packaging and containers, Penalties, Radiation protection, Radiography, Reporting and recordkeeping requirements, Scientific equipment, Security measures, X-rays.

10 CFR Part 36

Byproduct material, Criminal penalties, Nuclear energy, Nuclear materials, Radiation protection, Reporting and recordkeeping requirements, Scientific equipment, Security measures.

10 CFR Part 39

Byproduct material, Criminal penalties, Labeling, Nuclear energy, Nuclear material, Occupational safety and health, Oil and gas exploration—well logging, Penalties, Radiation protection, Reporting and recordkeeping requirements, Scientific equipment, Security measures, Source material, Special nuclear material.

Dated at Rockville, Maryland, this 3rd day of March, 2020.

For the Nuclear Regulatory Commission.

Margaret M. Doane,

Executive Director for Operations.

[FR Doc. 2020–05296 Filed 3–17–20; 8:45 am]

BILLING CODE 7590–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 30

[EPA–HQ–OA–2018–0259; FRL–10004–72–ORD]

RIN 2080–AA14

Strengthening Transparency in Regulatory Science

AGENCY: Environmental Protection Agency (EPA).

ACTION: Supplemental notice of proposed rulemaking.

SUMMARY: This supplemental notice of proposed rulemaking (SNPRM) includes clarifications, modifications and additions to certain provisions in the Strengthening Transparency in Regulatory Science Proposed

Rulemaking (''2018 proposed rulemaking,'' Ref. 1), published on April 30, 2018. This SNPRM proposes that the scope of the rulemaking apply to influential scientific information as well as significant regulatory decisions. This notice proposes definitions and clarifies that the proposed rulemaking applies to data and models underlying both pivotal science and pivotal regulatory science. In this SNPRM, EPA is also proposing a modified approach to the public availability provisions for data and models that would underly significant regulatory decisions and an alternate approach. Finally, EPA is taking comment on whether to use its housekeeping authority independently or in conjunction with appropriate environmental statutory provisions as authority for taking this action.

DATES: Comments must be received on or before April 17, 2020.

ADDRESSES: You may send comments, identified by Docket ID No. EPA–HQ–OA–2018–0259, by any of the following methods:

Federal eRulemaking Portal: https://www.regulations.gov/ (our preferred method). Follow the online instructions for submitting comments.

Mail: U.S. Environmental Protection Agency, EPA Docket Center, Office of Research and Development Docket, Mail Code 28221T, 1200 Pennsylvania Avenue NW, Washington, DC 20460.

Hand Delivery/Courier: EPA Docket Center, WJC West Building, Room 3334, 1301 Constitution Avenue NW, Washington, DC 20004. The Docket Center's hours of operations are 8:30 a.m.—4:30 p.m., Monday—Friday (except Federal Holidays).

Instructions: All submissions received must include the Docket ID No. for this rulemaking. Comments received may be posted without change to *https://www.regulations.gov/,* including any personal information provided.

FOR FURTHER INFORMATION CONTACT: Cheryl A. Hawkins, Office of Science Advisor, Policy and Engagement (8104R), Environmental Protection Agency, 1200 Pennsylvania Ave NW, Washington, DC 20460; telephone number: (202) 564–7307; email address: *osp_staff@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Executive Summary

A. Does this action apply to me?

This SNPRM does not regulate any entity outside the Federal Government. Rather, the proposed requirements would modify the EPA's internal procedures regarding the transparency of science underlying regulatory decisions. However, the Agency recognizes that any entity interested in EPA's regulations may be interested in this proposal. For example, this proposal may be of particular interest to entities that conduct research or another scientific activity that is likely to be relevant to EPA's regulatory activity.

B. What is the Agency's authority for taking this action?

On April 30, 2018, in the **Federal Register** at 83 FR 18768 EPA published the Strengthening Transparency in Regulatory Science Proposed Rulemaking (''2018 proposed rulemaking,'' Ref. 1). The 2018 proposed rulemaking cites as authority several environmental statutes that EPA administers: The Clean Air Act; the Clean Water Act; the Safe Drinking Water Act; the Resource Conservation and Recovery Act; the Comprehensive Environmental Response, Compensation, and Liability Act; the Federal Insecticide, Fungicide, and Rodenticide Act; the Emergency Planning and Community Right-To-Know Act and the Toxic Substances Control Act. Subsequently, in the **Federal Register** at 83 FR 24255, May 25, 2018, EPA published a document extending the comment period and announcing a public hearing on the 2018 proposed rulemaking to be held on July 18, 2018 (Ref. 2). That document identified 5 U.S.C. 301 as a source of authority in addition to those statutes cited in the 2018 proposed rulemaking. With respect to the authorities cited in the 2018 proposal, EPA is clarifying that the citation to the Resource Conservation and Recovery Act (''RCRA'') section 7009, 42 U.S.C. 6979, should be to RCRA section 8001, 42 U.S.C. 6981; the citation to the Comprehensive Environmental Response, Compensation, and Liability Act (''CERCLA'') section 116, 42 U.S.C. 9616, should be to CERCLA section 115, 42 U.S.C. 9615; and including the Clean Water Act section 501, 33 U.S.C. 1361.

EPA is authorized to promulgate this regulation under its housekeeping authority. The Federal Housekeeping Statute provides that ''[t]he head of an Executive department or military department may prescribe regulations for the government of his department, the conduct of its employees, the distribution and performance of its business, and the custody, use, and preservation of its records, papers, and property.'' 5 U.S.C. 301. As the Supreme Court discussed in *Chrysler Corp* v. *Brown,* the intended purpose of section 301 was to grant early Executive departments the authority ''to govern internal departmental affairs.'' [1] As the Supreme Court further notes, section 301 authorizes ''what the [Administrative Procedure Act] terms 'rules of agency organization, procedure or practice' as opposed to substantive rules.'' [2]

EPA is not one of the 15 ''Executive Departments'' listed at 5 U.S.C. 101. However, EPA gained housekeeping authority through the Reorganization Plan No. 3 of 1970, 84 Stat. 2086 (July 9, 1970). The Reorganization Plan created EPA, established the Administrator as ''head of the agency'' and transferred functions and authorities of various agencies and Executive departments to EPA.

Section 2(a)(1)–(8) of the Reorganization Plan transferred to EPA functions previously vested in several agencies and executive departments including the Departments of Interior and Agriculture. Section 2(a)(9) also transferred so much of the functions of the transferor officers and agencies ''as is incidental to or necessary for the performance by or under the Administrator of the functions transferred.''

The Office of Legal Counsel has opined that the Reorganization Plan ''convey[s] to the [EPA] Administrator all of the housekeeping authority available to other department heads under section 301'' and demonstrates that ''Congress has vested the Administrator with the authority to run EPA, to exercise its functions, and to issue regulations incidental to the performance of those functions.'' [3]

Courts have considered EPA to be an agency with section 301 housekeeping authority. The U.S. Court of Appeals for the Second Circuit, in *EPA* v. *General Elec. Co.,* 197 F.3d 592, 595 (2d Cir. 1999), found that ''the Federal Housekeeping Statute, 5 U.S.C. 301, authorizes government agencies such as the EPA to adopt regulations regarding 'the custody, use, and preservation of [agency] records, papers, and property.' '' The Fourth Circuit Court of Appeals, in *Boron Oil Co.* v. *Downie,* 873 F.2d 67, 69 (4th Cir. 1989), held that the district court exceeded its jurisdiction where it compelled testimony contrary to duly promulgated EPA regulations which EPA argued were authorized by section 301.

EPA's housekeeping authority was established by the Reorganization Plan.

[1] *Chrysler Corp.* v. *Brown,* 441 U.S. 281, 309 (1979).

[2] *Id.* at 310.

[3] Authority of EPA to Hold Employees Liable for Negligent Loss, Damage, or Destruction of Government Personal Property, 32 O.L.C. 79, 2008 WL 4422366 at *4 (May 28, 2008) (''OLC Opinion'').

As indicated by the case law and the OLC Opinion, it has long been recognized that EPA has been granted full section 301 or equivalent authority. Therefore, EPA has ample authority to promulgate regulations that govern internal agency procedures.

The 2018 proposed rulemaking, as supplemented by this SNPRM and this accompanying preamble, describes how EPA will handle studies when data and models underlying science that is pivotal to EPA's significant regulatory decisions or influential scientific information are or are not publicly available in a manner sufficient for independent validation and analysis. The rule would not regulate the conduct or determine the rights of any entity outside the federal government.[4] Rather, it exclusively pertains to the internal practices of the EPA.

Finally, EPA in the 2018 proposed rulemaking, as supplemented by this SNPRM and this accompanying preamble, does not propose to interpret provisions of a particular statute or statutes that it administers. Instead, in this action, EPA proposes a rule of agency procedure to establish an agency wide approach to handling studies when the data and models underlying EPA's significant regulatory decisions and influential scientific information are publicly available and when those data and models are not publicly available. Therefore, this is a proposed internal rule of agency procedure.

This internal agency procedure is intended to be consistent with the statutes that EPA administers and EPA plans to implement this procedural rulemaking in accordance with all applicable statutory and regulatory requirements. Indeed, as discussed in this SNPRM, EPA is also proposing options that would allow EPA to consider studies even if the underlying data and models are not publicly available. [See Section IV.] The Agency seeks comment on whether this approach may improve consistency between this proposed rulemaking and certain provisions of those statutes that refer to standards for data availability. Nonetheless, in the event the procedures outlined in the proposed rulemaking conflict with the statutes that EPA administers, or their implementing regulations, the statutes and regulations will control. Moreover, EPA is considering how to proceed, apart from this supplemental proposal, to establish regulations interpreting provisions of, and/or exercising substantive rulemaking authority delegated to it by programmatic statutes, to include one or more of those statutes cited as authority in the 2018 proposed rulemaking as clarified in this SNPRM.

Although this is a rule of internal agency procedure and EPA does not propose to interpret provisions of a particular statute or statutes that it administers, EPA is taking comment on whether to use its housekeeping authority independently as authority or in conjunction with the environmental statutory provisions cited as authority in the 2018 proposed rulemaking (as clarified in this SNPRM). The Agency continues to consider whether it is appropriate to rely on its authority in the above-reference environmental statutory provisions (potentially in conjunction with its housekeeping authority). The Agency will consider comments on this issue submitted in response to the 2018 proposal and in response to this SNPRM.

C. What action is the Agency taking?

EPA is issuing this SNPRM to clarify, modify and supplement certain provisions included in the 2018 proposed rulemaking in response to some of the public comments received on the 2018 proposed rulemaking (83 FR 18768), as well as to ensure consistency with the April 2019 release of the White House's Office of Management and Budget (OMB) Memorandum to the Heads of Executive Departments and Agencies entitled Implementation of the Information Quality Act (OMB M–19–15, Ref. 3). This memorandum is directly relevant to several of the provisions of the 2018 proposed rulemaking because it updates implementation of OMB's 2002 Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies to, among other things, reflect recent innovations and policies surrounding information access.

First, EPA is modifying the regulatory text initially proposed in the 2018 proposed rulemaking at 40 CFR 30.3, 30.5, 30.6 and 30.9 so that these provisions would apply to data and models, not only dose-response data and dose-response models. In addition, EPA is clarifying that the use of the terms ''model assumptions'' and ''models'' in the proposed regulatory text at 40 CFR 30.6 apply to the assumptions that drive the model's analytic results. EPA has modified the regulatory text at 40 CFR 30.6 to reflect this clarification. This approach is consistent with OMB M–19–15 (Ref. 3), which highlights the need to characterize the sensitivity of an agency's conclusions to analytic assumptions.

Second, EPA is proposing to expand the scope of this rulemaking to apply to influential scientific information[5] [6] as well as significant regulatory actions. EPA is proposing to add definitions for ''influential scientific information'' and ''pivotal science'' at 40 CFR 30.2 that will pertain to the science underlying influential scientific information, which are not regulatory, and is making conforming changes to proposed 40 CFR 30.3, 30.5, 30.6 and 30.7. EPA is retaining the definition of ''pivotal regulatory science'' from the 2018 proposed rulemaking regulatory text.

Third, EPA is modifying, deleting and proposing new regulatory text in addition to proposing definitions for ''influential scientific information'' and ''pivotal science'' at proposed 40 CFR 30.2. EPA is deleting the first paragraph of the 2018 proposed rulemaking regulatory text at 40 CFR 30.2. EPA is deleting the definition of ''research data'' at 40 CFR 30.2. EPA is proposing definitions for the terms ''Capable of being substantially reproduced'', ''Data'', ''Independent validation'', ''Influential scientific information,'' ''Model'', ''Pivotal science'', ''Publicly available'' and ''Reanalyze.'' These revisions are intended to provide clarity on key terminology used in the regulatory text in the 2018 proposed rulemaking as well as in this supplemental proposal.

Fourth, EPA is deleting the 2018 proposed regulatory text at 40 CFR 30.10. This change is being made to be consistent with the deletion of ''research data'' in 40 CFR 30.2 because 40 CFR 30.10 would have required EPA to implement this rulemaking to be consistent with the definition of ''research data.'' With the deletion of

[4] *See also United States* v. *Manafort,* 312 F. Supp. 3d 60, 75 (D.D.C. 2018) (explaining that the Department of Justice ''was not at all ambiguous about what it was doing when it promulgated the Special Counsel Regulations [under the authority of 5 U.S.C. 301], and it emphasized that it was not creating a substantive rule.'').

[5] The term ''influential scientific information'' means 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 (OMB M–05–03). A ''highly influential scientific assessment'' is a subset of influential scientific information and refers to ''an evaluation of a body of scientific or technical knowledge that typically synthesizes multiple factual inputs, data, models, assumptions, and/or applies best professional judgment to bridge uncertainties in the available information'' and that the dissemination of such assessment could have ''a potential impact of more than $500 million in any one year on either the public or private sector or that the dissemination is novel, controversial, or precedent-setting, or has significant interagency interest'' (OMB M–05–03).

[6] See EPA's Peer Review Agenda at *https://cfpub.epa.gov/si/si_public_pr_agenda.cfm.*

''research data'' from proposed 40 CFR 30.2, proposed 40 CFR 30.10 is no longer needed.

Fifth, EPA is proposing a modified version of the regulatory text at 40 CFR 30.5 from that proposed in the 2018 proposed rulemaking. Under this new approach to proposed 40 CFR 30.5, when promulgating significant regulatory decisions or finalizing influential scientific information, the Agency will only use pivotal regulatory science and/or pivotal science if the data and models are available in a manner sufficient for independent validation. This includes studies with data and models that are publicly available as well as studies with restricted data and models (*i.e.,* those that include confidential business information (CBI), proprietary data, or Personally Identifiable Information (PII) that cannot be sufficiently de-identified to protect the data subjects) if there is tiered access to these data and models in a manner sufficient for independent validation. Tiered access includes the appropriate techniques used to reduce the risk of re-identification and, therefore, mitigate certain disclosure privacy risks associated with providing such access.

As an alternative, EPA is proposing that under proposed 40 CFR 30.5, when promulgating significant regulatory decisions or finalizing influential scientific information, other things being equal, the Agency will give greater consideration to studies where the underlying data and models are available in a manner sufficient for independent validation either because they are publicly available or because they are available through tiered access when the data includes CBI, proprietary data, or PII that cannot be sufficiently de-identified to protect the data subjects. The Agency will identify those studies that are given greater consideration and will provide a short description of why greater consideration was given. As discussed later in the preamble, such approaches to increasing access to data and models can often allow stakeholders to reanalyze the data and models and explore the sensitivity of the conclusions to alternative assumptions while accessing only the data and aspects of the models that they need. This proposal would apply to reviews of data, models, and studies at the time a rule is developed or influential scientific information is finalized, regardless of when the data and models were generated. See Section IV of this preamble for a description of these proposals.

Sixth, EPA is modifying 40 CFR 30.9 to describe the factors the Administrator would consider in determining whether to grant an exemption to the proposed public availability requirements for using data and models in significant regulatory decisions and influential scientific information.

Seventh, the EPA is proposing the option of using its housekeeping authority independently as authority for taking this action or in conjunction with the environmental statutory provisions cited as authority in the 2018 proposed rulemaking (as clarified in this supplemental proposal). The Agency continues to consider whether it is appropriate to rely on its authority in the above-referenced environmental statutory provisions (potentially in conjunction with its housekeeping authority). The Agency will consider comments on this issue submitted in response to the 2018 proposal and in response to this SNPRM. Section 301 authority as transferred to EPA in Reorganization Plan No. 3 of 1970 provides appropriate authority for EPA to promulgate regulations that govern internal agency procedures. This action establishes internal agency procedures governing how EPA employees will handle studies when the data and models underlying science that is pivotal to EPA's significant regulatory decisions and/or influential scientific information are or are not publicly available.

The 2018 proposed rulemaking solicited comment on all aspects of the proposed rulemaking. This SNPRM solicits comment only on the changes and additions to the proposed regulatory text discussed in this supplemental document. Comments submitted in response to this supplemental document that address aspects of the 2018 proposed rulemaking that are not addressed, altered, or replaced by this SNPRM will be deemed outside the scope of this supplemental action.

D. Why is the Agency taking this action?

EPA received extensive comment on the 2018 proposed rulemaking regarding the clarity of certain aspects of the proposed rulemaking and the challenges in making all dose-response data and models publicly available. The intent of this supplemental proposal SNPRM is to address certain concerns raised about the clarity of the 2018 proposed rulemaking; to clarify consistency with OMB M–19–15, OMB M–05–03 (Final Information Quality Bulletin for Peer-Review, Ref. 4), and Executive Order 13891 (Ref. 5); to propose an alternate 40 CFR 30.5 provision for availability of data and models underlying pivotal regulatory science and pivotal science, and to propose relying on 5 U.S.C. 301 independently or in conjunction with the environmental statutory provisions cited as authority in the 2018 proposed rulemaking (as clarified in this SNPRM). The Agency continues to consider whether it is appropriate to rely on its authority in the above-reference environmental statutory provisions (potentially in conjunction with its housekeeping authority). The Agency will consider comments on this issue submitted in response to the 2018 proposal rulemaking and in response to this SNPRM.

II. Applicability to Data and Models

As identified by some public commenters, the 2018 proposed rulemaking did not put its discussion of increasing access to the data and models underlying pivotal regulatory science into the context of the broader approach that EPA uses to evaluate the entire body of scientific literature—that is, before it identifies candidates for ''pivotal regulatory science.'' Under this regulation EPA would continue to use standard processes for identifying, evaluating, and reviewing available data, models, and studies. When the Agency has potentially identified multiple key studies or models of similar quality that could drive its subsequent decisions, the Agency will investigate the availability of the underlying data. If, for example, multiple high-quality studies exist but only two studies have data and models that are available for independent validation and reanalysis, EPA would only include those two studies as pivotal regulatory science and/or pivotal science in accordance with the 2018 proposed rulemaking. However, under the alternative approach in this supplemental proposal, EPA would consider using all available high-quality studies but give greater consideration to those two studies with data available for independent validation.

As highlighted in some public comments, the terms ''dose-response data and models,'' ''dose-response models,'' ''models'' and ''model assumptions'' are not used consistently throughout the regulatory text of the 2018 proposed rulemaking. For example, some parts of the regulatory text appear to limit applicability of certain provisions to only dose-response models.[7] In others, the requirements would apply more broadly. EPA is now proposing a broader applicability. Transparency of EPA's science should not be limited to dose-response data and dose-response models, because other

[7] See § 30.6.

types of data and models will also drive the requirements and/or quantitative analysis of EPA final significant regulatory decisions and influential scientific information.

EPA is modifying the proposed regulatory text at 40 CFR 30.3, 30.5, 30.6 and 30.9 by deleting the term ''dose-response,'' except in one instance. In proposed 40 CFR 30.6, EPA is not deleting ''dose response'' from the sentence specific to parametric dose-response models. EPA is also removing ''including assumptions of a linear, no-threshold dose response'' from 40 CFR 30.6, because this could imply that the regulation is specific to those particular assumptions. This is not the intent of proposed 40 CFR 30.6.

Consistent with this broader approach to transparency, the proposed requirements of this rule would apply broadly to data and models underlying pivotal regulatory science and pivotal science which support significant regulatory decisions and influential scientific information, respectively, rather than simply to dose-response data and models. Some, but not the only, examples of information that would be considered to be data and models, in addition to dose-response data and dose-response models, include environmental fate studies, bioaccumulation data, water-solubility studies, environmental fate models, engineering models, data on environmental releases, exposure estimates, quantitative structure activity relationship data, and environmental studies. The proposed definitions of ''data'' and ''models'' are discussed more fully in Section III.B of this preamble.

In addition, EPA is clarifying that the use of the terms ''model assumptions'' and ''models'' in the proposed regulatory text at 40 CFR 30.6 apply to the assumptions that drive the model's analytic results, not to each model assumption used in the model. EPA has modified the regulatory text at 40 CFR 30.6 to reflect this clarification.

EPA requests comment on the applicability of proposed 40 CFR 30.3, 30.5, 30.6 and 30.9 to data and models.

III. Definitions

A. ''Reanalyze'' and ''Independent Validation''

To improve the clarity of the proposed requirements, EPA is proposing definitions for certain terms.

In the 2018 proposed rulemaking, EPA used the terms ''replicate'' and ''reproducible'' and related terms. ''Replicate'' is used in the proposed regulatory text at 40 CFR 30.5. That section reads, in pertinent part, ''[I]nformation 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 . . .'' ''Replication'' and ''reproducibility'' are both used in the 2018 proposed rulemaking preamble though neither is defined. Neither ''reproducibility'' nor its cognates are used in the regulatory text. ''Replicate'' was used but not defined in the regulatory text and its meaning was not discussed in the preamble.

Commenters contended that EPA was not clear about what it meant by the term ''replicate'' and that EPA appears to have conflated the term with ''reproducible.'' Commenters interpreted the term ''replicate'' in several different ways. For example, some commenters contended that EPA used the term ''replicate'' but actually meant ''reanalyze.'' EPA finds that these comments have merit and has determined that the intent of the term ''replicate'' should be clarified by establishing a regulatory definition.

EPA has considered the definitions in the National Academy of Sciences (NAS) ''*Principles and Obstacles for Sharing Data from Environmental Health Research*.'' (Ref. 6, NAS Workshop Report), Pellizzari, et al. ''*Reproducibility: A Primer on Semantics and Implications for Research*'' (Ref. 7), and Goodman, et al. ''*What does research reproducibility mean?*'' (Ref. 8). As demonstrated by these documents, there are varying definitions and understandings of these terms in the scientific community. Several commenters pointed to the use of the terms in the NAS Workshop Report (Ref. 6). The definitions in the NAS Workshop Report (Ref. 6) define ''reanalysis,'' ''replication,'' and ''reproduce'' as follows:

> A reanalysis is when you conduct a further analysis of data. A person doing a reanalysis of data may use the same programs and statistical methodologies that were originally used to analyze the data or may use alternative methodologies, but the point is to analyze exactly the same data to see if the same result emerges from the analysis.
>
> Replication means that you actually repeat a scientific experiment or a trial to obtain a consistent result. The second experiment uses exactly the same protocols and statistical programs but with different data from a different population. The goal is to see if the same results hold with data from a different population.
>
> When you reproduce, you are producing something that is very similar to that research, but it is in a different medium or context. In other words, a researcher who is reproducing an experiment addresses the same research question but from a different angle than the original researcher did.

EPA's use of ''replicate'' in the proposed regulatory text at 40 CFR 30.5 in the 2018 proposed rulemaking is generally consistent with the NAS Workshop Report (Ref. 6) definition of ''reanalysis.'' However, as illustrated by Refs. 4–6, and in the public comments EPA received on the 2018 proposed rulemaking, these terms are not consistently used or defined in the scientific literature. EPA now proposes to use the term ''reanalyze'' instead of ''replicate'' in 40 CFR 30.5 and is clarifying the intent of the proposed regulation by proposing a definition of ''reanalyze'' at proposed 40 CFR 30.2 as ''to analyze exactly the same data to see if the same result emerges from the analysis by using the same or different programs and statistical methodologies that were originally used to analyze the data.'' In addition to identifying potential analytical errors in the original work, reanalyzing the data would allow assessment of the robustness of the original analysis and conclusions by, for instance, showing the variability that can occur when a previously omitted variable is added to the statistical model, different functional form assumptions are made (*e.g.,* a linear marginal effect of treatment), or different assumptions are made when estimating standard errors and drawing statistical inferences (*e.g.,* allowing for spatial correlation in error terms).

In the 2018 proposed rulemaking, EPA did not define ''independent validation.'' The definition of ''independent validation'' depends on how the term ''reanalyze'' is defined. Independent validation for a scientific study that is being repeated by conducting a second scientific study would be different than independent validation where the data underlying a study is being reanalyzed to determine if the same results can be obtained. Thus, consistent with the proposed definition of ''reanalyze'' at proposed 40 CFR 30.2, EPA is proposing to define ''independent validation'' as the reanalysis of study data by subject matter experts who have not contributed to the development of the original study to demonstrate that the same analytic results are capable of being substantially reproduced. ''Capable of being substantially reproduced'' means that independent analysis of the original or supporting data using identical methods would generate similar analytic results, subject to an acceptable degree of imprecision or error.

EPA's interpretation of ''capable of being substantially reproduced'' as

included in the proposed definition above builds on the description in the ''*Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies*'' (Ref. 9). These guidelines, which were issued by the Office of Management and Budget, are intended to help agencies ensure and maximize the quality, utility, objectivity and integrity of the information that they disseminate.

EPA is requesting comment on the proposed definitions of ''reanalyze'' and ''independent validation'' at proposed 40 CFR 30.2.

B. Data and Models

Given the use of the term ''data and models'' in proposed 40 CFR 30.3, 30.5, 30.6 and 30.9 as described in Section II of this preamble, EPA is proposing to define ''data'' and ''models'' at proposed 40 CFR 30.2. EPA proposes to broaden the scope of the proposal by deleting the modifying term ''dose-response,'' as indicated above, so as to extend the reference to data and models underlying pivotal regulatory science and pivotal science used to support significant regulatory decisions and influential scientific information, respectively, not simply dose-response data and dose-response models. Examples of information that would be considered to be data and models for purposes of the proposed rulemaking include environmental fate studies, bioaccumulation data, water-solubility studies, environmental fate models, engineering models, data on environmental releases, exposure estimates, quantitative structure activity relationship data, and environmental studies. This list is not exhaustive but is intended to provide examples of the range of information that would be considered to be within the scope of data and models.

1. *Data and research data.* Data has been defined to mean, in part, the recorded factual material commonly accepted in the scientific community as necessary to validate research findings (Ref. 10). As noted by public commenters and in the NAS Workshop Report (Ref. 6), there are different stages of these data. ''There are raw data, which come straight from the survey or the experiment. There are cleaned-up data, which consist of the raw data modified to remove obvious errors.'' (These are the data that are ready to be analyzed to extract relevant information.) ''There are processed data, which are data that have been computed and analyzed to extract relevant information. There is the final clean data set that is provided with a publication. And there are the metadata that describe the data'' (Ref. 6). These different data sets or stages of data may be used for different purposes and in different contexts.

The Agency received comment asking EPA to clarify what stage of data would need to be publicly available to allow for independent validation. Thus, EPA is incorporating the concept of stage of data with the basic concept of research data as ''recorded factual material commonly accepted in the scientific community as necessary to validate research findings'' from its definition at 2 CFR 200.315. For purposes of independent validation through reanalysis, the stage of data would be the cleaned-up or analyzable data set in which obvious errors have been removed. Obvious errors do not include data that could be characterized as outliers. These data are the cleaned-up or analyzable data set (Ref. 6). Therefore, EPA is proposing to define ''data'' as the set of recorded factual material commonly accepted in the scientific community as necessary to validate research findings in which obvious errors, such as keystroke or coding errors, have been removed and that is capable of being analyzed by either the original researcher or an independent party. EPA requests comment on this proposed definition and whether the definition of ''data'' should apply to another stage of data described in Ref. 6. The focus on this later stage of data is consistent with the Federal Government's approach to data access, and specifically to EPA's ''*2016 Plan to Increase Access to Results of EPA-Funded Scientific Research*'' (Ref. 11). Finally, EPA requests comment on whether there is another definition of ''data'' that should be considered.

EPA is deleting the 2018 proposed 40 CFR 30.2 definition of ''research data,'' because this definition excludes ''trade secrets, commercial information, materials necessary to be held confidential by a researcher until they are published, or similar information which is protected under law'' and ''[p]ersonnel and medical information and similar information the disclosure of which would constitute a clearly unwarranted invasion of personal privacy, such as information that could be used to identify a particular person in a research study.'' These types of data are intended to be subject to this rulemaking. To conform with this change, EPA is deleting the 2018 proposed 40 CFR 30.10 regulatory text because it would require EPA implementation of this rulemaking to be consistent with the definition of ''research data.''

2. Model. EPA is proposing to define ''model'' as it is defined in EPA's *Guidance on the Development, Evaluation, and Application of Environmental Model*s (Ref. 12). EPA's guidance document was produced to aid in strengthening the Agency's development, evaluation and use of models. In this guidance document, a model is described as ''a simplification of reality that is constructed to gain insights into select attributes of a physical, biological, economic, or social system. A formal representation is characterized as the behavior of system processes, often in mathematical or statistical terms. The basis can also be physical or conceptual.'' This definition is based in part on the National Research Council's (NRC) 2007 report *Models in Environmental Regulatory Decision Making* (Ref. 13). As noted by the NRC, models can be of many different forms. They can be computational, physical, empirical, conceptual or a combination of one or more types. EPA is requesting comment on the proposed definition of ''model'' at proposed 40 CFR 30.2.

C. Publicly Available

In the 2018 proposed rulemaking, EPA used the term ''publicly available'' but did not define it at 40 CFR 30.2 or in the preamble to the 2018 proposed rulemaking. Given its use at 40 CFR 30.1, 30.5 and 30.9, EPA is proposing to define it. Publicly available information is often defined to mean information that is made available to the general public (*e.g.,* see 40 CFR 2.201, 17 CFR 160.3, 16 CFR 313.3). EPA is proposing to define it similarly to how it is defined at 16 CFR 313.3. Although the overall purpose of the regulations at 16 CFR 313 is different than the purpose of this rulemaking, the meaning of information that is available to the general public should not vary. This would encompass information legally available from government sources, the media and the internet. EPA is requesting comment on the proposed definition of ''publicly available'' at proposed 40 CFR 30.2.

IV. Availability of Data and Models

In the 2018 proposed rulemaking, EPA proposed to require at 40 CFR 30.5 that ''[w]hen promulgating significant regulatory decisions, the Agency shall ensure that dose-response data and models underlying pivotal regulatory science are publicly available in a manner sufficient for independent validation.'' EPA received a large number of comments stating that the approach in the 2018 proposed rulemaking would likely preclude the use of valid data and models from

consideration as pivotal regulatory science, because the proposed requirement to make data and models publicly available in a manner sufficient for independent validation would prevent the use of data and models that include CBI data, proprietary data, PII data that cannot be sufficiently de-identified to protect the data subjects, as well as many older studies. While having these data and models publicly available provides the greatest transparency, these commenters expressed concern that this approach could limit the use of certain data and models in EPA's significant regulatory decisions. Based on a consideration of these comments, EPA is proposing a modified version of the 2018 proposed rulemaking regulatory text at 40 CFR 30.5. Proposed 40 CFR 30.5 would allow Agency consideration of studies where there is tiered access to data and models that have CBI, proprietary data, or PII that cannot be sufficiently de-identified to protect the data subjects. For all other studies, data and models should be publicly available if the studies are to be used as pivotal regulatory science or pivotal science.

As discussed in OMB M–19–15 (Ref. 3), risk reduction techniques include creating multiple versions of a single dataset with varying levels of specificity and protection. The benefit of tiered access is that data users who wish to conduct activities with a statistical purpose without first obtaining special authorization have access to the versions of the data in the least restricted tiers, allowing them to conduct research while protecting confidentiality.

EPA is also proposing an alternative approach to today's proposed 40 CFR 30.5. Under alternative proposed 40 CFR 30.5, when promulgating significant regulatory decisions or finalizing influential scientific information, the Agency will, other things equal, give greater consideration to studies where the underlying data and models are available in a manner sufficient for independent validation either because the information is publicly available or available through tiered access when the data include CBI, proprietary data, or PII and appropriate techniques have been used to reduce the risk of re-identification. In developing the significant regulatory decision or influential scientific information, the EPA will identify those studies that are given greater consideration and provide a short description of why greater consideration was given. However, the Agency may still consider studies where there is no access or limited access to underlying data and models.

EPA is also clarifying that the Agency does not intend to make all data and models underlying pivotal regulatory science and pivotal science publicly available. There may be instances where EPA does not own the data and models, lacks access to part or all of the data and models or does not have the authority to provide access to part or all of the data and models. Rather, EPA is describing how it will handle studies based on whether the underlying data and models are publicly available.

Both today's proposal and alternate proposal are consistent with EPA's statements in the April 2018 proposed rulemaking that ''access to dose response data and models underlying pivotal regulatory science'' should be done ''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'' (Ref. 1). Both approaches are also based on EPA's recognition that there are statutory restrictions to public availability for some data and models that could make independent validation difficult. Further, both of these approaches are consistent with the OMB's M–19–15 (Ref. 3). OMB's implementation updates direct federal agencies to ''explore methods that provide wider access to datasets while reducing the risk of disclosure of [PII]. . .[T]iered access offers promising ways to make data widely available while protecting privacy'' (Implementation Update 3.5, Ref. 3). In addition, ''Agencies should prioritize increased access to the data and analytic frameworks (*e.g.,* models) used to generate influential information'' while being ''consistent with statutory, regulatory, and policy requirements for protections of privacy and confidentiality, proprietary data, and confidential business information'' (Implementation Update 3.4, Ref. 3). This proposal is also consistent with OMB *Memorandum 13–13: Open Data Policy—Managing Information as an Asset* (Ref. 14).

Under a tiered approach to accessing data and models that include CBI, proprietary data, or PII that cannot be sufficiently de-identified to protect the data subjects, access is more restricted for more sensitive data and models. Thus, the amount of information available for analysis is dictated by the tier. The greatest amount of information is made available at the most restricted access tier. Access to data involving PII would be consistent with the requirements of the Common Rule, the Health Insurance Portability and Accountability Act (HIPPA), the 21st Century Cures Act, the Privacy Act, and other relevant laws and regulations, and EPA privacy policies. Reanalyzing findings of studies based on data and models that include PII (*e.g.,* residence) or CBI may not be possible given the degree of perturbation caused by de-identification that would be needed for the information to be made publicly available. Restricted access for researchers through secure data enclaves for PII or through non-disclosure agreements for CBI may result in access to sufficient information about the data and models to allow for independent validation. This ability to reanalyze findings may be much more limited for less restricted tiers. Thus, reanalysis of findings for some data and models may be limited to authorized researchers and not possible for the general public.

A model of tiered access for data involving PII is the Research Data Center (RDC), National Center for Health Statistics (NCHS), Centers for Disease Control (CDC). The NCHS operates the RDC to allow researchers access to restricted-use data. The RDC provides access to the restricted-use data while protecting the confidentiality of survey respondents, study subjects, or institutions. For access to the restricted-use data, researchers must submit a research proposal outlining the need for restricted-use data. The submitted research proposal is intended to provide a framework for NCHS to identify potential disclosure risks and how the data will be used (Ref. 15). EPA is currently conducting a pilot study using the RDC's secure data enclave to host EPA datasets in a restricted use environment.

Development of standard data repositories is still ongoing. For example, the White House Office of Science and Technology Policy recently solicited public comments on a draft set of characteristics of data repositories used to locate, manage, share, and use data resulting from federally-funded research (85 FR 3085). The effort is intended to help federal agencies provide more consistent information on desirable characteristics of data repositories ''for data subject to agency Public Access Plans and data management and sharing policies, whether those repositories are operated by government or nongovernmental entities.'' Information received during this public comment period will, among other things, help inform improved guidance and best practices related to preserving and providing access to data.

Access to CBI data would continue to be provided consistent with the

environmental statutes EPA implements and the regulations at 40 CFR part 2, subpart B, which govern CBI. These regulations establish basic rules governing business confidentiality claims, how EPA handles business information that is or may be entitled to confidential treatment, and how EPA determines whether information is entitled to confidential treatment for reasons of business confidentiality. Various statutes under which EPA operates contain special provisions concerning the entitlement to confidential treatment of information gathered under such statutes. The regulations at 40 CFR part 2 subpart B prescribe rules for treating certain categories of business information obtained under the various statutory provisions.

In accordance with these statutes, both the proposed and alternative 40 CFR 30.5 provide that access to underlying data and models that include CBI, proprietary information, or PII, for the subset of studies that could be considered pivotal science, may be limited to authorized officials and researchers and not provided to the general public.

Proposed 40 CFR 30.5 would maintain the temporal approach to data and models taken in the regulatory text of 40 CFR 30.5 of the 2018 proposed rulemaking, and thus would apply to data and models evaluated at the time a significant regulatory action or influential scientific information is developed, regardless of when the data and models were generated. EPA is requesting comment on whether this should apply only to data and models that are generated (*i.e.,* when the development of the data set or model has been completed or updated) after the effective date of this rulemaking. If the proposed or alternative approach were finalized, EPA would consider the availability of underlying data and models only for studies that are potentially pivotal to EPA's significant regulatory decisions or influential scientific information that are developed in the future.

Although the ability to independently validate pivotal regulatory science or pivotal science is a key component of this rulemaking, EPA would like to clarify that neither the proposed nor the alternative 40 CFR 30.5 would require that EPA, a member of the public or other entity must independently validate a study before it can be considered to be pivotal regulatory science or pivotal science. EPA would also like to clarify that independent validation is not required under proposed 40 CFR 30.7 which describes the role of independent peer review.

EPA is requesting comment on the regulatory text being proposed today for 40 CFR 30.5. For alternate proposed 40 CFR 30.5, EPA is also requesting comment on how much consideration should be given to studies when there is limited or no access to the underlying data and models. In addition, EPA is requesting comment on how to ensure that, over time, more of the data and models underlying the science that informs significant regulatory decisions and influential scientific information are available to the public for independent validation in a manner that honors legal and ethical obligations to reduce the risks of unauthorized disclosure and re-identification. Finally, EPA is interested in comments about how to provide sufficient incentives and support to researchers to increase access to the data that may be used as pivotal regulatory science or pivotal science. Such comments will be used to develop implementation guidance.

V. Exemption by the Administrator

The 2018 proposed rulemaking includes a provision at 40 CFR 30.9 allowing the Administrator to grant exemptions from the rule on a case-by-case basis if he or she determines that compliance is impracticable because it is not feasible to ensure that data and models underlying pivotal regulatory science are publicly available in a manner that is consistent with law and protects privacy and confidentiality. EPA is clarifying that the exemption may be given if compliance is impracticable because technological barriers render sharing of the data or models infeasible.

EPA is also modifying the scope of the data and models that can be considered when determining whether to grant an exemption. The underlying data, models and computer code for some studies, particularly older studies, may not be readily publicly available because of the technological barriers to data and model sharing (*e.g.,* differences in data storage devices or data retention practices) that existed when they were developed. Thus, in 40 CFR 30.9(a), EPA is proposing to use the age of data and models as a factor in the determination that compliance with the rule is impracticable. This modification of scope is intended to acknowledge the evolution of best practices for information sharing given innovations in information generation, access, management and use (See Ref. 3). EPA is proposing that a study or studies would be eligible for consideration under 40 CFR 30.9(a), regardless of whether they contain CBI, proprietary information, or PII, if the underlying data or models were collected, completed or updated before the effective date of this rule. EPA requests comment on this consideration of the age of data and models in determining the feasibility of making underlying data and models publicly available. EPA also requests comment on whether there are aspects other than the year the data or model was collected, completed or updated that EPA should consider in determining whether to grant an exemption in order to evaluate the technological barriers to sharing.

The 2018 proposed rulemaking also included a provision at 40 CFR 30.9 allowing the Administrator to grant exemptions from the rule on a case-by-case basis if he or she determines that compliance is impracticable because it is not feasible to conduct independent peer review on all pivotal regulatory science. EPA is deleting that provision of the proposed exemption because EPA does not believe that peer review of pivotal regulatory science or pivotal science would be infeasible. Thus, EPA no longer believes the provision is necessary.

VI. References

The following is a listing of the documents that are specifically referenced in this notice. The docket includes these documents and other information considered by EPA, including documents referenced within the documents that are included in the docket, even if the referenced document is not physically located in the docket. For assistance in locating these other documents, please consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

1. EPA. Strengthening Transparency in Regulatory Science; Proposed Rule. **Federal Register** (83 FR18768, April 30, 2018) (FRL–9977–40).

2. EPA. Strengthening Transparency in Regulatory Science; Extension of Comment Period and Notice of Public Hearing **Federal Register** (83 FR. 24255, May 25, 2018).

3. OMB (Office of Management and Budget). (2019). Improving Implementation of the Information Quality Act. Memorandum for the Heads of Executive Departments and Agencies. OMB Issuance M–19–15. Washington, DC: Executive Office of the President. *https://www.whitehouse.gov/wp-content/uploads/2019/04/M-19-15.pdf.*

4. OMB (Office of Management and Budget). (2004). Memorandum for the Heads of Executive Departments and Agencies on Final Information Quality Bulletin for Peer-Review. *https://obamawhitehouse.archives.gov/sites/default/files/omb/assets/omb/memoranda/fy2005/m05-03.pdf.*

5. OMB (Office of Management and Budget). (2019). Executive Order 13891 of

October 9, 2019. Promoting the Rule of Law Through Improved Agency Guidance Documents. 84 FR 199. *https://www.govinfo.gov/content/pkg/FR-2019-10-15/pdf/2019-22623.pdf.*

6. NAS (National Academies of Sciences, Engineering, and Medicine). (2016). Principles and obstacles for sharing data from environmental health research: Workshop summary. Washington, DC: The National Academies Press. *https://doi.org/10.17226/21703.*

7. Pellizzari, YE; Lohr, K, Blatecky, A.; Creel, D. (2017). Reproducibility: A Primer on Semantics and Implications for Research. Research Triangle Park, NC: RTI Press.

8. Goodman, SN; Fanelli, D; Ioannidis, JPA. (2016). What does research reproducibility mean? Sci Translational Medicine 8: 341ps12. *https://doi.org/10.1126/scitranslmed.aaf5027.*

9. OMB (Office of Management and Budget). (2002). Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies; Final guidelines. 67 FR 8452–8460. *https://www.govinfo.gov/content/pkg/FR-2002-02-22/pdf/R2-59.pdf.*

10. OMB (Office of Management and Budget). (2013). Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards; Final Rule. 78 FR 78589–78691. *https://www.govinfo.gov/content/pkg/FR-2013-12-26/pdf/2013-30465.pdf.*

11.U.S. EPA (U.S. Environmental Protection Agency).(2016). Plan to Increase Access to Results of EPA-Funded Scientific Research. (EPA/601–R–16–005). Washington, DC: U.S. Environmental Protection Agency. *https://www.epa.gov/sites/production/files/2016-12/documents/epascientificresearchtransperancyplan.pdf.*

12. U.S. EPA (U.S. Environmental Protection Agency). (2009). Guidance on the Development, Evaluations, and Application of Environmental Models. (EPA/100/K–09/003). Washington, DC: US. Environmental Protection Agency. *https://www.epa.gov/sites/production/files/2015-04/documents/cred_guidance_0309.pdf.*

13. NRC (National Research Council). (2007). Models in Environmental Regulatory Decision Making. Washington, DC: The National Academies Press. *https://doi.org/10.17226/11972.*

14. OMB (Office of Management and Budget). (2013). Memorandum for the Heads of Executive Departments and Agencies on Open Data Policy-Managing Information as an Asset (*https://projectopen-data.cio.gov/policy-memo/*).

15. CDC (Centers for Disease Control). Research Data Center. *https://www.cdc.gov/rdc/index.htm.*

VII. Statutory and Executive Order Reviews

Additional information about these statutes and Executive Orders can be found at *https://www.epa.gov/laws-regulations/laws-and-executive-orders.*

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.

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. This action does not regulate any entity outside the federal government.

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.

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.

List of Subjects in 40 CFR Part 30

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

Dated: March 3, 2020.

Andrew R. Wheeler,

Administrator.

Therefore, 40 CFR part 30, as proposed to be added at 83 FR 18768 (April 30, 2018), is proposed to be amended as follows:

PART 30—TRANSPARENCY IN REGULATORY DECISIONMAKING

■ 1. The authority citation for part 30 is revised to read as follows:

Authority: 5 U.S.C. 301; 5 U.S.C. App.; Pub. L. 98–80, 84 Stat. 2086.

■ 2. Revise § 30.2 by adding the definitions for ''*Capable of being substantially reproduced*'', ''*Data*'', ''*Independent validation*'', ''*Influential scientific information*'' ''*Model*'', ''*Pivotal science*'', ''*Publicly available*'' and ''*Reanalyze*'' in alphabetical order to read as follows:

§ 30.2 What definitions apply to this part?

Capable of being substantially reproduced means that independent analysis of the original or supporting data using identical methods would generate similar analytic results, subject to an acceptable degree of imprecision or error.

Data means the set of recorded factual material commonly accepted in the scientific community as necessary to validate research findings in which obvious errors, such as keystroke or coding errors, have been removed and that is capable of being analyzed by either the original researcher or an independent party.

* * * * *

Independent validation means the reanalysis of study data by subject matter experts who have not contributed to the development of the study to demonstrate that the same analytic results reported in the study are capable of being substantially reproduced.

Influential scientific information means 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.

Model means a simplification of reality that is constructed to gain insights into select attributes of a physical, biological, economic, or social system. A formal representation of the behavior of system processes, often in mathematical or statistical terms. The basis can also be physical or conceptual.

* * * * *

Pivotal science means the specific scientific studies or analyses that underly influential scientific information.

Publicly available means lawfully available to the general public from federal, state, or local government records; the internet; widely distributed media; or disclosures to the general public that are required to be made by federal, state, or local law.

Reanalyze means to analyze exactly the same data to see if the same result emerges from the analysis by using the same or different statistical software, models, and statistical methodologies that were originally used to analyze the data, as well as to assess potential analytical errors and variability in the underlying assumptions of the original analysis.

* * * * *

■ 3. Revise § 30.3 to read as follows:

§ 30.3 How do the provisions of this part apply?

The provisions of this part apply to data and models, underlying pivotal science supporting influential scientific information and/or underlying pivotal regulatory science used to justify significant regulatory decisions regardless of the source of funding or identity of the party conducting the science. The provisions of this section do not apply to physical objects (like laboratory samples), drafts, and preliminary analyses. In the event the procedures outlined in this part conflict with statutes that EPA administers, or their implementing regulations, the statutes and regulations will control. Except where explicitly stated otherwise, the provisions of this part do not apply to any other type of agency action, including individual party adjudications, enforcement activities, or permit proceedings.

[Option 1]

■ 4. Revise § 30.5 to read as follows:

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

When promulgating significant regulatory decisions or finalizing influential scientific information, the Agency will only use pivotal regulatory science and/or pivotal science that includes studies with restricted data and models (*i.e.,* those that include confidential business information (CBI), proprietary data, or Personally Identifiable Information (PII) that cannot be sufficiently de-identified to protect the data subjects) if there is tiered access to these data and models in a manner sufficient for independent validation, and studies that do not include restricted data and models if the data and models 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 manner that is consistent with law, protects privacy, confidentiality, confidential business information, and is sensitive to national and homeland security. Information is considered ''available in a manner sufficient for independent validation'' when it includes the information necessary to understand, assess, and reanalyze findings. This may include, for example:

(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.

(f) The provisions of this section apply to data and models underlying pivotal regulatory science or pivotal science regardless of who funded or conducted the underlying data, models, or other regulatory science or pivotal science. The agency shall make reasonable efforts to explore methodologies, technologies, and institutional arrangements for making such data and models 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 and models are controlled by third parties, EPA may work with those parties to endeavor to make the data and models available in a manner that complies with this section.

[Option 2]

■ 5. Revise § 30.5 to read as follows:

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

(a) When promulgating significant regulatory decisions or finalizing influential scientific information, the Agency will, other things equal, give greater consideration to studies where the underlying data and models are publicly available in a manner sufficient for independent validation. The Agency will also give greater consideration to studies based on data and models that include confidential business information, proprietary information or personally identifiable information if these data and models were available through restricted access, such as through a secure data enclave, in a manner sufficient for independent validation. Where there is no access to data and models, or access is limited, the Agency may still consider these studies, depending on the other attributes of the studies. Furthermore, the Agency will identify those studies that are given greater consideration and provide a short description of why greater consideration was given. Where the Agency is making data or models publicly available, it shall do so in a manner that is consistent with law, protects privacy, confidentiality, confidential business information, and is sensitive to national and homeland security. Information is considered ''available in a manner sufficient for independent validation'' when it includes the information necessary to understand, assess, and reanalyze findings. This may include, for example:

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

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

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

(4) Recorded factual materials; and

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

(b) The provisions of this section apply to data and models underlying pivotal regulatory science or pivotal science regardless of who funded or conducted the underlying data, models, or other regulatory science or pivotal science. The agency shall make reasonable efforts to explore methodologies, technologies, and institutional arrangements for making such data and models 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 and models are controlled by third parties, EPA may work with those parties to endeavor to make the data and models available in a manner that complies with this section.

■ 6. Revise § 30.6 to read as follows:

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

EPA shall describe and document any assumptions and methods used and shall describe variability and uncertainty. EPA shall evaluate the appropriateness of using default assumptions on a case-by-case basis. EPA shall clearly explain the scientific basis for critical assumptions used in the analysis that drove the analytical results and subsequent decisions and shall present analyses showing the sensitivity of the modeled results to alternative assumptions. When available, EPA shall give explicit consideration to high quality studies, including but not limited to those 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.

■ 7. Revise § 30.7 to read as follows:

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

EPA shall conduct independent peer review on all pivotal regulatory science used to justify significant regulatory decisions and on all pivotal science underlying influential scientific information, consistent with the requirements of the OMB Final Information Quality Bulletin for Peer Review 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.

■ 8. Revise § 30.9 to read as follows:

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

The Administrator may grant an exemption to this part on a case-by case basis if he or she determines that compliance is impracticable because technological barriers render sharing of the data or models infeasible, the development of the data or model was completed or updated before [*EFFECTIVE DATE OF FINAL RULE*] or making the data and models publicly available would conflict with laws governing privacy, confidentiality, confidential business information, or national and homeland security.

[FR Doc. 2020–05012 Filed 3–17–20; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 721 and 725

[EPA–HQ–OPPT–2020–0094; FRL–10005–76]

RIN 2070–AB27

Significant New Use Rules on Certain Chemical Substances (20–3.B)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing significant new use rules (SNURs) under the Toxic Substances Control Act (TSCA) for chemical substances which are the subject of premanufacture notices (PMNs) and a microorganism that was the subject of a Microbial Commercial Activity Notice (MCAN). This action would require persons to notify EPA at least 90 days before commencing manufacture (defined by statute to include import) or processing of any of these chemical substances for an activity that is designated as a significant new use by this proposed rule. This action would further require that persons not commence manufacture or processing for the significant new use until they have submitted a Significant New Use Notice, and EPA has conducted a review of the notice, made an appropriate determination on the notice under TSCA, and has taken any risk management actions as are required as a result of that determination.

DATES: Comments must be received on or before April 17, 2020.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA–HQ–OPPT–2020–0094, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.
- *Mail:* Document Control Office (7407M), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.html.*

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: *For technical information contact:* Kenneth Moss, Chemical Control Division (7405M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; telephone number: (202) 564–9232; email address: *moss.kenneth@epa.gov.*

For general information contact: The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554–1404; email address: *TSCA-Hotline@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you manufacture, process, or use the chemical substances contained in this proposed rule. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include: