

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 30

[EPA-HQ-OA-2018-0259; FRL-10019-07-ORD]

RIN 2080-AA14

Strengthening Transparency in Pivotal Science Underlying Significant Regulatory Actions and Influential Scientific Information

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This action establishes how the Environmental Protection Agency (EPA) will consider the availability of dose-response data underlying pivotal science used in its significant regulatory actions and influential scientific information. When promulgating significant regulatory actions or developing influential scientific information for which the conclusions are driven by the quantitative relationship between the amount of dose or exposure to a pollutant, contaminant, or substance and an effect, the EPA will give greater consideration to studies where the underlying dose-response data are available in a manner sufficient for independent validation. This action also requires the EPA to identify and make publicly available the science that serves as the basis for informing a significant regulatory action at the proposed or draft stage to the extent practicable; reinforces the applicability of peer review requirements for pivotal science; and provides criteria for the Administrator to exempt certain studies from the requirements of this rulemaking.

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

ADDRESSES: The EPA has established a docket for this action under Docket ID No. **EPA-HQ-OA-2018-0259**. All documents in the docket are listed on the <http://www.regulations.gov> web site. Although listed in the index, some information is not publicly available, e.g., confidential business information (CBI) information or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form in the EPA Docket Center, WJC West Building, Room 3334, 1301 Constitution Avenue NW, Washington, DC 20004. The Docket Center's hours are 8:30 a.m. to 4:30 p.m., Monday through Friday (except Federal Holidays). Publicly available docket materials are available electronically through <http://www.regulations.gov>.

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I. General Information

A. Does this action apply to me?

This final rule does not regulate any entity outside the EPA. Rather, the requirements modify the EPA's internal procedures regarding the transparency of pivotal science underlying significant regulatory actions¹ and influential scientific information. However, the Agency recognizes that any entity interested in the EPA's regulations may be interested in this final rule. For example, this final rule may be of interest to entities that conduct research or another scientific activity that is likely to be relevant to the EPA's regulatory activity or development of influential scientific information. This rule has no retrospective effect on either final significant regulatory actions or influential scientific information.

B. What action is the Agency taking?

The EPA is issuing this final rule to help strengthen the transparency of the dose-response data underlying certain EPA actions and to set the overarching structure and principles for transparency of pivotal science in significant regulatory actions and influential scientific information. This rule has a much narrower scope than the 2018 proposal and the 2020 SNPRM. The rule describes how the EPA will determine the consideration to afford pivotal science of the EPA's significant regulatory actions and influential scientific information for which the conclusions are driven by the quantitative relationship between the amount of dose or exposure to a pollutant, contaminant, or substance and an effect based on the availability of the underlying dose-response data and other applicable factors. This rule builds upon prior EPA actions in response to government-wide data access and sharing policies.

First, the EPA is requiring that, when promulgating significant regulatory actions or developing influential scientific information, the Agency will determine which studies constitute

¹ Consistent with OMB guidance, this rule would not apply to the following regulatory actions: individual party adjudications, enforcement activities, site-specific actions, or permit proceedings.

pivotal science and give greater consideration to those studies determined to be pivotal science for which the underlying dose-response data are available in a manner sufficient for independent validation.

Second, the EPA is establishing provisions for how the requirements of this part will apply. This rule sets the overarching structure and principles for transparency of pivotal science in significant regulatory actions and influential scientific information. The final rule provides that if implementing the rule results in any conflict between this rule and the environmental statutes that the EPA administers, and their implementing regulations, this rule will yield and the statutes and regulations will be controlling.

Third, this rule requires that the EPA shall clearly identify all science that serves as the basis for informing a significant regulatory action. The EPA shall make all such science that serves as the basis for informing a significant regulatory action publicly available to the extent practicable using standards for protecting identifiable information.

Fourth, the EPA is establishing requirements for the independent peer review of pivotal science.

Fifth, the EPA is finalizing a provision that provides criteria for the Administrator to consider when granting case-by-case exemptions to the requirements of this rule.

The EPA is also defining the following terms for the purposes of this rule: “data,” “dose-response data,” “independent validation,” “influential scientific information,” “pivotal science,” “publicly available,” “reanalyze,” “science that serves as the basis for informing a significant regulatory action,” and “significant regulatory actions.”

Finally, the EPA intends to issue implementation guidelines that will help execute this final rule consistently across programs. This may include the process for designating key studies as

pivotal science, documenting the availability of dose-response data, and requesting an Administrator's exemption.

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

The EPA is authorized to issue this rule under its authority to promulgate housekeeping regulations governing its internal affairs (hereinafter, "housekeeping authority"). This final rule describes how the EPA will determine the consideration to afford pivotal science of the EPA's final significant regulatory actions and influential scientific information based on the availability of the underlying dose-response data and other applicable factors. This rule exclusively pertains to the internal practices of the EPA and does not regulate the conduct or determine the rights or obligations of any entity outside the federal government.

The Federal Housekeeping Statute (5 U.S.C. 301) 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." 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."² As the Supreme Court further explained, section 301 authorizes "what the [Administrative Procedure Act] terms 'rules of agency organization, procedure or practice' as opposed to substantive rules."³

While the EPA is not one of the "Executive departments" referred to in 5 U.S.C. 101, the EPA gained housekeeping authority equivalent to that granted to Executive departments in

² *Chrysler Corp. v. Brown*, 441 U.S. 281, 309 (1979).

³ *Id.* at 310.

section 301 through the Reorganization Plan No. 3 of 1970, 84 Stat. 2086 (July 9, 1970), which created the EPA. The Reorganization Plan established the Administrator as “head of the agency,” transferred functions and authorities of various agencies and Executive departments to the EPA, and gave the EPA the authority to promulgate regulations to carry out the transferred functions.

Section 2(a)(1)-(8) of the Reorganization Plan transferred to the EPA functions previously vested in several agencies and Executive departments including the Departments of the 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” and provided that “[t]he transfers to the Administrator made by this section shall be deemed to include the transfer of [] authority, provided by law, to prescribe regulations relating primarily to the transferred functions.” The Federal Housekeeping Statute was existing law at the time the Reorganization Plan was enacted. Further, the Reorganization Plan does not limit the authority to promulgate regulations only to the transferred functions, but rather it transfers all authority that “relate[s]” to the transferred functions. Housekeeping authority is ancillary to the transferred functions because it allows the EPA to establish standard, internal procedures that are necessary to carry out and support those functions. Accordingly, the concomitant federal housekeeping authority to issue procedural rules was transferred to the EPA.

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.”⁴

Courts have recognized the EPA as an agency with federal housekeeping authority. The U.S. Court of Appeals for the Second Circuit, in *EPA v. General Elec. Co.*, 197 F.3d 592, 595 (2nd 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 U.S. Court of Appeals for the Fourth Circuit, in *Boron Oil Co. v. Downie*, 873 F.2d 67, 69 (4th Cir. 1989), held that the district court had exceeded its jurisdiction when it had compelled testimony contrary to duly promulgated EPA regulations, which the EPA argued were authorized by section 301. The Second and Fourth Circuits did not directly address whether the EPA was an “Executive department,” but rather recognized that the EPA has the authority to issue regulations governing its internal affairs and assumed that authority comes from section 301. Indeed, if the EPA did not possess housekeeping authority, the EPA would not be able to efficiently carry out its daily functions, which would in turn compromise the EPA’s ability to exercise its duties as a federal regulatory agency.

On April 30, 2018, the EPA published the Strengthening Transparency in Regulatory Science Proposed Rulemaking (“2018 proposed rule,” Ref. 5). The 2018 proposed rule cites as authority several environmental statutes that the EPA administers: the Clean Air Act (CAA); the Clean Water Act (CWA); the Safe Drinking Water Act (SDWA); the Resource Conservation and Recovery Act (RCRA); the Comprehensive Environmental Response,

⁴ 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”).

Compensation, and Liability Act (CERCLA); the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA); the Emergency Planning and Community Right-To-Know Act (EPCRA); and the Toxic Substances Control Act (TSCA). Subsequently, on May 25, 2018, the EPA published a document extending the comment period and announced a public hearing on the 2018 proposed rule to be held on July 18, 2018 (Ref. 6). That document identified 5 U.S.C. 301 as a source of authority in addition to those statutes cited in the 2018 proposed rule.

On March 18, 2020, in the Federal Register at 85 FR 15396, the EPA published the Strengthening Transparency in Regulatory Science Supplemental Notice of Proposed Rulemaking (“2020 SNPRM,” Ref. 7), in which the EPA clarified some of the citations in the 2018 proposed rule (Ref. 5). However, because this is purely a procedural rule, the EPA is not relying on any substantive environmental statutes as authority.

This action is a procedural rule within the scope of the EPA’s housekeeping authority. As the Supreme Court explained in *Chrysler Corp.*, rules of internal agency management are considered procedural rules as opposed to substantive rules under the APA.⁵ Even if there could be downstream practical effects on the voluntary behavior of outside parties and on outside parties’ interactions with the EPA, such impacts do not render this procedural rule substantive. (See *American Hosp. Ass’n v. Bowen*, 834 F.2d 1037, 1051 (D.C. Cir. 1987)—“[A]gency rules that impose ‘derivative,’ ‘incidental,’ or ‘mechanical’ burdens upon regulated individuals are considered procedural, rather than substantive.”). As the Supreme Court explained in *Chrysler Corp.*, “the central distinction among agency regulations found in the APA is that between ‘substantive rules’ on the one hand and ‘interpretive rules, general statements of policy, or rules of agency organization, procedure, or practice on the other.’”⁶ The Supreme Court further

⁵ *Chrysler Corp.*, 441 U.S. 281 at 301-02.

⁶ *Id.* at 301 (quoting 5 U.S.C. § 553(b), (d)).

clarified that unlike procedural rules, substantive rules have legal force and effect on individual rights and obligations, and noted that whether a rule affects individual rights and obligations is an “important touchstone” for distinguishing substantive rules from other types of rules.⁷ This final rule does not regulate the rights and obligations of any party outside of the EPA let alone have legal force and effect on them. Any incidental impacts on voluntary behavior outside of the EPA do not render this a substantive rule.

Some public commenters asserted that the EPA lacks the authority under the substantive environmental statutes that it administers to promulgate this rule. However, the EPA is relying exclusively on its housekeeping authority to promulgate this purely procedural rule. In this final procedural rule, the EPA does not interpret or apply provisions of a particular statute or statutes that it administers. The EPA will undertake such efforts in forthcoming actions, which will be either statute-specific science transparency regulations or programmatic regulations implementing this procedural rule. Some of these subsequent actions will be substantive rules issued under the associated environmental statutes and will be subject to judicial review. In this action, the EPA is finalizing a rule of internal agency procedures, including how the Agency will consider the availability of dose-response data underlying pivotal science used in its significant regulatory actions and influential scientific information for independent validation.

Some public commenters nonetheless took the position that this rule is substantive because it will affect the Agency’s interactions with regulated parties. First, and as discussed above, this final rule does not regulate any party outside of the EPA but rather exclusively governs the EPA’s internal process for determining the consideration to afford pivotal science with respect to certain actions. This rule does not require any researcher or other outside entity to provide

⁷ *Id.* at 302.

data or models to the EPA. Nor does the rule categorically exclude studies—even studies where the underlying dose-response data are not available for independent validation—and therefore any incidental impact on researchers who are developing science and deciding whether to make the underlying dose-response data available is negligible. Instead, it governs internal agency procedures for determining the consideration to afford various studies according to factors that include data availability. In doing so, the final rule provides greater transparency on the consideration the EPA will give pivotal science where the underlying dose-response data are or are not available for independent validation.

Certain commenters stated that the final rule is substantive because they asserted it imposes burdens on scientists who endeavor to have their research considered by the EPA when it makes regulatory decisions or develops influential scientific information. The EPA notes, however, that procedural rules do not alter the rights or interests of parties but they “may alter the manner in which the parties present themselves or their viewpoints to the agency,” without thereby becoming substantive rules (*James A. Hurson Assocs. v. Glickman*, 229 F.3d 277, 280 (D.C. Cir. 2000)). If researchers want to increase the likelihood that their studies receive greater consideration by the EPA, they may take steps to ensure that the underlying dose-response data are available to the greatest extent possible. But any such response to this final rule would be purely voluntary. It is not required by this rule.

Some commenters also argued that this rule is not procedural because they asserted it conflicts with the substantive environmental statutes administered by the EPA. However, this final rule does not interpret or apply the provisions of any environmental statutes; such efforts will occur in the subsequent actions under the relevant statutes described above. As this rule makes clear, if implementing this procedural rule would result in conflicts with existing

environmental statutes, and their implementing regulations, this rule will yield to the EPA statutes and regulations.

This is a rulemaking of agency organization, procedure, or practice. This procedural rule would not regulate any person or entity outside the EPA and would not affect the rights or obligations of outside parties. As a rule of Agency procedure, this rule is exempt from the notice-and-comment and delayed effective-date requirements set forth in the Administrative Procedure Act. See 5 U.S.C. 553(a)(2),(b)(A),(d). Nonetheless, the Agency voluntarily sought public comment on the proposed rule because it believed that the information and opinions supplied by the public would inform the Agency's views. *Vt. Yankee Nuclear Power Corp. v. Nat. Res. Def. Council, Inc.*, 435 U.S. 519, 524 (1978) (“Agencies are free to grant additional procedural rights in the exercise of their discretion.”) In addition, even assuming *arguendo* that the delayed effective-date requirement of the Act applied to this action, the EPA has determined that there would be good cause, consistent with 5 U.S.C. 553(d)(3), for making this final rule effective immediately because immediate implementation of the rule, with its goals of ensuring transparency and consistency in how the agency considers dose-response data underlying pivotal science to be used in significant regulatory decisions and influential scientific information, is crucial for ensuring confidence in EPA decision-making. Because this is a procedural rule that only applies internally to ensure that the EPA consistently considers data availability, the rationale for delayed effectiveness to allow reasonable time for non-EPA regulated entities to adjust their behavior before and prepare for the effective date of the new requirements does not apply. See *Omnipoint Corp. v. Fed. Comm’n Comm’n*, 78 F.3d 620, 630 (D.C. Cir. 1996); see also *United States v. Gavrilovic*, 551 F.2d 1099, 1104 (8th Cir. 1977) (quoting legislative

history). For these reasons, the Agency finds that good cause exists under APA section 553(d)(3) to make this rule effective immediately upon publication.

II. Background

A. Summary of 2018 proposed rule

In the 2018 proposed rule (Ref. 5), the EPA proposed adding 40 CFR part 30, which would direct the EPA to ensure that the pivotal regulatory science underlying its actions is publicly available in a manner sufficient for independent validation. The EPA proposed to take this action under the 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 conduct of and reliance on scientific activity to inform those functions.

In the 2018 proposed rule, the EPA defined "dose-response data and models," "pivotal regulatory science," "regulatory decisions," "regulatory science," and "research data" (proposed 40 CFR 30.2).

Many of the provisions in proposed 40 CFR part 30 applied to dose-response models and data, regardless of the source of funding or identity of the party who developed the model or generated the data. Specifically, the EPA proposed that the Agency would ensure that dose-response data and models underlying pivotal regulatory science were publicly available in a manner sufficient for independent validation, including releasing information necessary for the public to "understand, assess, and replicate findings" (proposed 40 CFR 30.5). The public release of such information would be consistent with law; protect privacy, confidentiality, and confidential business information (CBI); and be sensitive to national security interests.

In addition to proposing requirements for ensuring that dose-response data and models were

publicly available in a manner sufficient for independent validation, the EPA proposed additional requirements pertaining to the use of dose-response data and models underlying pivotal regulatory science. Proposed 40 CFR 30.6 would have required the EPA to: describe and document any assumptions and methods used; clearly explain the scientific basis for each model assumption used and present analyses showing the sensitivity of the modeled results to alternative assumptions; evaluate the appropriateness of using default assumptions (e.g., assumptions of a linear, no-threshold dose-response) on a case-by-case basis; and when available, 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, the use of various threshold models across the dose or exposure range, and models that investigate factors that might account for spatial heterogeneity.

The 2018 proposed rule also included requirements that pertained more broadly to the use of studies in Agency actions and pivotal regulatory science. Proposed 40 CFR 30.4 would have required the EPA to clearly identify all studies relied upon when taking any final Agency action and make all such studies available to the public to the extent practicable. Proposed 40 CFR 30.7 would have required the EPA to conduct independent peer review of all pivotal regulatory science used to justify regulatory decisions. As part of the peer review, the EPA would have been required to ask peer reviewers to articulate the strengths and weaknesses of the Agency's justification for the assumptions applied and the implications of those assumptions for the results.

Finally, the 2018 proposed rule would have allowed for the EPA Administrator to grant exemptions to the requirements of the rule when the Administrator determined that compliance

would be impracticable because it was not feasible to either (1) ensure that all dose-response data and models underlying pivotal regulatory science were publicly available in a manner sufficient for independent validation, in a fashion consistent with law; protective of privacy, confidentiality, and CBI; and sensitive to national security interests; or (2) conduct independent peer review on all pivotal regulatory science used to justify regulatory decisions for reasons outlined in Section IX of the OMB Bulletin for Peer Review (Ref. 8).

The EPA solicited comment on the 2018 proposed rule generally and on specific provisions in the proposal, including the legal authority for the proposed rule, the scope of the proposal, public access to dose-response data and models, and how the proposed rule should be implemented.

B. Summary of 2020 supplemental notice of proposed rulemaking

The 2020 SNPRM (Ref. 7) included clarifications, modifications, and additions to certain provisions in the 2018 proposed rule. The 2020 SNPRM also revised the authority cited in proposed 40 CFR part 30; revised proposed 40 CFR 30.2, 30.3, 30.5, 30.6, 30.7, and 30.9; and deleted proposed 40 CFR 30.10.

Through the 2020 SNPRM, the EPA modified proposed 40 CFR part 30 to expand the scope of the 2018 proposed rule, clarified the intent of the 2018 proposed rule, and solicited public comment on two proposed approaches for how the Agency would consider data and model availability when evaluating studies. The 2020 SNPRM modified the scope of the 2018 proposed rule in two ways: (1) expanded “dose-response data and models” to “data and models,” and (2) expanded the applicability of the proposed requirements to influential scientific information, which was defined in the 2020 SNPRM as the “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,” consistent with the definition of “influential scientific information” provided in the OMB Final Information Quality Bulletin for Peer Review (Ref. 8). As a result of the 2020 SNPRM, the provisions in proposed 40 CFR part 30 would have applied to data and models, regardless of the source of funding or identity of the party who developed the model or generated the data, underlying pivotal science or pivotal regulatory science. The EPA modified proposed 40 CFR 30.2, 30.3, 30.6, and 30.9 to reflect this change in scope of the proposed rulemaking.

With the expanded scope, the EPA proposed that data and models underlying pivotal regulatory science and pivotal science be available in a manner sufficient for independent validation. To clarify its intent, in the 2020 SNPRM the EPA modified and added proposed definitions for key terminology, including “data,” “model,” “publicly available,” and “independent validation.” Specifically, the EPA clarified that “independent validation” of data and models, as proposed, meant 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” (2020 SNPRM proposed 40 CFR 30.2). In the 2020 SNPRM, the EPA also proposed definitions for “reanalyze” and “capable of being substantially reproduced” to further clarify the intent of the rulemaking.

In proposed 40 CFR 30.5, the EPA solicited public comment on two approaches for how the Agency would consider data and model availability when evaluating studies underlying pivotal regulatory science and pivotal science. Under the first approach, the Agency would have only used pivotal regulatory science or pivotal science where the underlying data and models were either publicly available for independent validation or, in the case of restricted data and models (e.g., those that include CBI, proprietary data, or personally identifiable information (PII) that

cannot be sufficiently de-identified to protect the data subjects), available through restricted access in a manner sufficient for independent validation. Under the second approach, the EPA would have, other things equal, given greater consideration to studies where the underlying data and models were either publicly available in a manner sufficient for independent validation or, in the case of restricted data and models, available through restricted access in a manner sufficient for independent validation. Proposed 40 CFR 30.9 would have allowed the EPA Administrator to grant an exemption to the requirements in proposed 40 CFR part 30 if the Administrator determined that compliance was impracticable because technological barriers rendered sharing of the data or models infeasible; the development of the data or model was completed or updated before the effective date of this final rule; or by making the data and models publicly available, it would have conflicted with laws governing privacy, confidentiality, CBI, or national security interests.

Finally, the EPA clarified in the 2020 SNPRM that it is authorized to promulgate this rulemaking under its housekeeping authority and revised the authority cited in proposed 40 CFR part 30 accordingly. The Agency solicited public comment on whether to use its housekeeping authority independently or in conjunction with the environmental statutory provisions cited as authority in the 2018 proposed rule, which were further clarified in the 2020 SNPRM.

III. Description of final rule and responses to significant comments

A. Purpose and effect of the action

1. *Purpose.* The EPA is committed to its mission of protecting human health and the environment through sound policy decisions that are informed by robust scientific and technical research. Because of the potential impact of the EPA's significant regulatory actions and influential scientific information on American lives and livelihoods, the American people

deserve environmental decisions and policies that are based on the best scientific information. Only through continuous improvement to its procedures, especially those focused on transparency, can the EPA fully demonstrate that commitment.

The purpose of this action is to increase transparency by codifying internal procedural requirements for how the EPA will consider the availability of the underlying dose-response data that it relies upon to promulgate significant regulatory actions and develop influential scientific information. These requirements build upon open data initiatives in the federal government and scientific community and advance the EPA's mission and commitment to the public by prioritizing transparency of the underlying dose-response data in pivotal science for the most impactful of EPA's assessments and regulatory actions. Where underlying dose-response data in pivotal science are available, subject matter experts could independently reanalyze the data to affirm original research conclusions, check for errors, test alternative assumptions, and better understand and evaluate the implications of the uncertainty used in the original analysis. Such independent reanalyses will subsequently enable the EPA to make stronger, data-driven decisions in future rulemakings or in revisions to existing rules or influential scientific information. This could occur through standard cyclical reviews (e.g., revisions to national ambient air quality standards, risk and technology reviews, national primary drinking water regulations), ad hoc revisions, or revisions through the information quality guidelines or other petition processes. Implementation of this rule will more effectively share pivotal science for external consideration and increase the opportunity for independent validation of pivotal science by subject matter experts. As data are better understood through independent reanalysis, the public will, if they so choose, be able to more effectively comment, engage, and hold the EPA accountable during the development of future significant regulatory actions and influential

scientific information.

The transparency provisions in this final rule are intended to build upon existing federal government efforts and provide incremental progress toward the Agency's goal of greater transparency. The EPA and the federal government have long encouraged open data initiatives, as the principle of transparency in regulatory decision-making and the other operations of government agencies is a fundamental behavior of good government that is inherently valuable to the public. For example, in 2002 the Office of Management and Budget (OMB) released its *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies*, which includes discussion of the importance of the reproducibility of analyses underlying influential information(Ref. 3). The EPA's 2016 *Plan to Increase Access to Results of EPA-Funded Scientific Research* noted that "transparency is a core EPA value" and that increased availability of research data would accelerate scientific breakthroughs that support the Agency's mission and policymaking efforts (Ref. 9). The EPA's *Open Government Plan 5.0* (Ref. 10) also details the EPA's progress in implementing the tenets of the numerous data transparency initiatives in the federal government prior to 2018, including the Office of Management and Budget (OMB) M-10-06 (Ref. 11), the Office of Science and Technology Policy Memorandum of February 22, 2013 (Ref. 12), and OMB M-13-13 (Ref. 4). In 2019, Congress passed the Foundations for Evidence-Based Policymaking Act of 2018 (or OPEN Government Data Act, Pub. L. 115-435) into law, which included requirements for federal agencies to prioritize making their data available to the public, and OMB has released additional guidance for implementing the act (Refs.13, 14).

The scientific community has also embraced greater data transparency, as evidenced by data sharing and availability requirements for many high-impact journals (Ref. 15) and the emergence

of organizations, such as the Center for Open Science, and international initiatives like Findable, Accessible, Interoperable, and Reusable (FAIR) data principles; Facilitate Open Science Training in European Research (FOSTER); and Guidelines for Transparency and Openness Promotion (TOP) in Journal Policies and Practices that incentivize greater transparency in research (Refs. 16, 17).

The EPA supports these efforts and is pursuing an incremental approach to maximizing transparency in the science that it relies upon to ensure that implementation is done in a thoughtful and deliberate way that focuses on the EPA's most impactful actions, minimizes unintended consequences, and informs future transparency requirements. As further described in Section II.B of this preamble, the EPA is focusing on the underlying dose-response data for this rulemaking because of the influence these data have on particularly impactful decisions at the Agency. Risk assessments and regulations that target emissions and risk reduction of one or more pollutants, contaminants, or substances are integral to the Agency's mission and the underlying dose-response data that inform the quantitative value used to evaluate and mitigate potential risk are critical to understanding the assessment or regulatory action. In addition, the data underlying the dose-response assessment are more distinct than the broad range of data informing an entire risk assessment. Therefore, the EPA is concentrating its current efforts to increase transparency on a well-defined step in the quantitative assessment of risk supporting specific Agency actions. This final rule provides an important step in furthering the progress already being made toward maximizing transparency and will provide important insight for developing future statute-specific requirements.

Most public commenters on the purpose of the 2018 proposed rule and the 2020 SNPRM supported the concept of greater transparency, but questioned the "problem" the EPA was trying

to fix. Other commenters indicated that it was not clear how greater data availability would fix these perceived problems, given what they asserted were limited detail in the proposed rule. Some public commenters and members of the EPA's Science Advisory Board (SAB) also suggested that issues related to transparency are or may be fixed with existing guidance, mechanisms, and other requirements. Other commenters questioned the motivation for the rulemaking, asserting that the rulemaking was the result of political interests, rather than scientific need; that it was biased to benefit industry; or that it was a deliberate attempt to suppress human health and climate studies. Some commenters contended that there was little evidence of a widespread reanalysis issue in science or, in particular, studies that would inform environmental policy. Other commenters contended that the rulemaking was at odds with the Agency's mission and would result in decreased environmental and human health protections. Some commenters asserted that the rule would lead to increased litigation and limit the public's trust in the EPA. Other commenters contended that the rule was inconsistent with practices in other federal agencies and may adversely impact other federal and state agencies that rely on EPA assessments.

Commenters supporting the rulemaking generally asserted that the greater transparency provided in the proposal and SNPRM was necessary and important for developing sound and scientifically robust regulations. Some commenters stated that transparency is a principle of good government. Some commenters noted specific benefits to greater transparency, including more effective public scrutiny and scientific debate, less political rhetoric, and clearer, more efficient regulations. Some commenters provided specific examples of EPA regulations or risk assessments that have relied on incorrect data or would have been improved with greater transparency. Other commenters contended that greater transparency was consistent or

complementary with research and publishing policies, federal government policies, and the scientific method, while other commenters asserted that the rule would be an important improvement to transparency at the EPA.

The EPA continues to believe that codifying internal procedures aimed at prioritizing transparency in significant regulatory actions and influential scientific information into regulation will improve the opportunity for the public to access the EPA's scientific analyses and resulting regulatory actions in a way that is beneficial to the scientific process, the Agency's mission, and the public's health and safety. This rule is designed to build upon OMB M-19-15 (Ref. 18), which highlights the need to characterize the sensitivity of an agency's conclusions to analytic assumptions, as well as other federal guidance documents that require greater data transparency (Ref. 18). The EPA's attention to data transparency is also responsive to the broader interest in greater data and model transparency observed in the numerous transparency initiatives in the scientific community and federal government, as well as the criticism the EPA has received from members of the public, scientific community, and Congress on the transparency of the scientific basis for EPA's decisions in previous influential scientific information assessments and regulatory actions (Refs. 19, 20, 21, 22, 23). The EPA's continued progress toward maximizing transparency is vital to building and maintaining trust with the public and credibility in the Agency's decisions.

The EPA disagrees with the contention that this rule is politically motivated, as transparency assumes no political ideology, nor is this rule likely to result in decreased human health or environmental protections, as the benefits of greater data transparency and the significance of reanalyzing and validating study results are well-documented in scientific literature. McNutt (2014) noted, "reproducibility, rigor, transparency, and independent verification are cornerstones

of the scientific method” (Ref. 24). The National Academies of Sciences, Engineering, and Medicine (NAS) workshop on Reproducibility and Replicability in Science also noted that “certainly, reproducibility and replicability play an important role in achieving rigor and transparency” (Ref. 16).⁸ Munafò et al. (2017) state, “the credibility of scientific claims is rooted in the evidence supporting them, which includes the methodology applied, the data acquired, and the process of methodology implementation, data analysis and outcome interpretation. Claims become credible by the community reviewing, critiquing, extending and reproducing the supporting evidence. However, without transparency, claims only achieve credibility based on trust in the confidence or authority of the originator. Transparency is superior to trust” (Ref. 25). The 2019 NAS workshop on Reproducibility and Replicability in Science also concluded, “the scientific enterprise depends on the ability of the scientific community to scrutinize scientific claims and to gain confidence over time in results and inferences that have stood up to repeated testing” (Ref. 16). Importantly, the workshop also concluded that researchers, funding institutions, and journals could make advancements to improve reproducibility, rigor, and transparency (Ref. 16).

The EPA agrees that data transparency is vital for individuals who have not contributed to the study to be able to verify the quality and strength of published studies and agrees with commenters that the opportunity to independently validate the pivotal science that the EPA relies upon is important in furthering scientific understanding and the Agency’s mission. A presenter in a 2016 NAS workshop on Principles and Obstacles for Sharing Data from Environmental Health Research stated more directly that “for environmental policy making to be legitimate, the

⁸ The NAS workshop on Reproducibility and Replicability in Science defines “reproducibility” to mean the extent to which a researcher can obtain consistent computational results using the same input data, computational steps, methods, code, and conditions of analysis. The use of “reproducibility” by the NAS is consistent with the intent of the use of “independent validation” in this rule.

scientific reasoning behind a given decision—including the data supporting it—must be transparent” (NAS Workshop Report, Ref. 26). When data are widely available, researchers can validate research results and help identify and correct unintended errors, as well as reanalyze the data for new and different purposes, examine novel questions, provide new scientific insights, and improve model development. In its April 24, 2020, letter to EPA Administrator Wheeler (Ref. 27), the EPA’s SAB noted that it

“recognizes the importance of this rule and its purpose, establishing transparency of the influential scientific information used for significant regulations and enhancing public access to scientific data and analytical methods to help ensure scientific integrity, consistency and robust analysis. Strengthening transparency by improving access to data can lead to an increase in the quantity and the quality of evidence that informs important regulatory and policy decisions. The scientific community is moving toward adopting the precept of sharing accurate data and information to increase credibility, high-quality outcomes and public confidence in science. The SAB supports the adoption of this precept.”⁹

The EPA also agrees with commenters that the scientific community and government agencies are making great strides in data transparency; however, improvements can still be made over existing policies and mechanisms. Many scientific publications, for example, require authors to make a data availability or data access statement, which discloses where and under what conditions the underlying study data are available. Yet the EPA cannot solely rely on data availability statements made in published research because initiatives toward greater data sharing and transparency amongst scientific journals and international organizations are still being implemented, are inconsistently enforced, and the true accessibility of data in a public repository is still limited (Refs. 28, 29, 30, 31, 32, 33). For example, Christensen et al. (2019) evaluated 1,072 peer-reviewed articles and “found that rates of data availability for empirical articles published after journals adopted data-sharing policies differ widely between journals, from 0

⁹ The SAB also provided several constructive comments and recommendations, which have been considered in the development of this final rule.

percent to 83 percent, with a mean of 35 percent” (Ref. 32). Stodden et al. (2018) noted they were only able to retrieve the dataset and code for 44 percent of the 204 computational studies published in *Science* in the 16 months after the publisher instituted its data availability requirements (Ref. 34). Therefore, the rule requirements for the EPA’s independent evaluation of the availability of data are necessary and critical to prioritizing data transparency in the pivotal science underlying its significant regulatory actions and influential scientific information.

Finally, focusing the final rule requirements on the underlying dose-response data is intended to address public comments concerning clarity of the rule, potential unintended consequences, and the potential for far-reaching impacts. The requirements provide a workable framework for evaluating pivotal science in the context of the availability of its underlying dose-response data, while balancing important technical considerations in order to ensure the Agency maintains a strong scientific basis for its decision-making. The incremental progress made possible by this rule provides an important step towards prioritizing transparency in particularly impactful EPA rules and assessments and will inform future statute-specific rulemakings.

2. Effect of this rule on the studies the EPA uses to support significant regulatory actions and influential scientific information. The EPA received significant comment on the effect of the 2018 proposed rule and 2020 SNPRM on the studies the Agency would be able to consider and use to support significant regulatory actions and influential scientific information. Many commenters asserted that the EPA’s action, if finalized, would limit the scientific studies the EPA could use because the EPA would exclude from consideration any studies where the underlying data and models could not be made publicly available or available in a manner sufficient for independent validation.

As discussed in Section III.B of this preamble, based on a consideration of the public

comments on the 2018 proposed rule and the 2020 SNPRM, the EPA is finalizing internal procedural requirements for how the Agency will consider the availability of underlying dose-response data of pivotal science when promulgating a significant regulatory action or developing influential scientific information that relies on dose-response data. The EPA is also further clarifying how the Agency will determine the consideration to afford to pivotal science in either significant regulatory actions or influential scientific information.

Consistent with existing Agency practice (Ref. 35), the EPA will review and evaluate all relevant scientific studies when developing significant regulatory actions and influential scientific information. The EPA will continue to use the following, established factors to assess the quality of studies used to develop significant regulatory actions and influential scientific information (Refs. 36, 37):

- Soundness – The extent to which the scientific and technical procedures, measures, methods or models employed to generate the information are reasonable for, and consistent with, the intended application.
- Applicability and Utility – The extent to which the information is relevant for the Agency’s intended use.
- Clarity and Completeness – The degree of clarity and completeness with which the data, assumptions, methods, quality assurance, sponsoring organizations and analyses employed to generate the information are documented.
- Uncertainty and Variability – The extent to which the variability and uncertainty (quantitative and qualitative) in the information or in the procedures, measures, methods or models are evaluated and characterized.
- Evaluation and Review – The extent of independent verification, validation and peer

review of the information or of the procedures, measures, methods or models.

When evaluating potential links between exposure to a pollutant, contaminant, or substance and effects and the nature of the dose-response relationship, the EPA will follow best practices and rely on the highest quality, most relevant studies in determining the potential for hazard due to exposure to a pollutant, contaminant, or substance. Where there is convincing and well-substantiated evidence (consistent with Agency guidelines on hazard identification and dose-response assessment) to support a relationship between exposure and effect, the EPA will identify a subset of those studies for use in characterizing the quantitative relationship between the amount of dose or exposure to a pollutant, contaminant, or substance and an effect. This will be based on the exposure situation being addressed, the quality of the studies, the reporting adequacy, and the relevance of the endpoints. From that subset, the specific dose-response studies or analyses that drive the requirements, quantitative analyses, or both will be identified as pivotal science (see Section III.E of this preamble).

Once the EPA has identified pivotal science—for either significant regulatory actions or influential scientific information—the EPA will then evaluate if the underlying dose-response data are available in a manner sufficient for independent validation. The EPA will give greater consideration to pivotal science for which the underlying dose-response data are either publicly available in a manner sufficient for independent validation or, in the case of PII, CBI, or proprietary data, available through restricted access that affords privacy in a manner sufficient for independent validation.

The EPA acknowledges, and agrees with commenters, that there may be pivotal science for which the underlying dose-response data are not publicly available due to technological feasibility or cannot be made available in a secure environment that still allows for independent

analysis. For example, dose-response data underlying older pivotal science may no longer be available or may not exist in a currently usable format. In these cases, the EPA may still use the pivotal science after either giving it lesser consideration or receiving an exemption from the requirements of this rule from the Administrator (see Section III.G of this preamble). See Section III.E of this preamble for a description of the factors the EPA will consider when determining the consideration to afford to pivotal science when the underlying dose-response data are not available for independent validation.

The EPA expects to identify pivotal science, and the consideration afforded to pivotal science, in proposed significant regulatory actions and external review drafts of influential scientific information, which will allow the subject matter experts, if they so choose, to independently validate the pivotal science and provide comment to the EPA. The EPA believes that this approach will allow the public to more effectively comment, engage, and hold the EPA accountable during the future development of specific significant regulatory actions and influential scientific information.

3. Effect of this rule on human health and environmental protection. Many commenters contended that the 2018 proposed rule and the 2020 SNPRM would prevent the EPA from meeting its statutory obligations and performing its mission of protecting human health and the environment. Some commenters asserted that, by excluding studies based on data availability, the EPA would develop regulatory decisions that are: (1) not based on high-quality studies or the best available science; and (2) potentially biased towards regulated parties. As a result, these commenters argued that human health and environmental protections would decrease. Several commenters contended that decreased human health and environmental protections would disproportionately affect communities of color, indigenous communities, and low-income

communities because these communities are more likely to live or work near sources of pollution.

The EPA considered these comments when finalizing this rule, and the EPA does not agree that its approach will lead to systematic bias towards certain types of stakeholder goals. As described above, the EPA is not categorically excluding any studies from consideration when promulgating significant regulatory actions or developing influential scientific information. Rather, the Agency will continue to evaluate the quality of all relevant studies, consistent with the intended use of the information. The EPA will also continue to rely on the highest quality, most relevant studies available in determining the potential for hazard due to exposure to a pollutant, contaminant, or substance.

When characterizing the quantitative relationship between the amount of dose or exposure to a pollutant, contaminant, or substance and an effect, the EPA will identify pivotal science and give greater consideration to pivotal science for which the underlying dose-response data are available in a manner sufficient for independent validation. Including this review of dose-response data availability for pivotal science is critical to the EPA's progress toward increased transparency and providing increased opportunity for scientific reanalysis and review by independent third parties. This approach will result in significant regulatory actions and influential scientific information that are based on high quality studies that maximize transparency, leading to human health and environmental protections consistent with the statutes the EPA administers.

In response to the 2018 proposed rule, the EPA received comments on perceived conflicts between the requirements included in the 2018 proposed rule and statutory requirements that direct EPA to consider certain data and information when developing Agency actions. For

example, some commenters contended that the requirements in the 2018 proposed rule conflicted with the FIFRA pesticide registration requirements and associated implementing regulations, which require registrants to submit data and information to the EPA to enable the Agency to make its unreasonable adverse effects determinations. These commenters argued that, under the 2018 proposed rule, the EPA would not be able to consider these data, which are often claimed as CBI, when evaluating the pesticide registrations because the data could not be made publicly available. In response to this comment and other similar comments, the EPA clarified in the 2020 SNPRM the relationship between this rulemaking, the environmental statutes and their implementing regulations by adding language to proposed 40 CFR 30.3 stating that statutory requirements and corresponding implementing regulations would control in the event of any conflicts.

With this final rule, the EPA is maintaining language from the 2020 SNPRM in 40 CFR 30.3 stating that statutory requirements and corresponding implementing regulations will control in the event of any conflict, and clarifying in this preamble that the requirements in this final rule set the overarching structure and principles for transparency in significant regulatory actions and influential scientific information. The EPA plans to promulgate either statute-specific transparency regulations or programmatic actions implementing this procedural rule, as appropriate, to clarify how the Agency will implement the provisions from this final rule for specific programs authorized under the statutes the EPA administers.

B. Dose-response data

The 2018 proposed rule focused on dose-response data and models, although not consistently. For example, some parts of the proposed regulatory text appear to limit applicability of certain provisions to only dose-response models. In others, the proposed

requirements would apply more broadly. Commenters noted this variability. As a result, in the 2020 SNPRM, the EPA proposed a consistent, broader applicability to data and models.

The EPA received significant comment on this proposed expansion of the applicability of the rulemaking to data and models. While some commenters supported this expansion, other commenters contended that the applicability to dose-response data and models was already very broad, and that the broader applicability would significantly limit the information that the EPA could consider in a broad ranges of assessments (e.g., bioaccumulation data, data on environmental releases, exposure estimates used by the EPA across the environmental statutes that it administers). Some commenters contended that the EPA did not provide sufficient rationale to support this expansion.

Based on the comments on the 2018 proposed rule and the 2020 SNPRM, taking into account the number of studies that would be subject to the rule, the EPA determined that the Agency should pursue an incremental approach to maximizing transparency in the science that it relies upon by focusing the final rule requirements on dose-response data and, in particular, only those studies that are integral to characterizing dose-response relationships (e.g., identifying candidate PODs). The EPA considered commenters' assertions that the scope of the 2018 proposed rule would be so broad as to make implementation infeasible. The 2018 proposed definition of "dose-response data and models" would apply to dose-response 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." This relationship of the dose-response data to the magnitude of a predicted health or environmental impact would require the consideration of an array of studies beyond those that characterize dose-response relationships, including, for example, studies that inform the dose-response modeling (e.g.,

benchmark response selection); studies that identify data for toxicokinetic adjustments that inform calculation of a human-equivalent point of departure (POD); and studies that inform the selection of uncertainty factors. The number of studies that are used to establish the relationship between dose-response data and models and the magnitude of a predicted health or environmental impact can potentially be very large. This may make implementing the rule, as proposed, more challenging for at least some significant regulatory actions and influential scientific information. While transparency in EPA decision-making is the purpose of this action, the EPA prefers an incremental approach. Rather than having this final rule apply to all the studies that support the assessment of the relationship of a dose or exposure of a pollutant, contaminant, or substance to the magnitude of a predicted health or environmental impact, the EPA is balancing transparency and feasibility by focusing on those studies that describe the quantitative relationship between the dose or exposure of a pollutant, contaminant, or substance and an effect. Specifically, the scope of dose-response data in this final rule is those studies consisting of the data integral to characterizing dose-response relationships. In some instances, this group will consist of a handful of studies. In other instances, where there are multiple toxicity endpoints, there may be more studies that are crucial to characterizing dose-response relationships. In some other cases, there may be a large number of studies that are used to characterize a dose-response relationship (e.g., where the dose-response is based on a meta-regression of epidemiology studies). However, not all of these studies would be considered pivotal science (see Section III.C.6 of this preamble for the definition of “pivotal science”).

Based on comments and other considerations, the EPA is concentrating its efforts in the final rule to increase transparency on dose-response data, as the dose-response data are discrete and the dose-response assessment is a well-defined and impactful step in the quantitative assessment

of risk. This final rule provides an important step in furthering progress toward maximizing transparency and will provide insight for future statute-specific requirements. Consistent with this targeted focus, the EPA is replacing the proposed definition of “dose-response data and models” at 40 CFR 30.2 with a definition of “dose-response data” (see Section III.C of this preamble).

C. Definitions

The 2018 proposed rule included proposed definitions for “dose-response data and models,” “pivotal regulatory science,” “regulatory decisions,” “regulatory science,” and “research data.” Some commenters stated that several of the proposed definitions were unclear, including some that seemed to overlap (e.g., “pivotal regulatory science” and “regulatory science”). Some commenters also stated that certain terms used in the proposed regulatory requirements were not clear and should be defined.

In response to these comments on the 2018 proposed rule, the EPA proposed in the 2020 SNPRM definitions for “capable of being substantially reproduced,” “data,” “independent evaluation,” “models,” “publicly available,” and “reanalyze.” In the 2020 SNPRM, the EPA also proposed a definition of “influential scientific information” to comport with the proposed expansion of the applicability of the rulemaking to influential scientific information.

Based on a consideration of the public comments on both the 2018 proposed rule and the 2020 SNPRM, the EPA is finalizing the definitions at 40 CFR 30.2 as follows.

1. *Capable of being substantially reproduced, independent validation, and reanalyze.* In the 2018 proposed rule, the EPA used the term “replicate” in the proposed regulatory text at 40 CFR 30.5 but did not define it at 40 CFR 30.2. Proposed 40 CFR 30.5 read, 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....” Some commenters contended that the EPA was not clear about what it meant by the term “replicate” and interpreted the term “replicate” in several different ways. For example, some commenters asserted that the EPA used the term “replicate” but actually meant “reanalyze.” The EPA finds that these comments have merit and is clarifying that the intent of the term in the proposed regulatory text at 40 CFR 30.5 was “reanalyze” rather than “replicate.” In the 2020 SNPRM, the EPA proposed using the term “reanalyze” instead of “replicate” and proposed at 40 CFR 30.2 a definition for “reanalyze.” Given that proposed 40 CFR 30.5 also included the term “independent validation” and that this term directly relates to “replicate,” the EPA also proposed a definition at 40 CFR 30.2 for this term. The proposed definition of “independent validation” included the term “capable of being substantially reproduced.” The EPA also defined this term because it was an important component of the definition of “independent validation.”

While commenters generally supported the inclusion of the proposed definitions for “capable of being substantially reproduced,” “independent validation,” and “reanalyze,” some commenters addressed aspects of the proposed definitions and suggested modifications. One commenter suggested replacing the term “validation” with “verification” because they asserted the term “validation” has specific meanings in the context of assay development and in the context of model development. The EPA understands that the term validation is used differently in some scientific disciplines than the EPA has defined it. However, for the purposes of this rule, the EPA has defined validation in terms of independent reanalysis.

Another commenter contended that the proposed definition of “independent validation” was inconsistent with the remainder of the proposal because it restricts the concept of “independent

validation” to “subject matter experts who have not contributed to the development of the study,” rather than the public as was the stated intent of the rule. Because this rule is about scientific data, the EPA finds it unlikely that without the necessary expertise, one could reasonably reanalyze the dose-response data underlying pivotal science. This final rule does not preclude the public from engaging subject matter experts to determine whether a study can be independently validated. Also, the definition cannot be considered solely in isolation. The regulatory text in which the term is used informs the extent of the availability of dose-response data underlying studies. Specifically, 40 CFR 30.5 requires, in part, that the dose-response data underlying studies that the EPA will consider as pivotal science be available in a manner sufficient for independent validation. Scientific information is considered available in a manner sufficient for independent validation when it includes the information necessary to understand, assess, and reanalyze findings. The efficacy of the reanalysis will depend on the expertise of the person conducting the reanalysis.

One commenter noted that the term “reproduced” in the proposed definition of “capable of being substantially reproduced” and the use of “capable of being substantially reproduced” in the proposed definition of “independent validation,” were inconsistent with the description of reproduce in the 2020 SNPRM preamble and the NAS Workshop Report (Ref. 26). The commenter contended that this adds confusion. Another commenter asserted that there is insufficient guidance or standards for what the term “substantially” means or who will make the determination (e.g., scientific staff with oversight of an EPA scientific advisory panel). Another commenter stated that there were inconsistencies with the proposed definitions for the terms “capable of being substantially reproduced” and “reanalyze.” Commenters asserted that the former proposed definition specifies the use of “identical methods,” whereas the latter proposed

definition specifies the use of the “same or different” methods.

The EPA finds that these comments have merit. The EPA is modifying the definition of “independent validation” in the final rule by replacing “capable of being substantially reproduced” with “produced.” The EPA will not finalize the proposed 40 CFR 30.2 definition of “capable of being substantially reproduced” because the term is not used in the final rule’s definition of “independent validation” or elsewhere in 40 CFR 30. As a result, “substantially” will not need to be defined or described in the final rule. The EPA is also modifying the definition of “reanalyze” to specify the use of the same methods because as proposed it specified the use of the “same or different” methods. This change was made so that the definition would be consistent with the final rule’s definition of “independent validation.”

2. *Data and models.* In the 2020 SNPRM, the EPA proposed a definition of “data” in response to comments on the 2018 proposed rule, contending that a definition for this term was needed to clarify the applicability of the rulemaking. Commenters requested that the EPA clarify which stage of data would need to be available to allow for independent validation. The stage of data that the EPA identified in the proposed 40 CFR 30.2 definition of “data” is based on the discussion of the different stages of data in the NAS Workshop Report (Ref. 26). The 2020 SNPRM adapted the description of the stage of data from the NAS Workshop Report (Ref. 26) that was data at the appropriate level of detail to allow for independent validation via reanalysis.

Several commenters asserted that the proposed definition of “data” was so broad that it could include potentially any information. One commenter contended that as published scientific results are often the final steps in a process involving several processing and analysis steps, the proposed definition of “data” definition did not identify what intermediate step of data processing would be subject to this rule. The commenter noted that determining which of the

multiple data processing and analysis steps that should be used would differ from study to study. Another commenter suggested that the EPA should identify the actual final dataset used in statistical analysis as the appropriate stage of data to be made available.

As the EPA described in the 2020 SNPRM, there are different stages of data. The EPA presented the different stages described in the NAS Workshop Report (Ref. 26), “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.” Since the purpose of 40 CFR 30.5 is to determine the consideration to afford to studies based on, among other factors, the availability of the underlying dose-response data that would support independent validation via reanalysis of the data underlying pivotal science, the appropriate stage of data would not be the processed data (data that have been computed and analyzed to extract relevant information) or the final clean data set that is provided with a publication. At these two stages of data, the analysis has already been conducted, and the results have already been determined. In order to determine if these results are valid, data that had not already been computed and analyzed are needed.

In this final rule, the EPA is not identifying a specific step in a multi-step analysis as the stage of data that would be sufficient for independent validation through reanalysis because this would be overly prescriptive and not informative. As noted by commenters, the step at which the final clean data set will be generated will vary from study to study. The level of detail required would be that needed for a separate party to reanalyze the study. The appropriate step is where the data are ready to be analyzed to extract relevant information.

One commenter requested that the EPA introduce and define a new term, “validated data,” which are the data with the proper level of quality assurance. While the EPA routinely conducts quality assurance to ensure that data are acceptable for use, the EPA does not see the need to create a separate definition. The focus of this rulemaking is the independent validation of the results of studies underlying pivotal science, not the quality assurance of the data itself.

Some commenters contended that the EPA should define “data” as the raw data in which obvious errors have not been removed. Other commenters stated that raw data in which obvious errors have not been removed would result in skewed analyses for third parties not familiar with the data collection process. Given concerns about potentially skewed analyses, the final definition of “data” maintains the stage of data in which obvious errors have been removed.

Some commenters also requested that the EPA define “model” to clarify the applicability of the rulemaking. In the 2020 SNPRM, the EPA proposed a definition of “model” at 40 CFR 30.2, but the Agency is not finalizing the definition of “model” because this regulation applies only to dose-response data (see Section III.B of this preamble).

3. *Dose-response data.* In the 2018 proposed rule, the EPA proposed a definition of “dose-response data and models.” The EPA did not receive significant comment on the definition of “dose-response data and models” itself. However, as discussed in Section III.B of this preamble, this final rule applies to dose-response data, and thus the EPA is not finalizing a definition for “dose-response data and models.” Rather, consistent with the applicability of this final rule, the EPA is finalizing a definition of “dose-response data” that is specific to the relationship between a dose or exposure and an effect.

4. *Influential scientific information.* In the 2020 SNPRM, the EPA proposed expanding the scope of the 2018 proposed rule to include influential scientific information and proposed to

define “influential scientific information” as “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,” consistent with the definition of “influential scientific information” provided in the OMB Final Information Quality Bulletin for Peer Review (Ref. 8).

The EPA received public comments in support of and against the Agency’s proposed 40 CFR 30.2 definition of “influential scientific information.” Some commenters believed that the proposed definition was too broad to be useful and, as a result, would apply to all scientific documents produced by the EPA. Other commenters believed that the proposed definition was too narrow and would not adequately capture the types of information that may be considered influential.

The EPA finds that these comments have merit, in part. The definition of “influential scientific information” at proposed 40 CFR 30.2 in the 2020 SNPRM is the same definition as in the OMB Final Information Quality Bulletin for Peer Review (Ref. 8). The EPA proposed to adopt this definition because it intended the scope to be consistent with how that term has been interpreted and applied in the context of peer review.¹⁰ Given that the definition is both established and has been routinely applied by the EPA, the EPA disagrees with the suggestion that the term is inherently too narrow or too broad. Rather than modify the proposed 40 CFR 30.2 definition of “influential scientific information,” the EPA is modifying 40 CFR 30.3 in the final rule to clarify the Agency’s intent that the requirements in 40 CFR 30.3 apply to influential scientific information, unless the influential scientific information is exempted from peer review requirements as described in Section IX of the OMB Final Information Quality Bulletin for Peer

¹⁰ For example, see the Environmental Protection Agency Annual Report on Peer Review Fiscal Year 2017 (October 1, 2016 – September 30, 2017) that the Agency submitted to OMB, <https://cfpub.epa.gov/si/EPA%20FY%202017%20Annual%20Peer%20Review%20Report.pdf>. Each annual report identifies influential scientific information and highly influential scientific assessments.

Review (Ref. 8). Consistent with this approach, the EPA is finalizing the definition of “influential scientific information” as proposed in the 2020 SNPRM.

5. *Pivotal science.* In the 2020 SNPRM, the EPA introduced the term “pivotal science,” defined in proposed 40 CFR 30.2 as “the specific scientific studies or analyses that underly [sic] influential scientific information.” This term was proposed as a parallel to “pivotal regulatory science,” defined in 40 CFR 30.2 of the 2018 proposed rule as “the specific scientific studies or analyses that drive the requirements and/or quantitative analysis of EPA significant regulatory decisions.”

The EPA received comment on the use of “regulatory” in “pivotal regulatory science.” Some commenters contended that there is no such thing as science that is regulatory; rather, there is science used to support regulation. Some commenters also noted that the terms “pivotal science” and “pivotal regulatory science” have similar scopes.

The EPA acknowledges that no scientific study is inherently regulatory; rather, the EPA uses science to inform its significant regulatory actions. In order to increase the clarity of this final rule, to take into account the similarities between the two definitions, and to more accurately describe the science that the EPA uses, the EPA is removing the term “pivotal regulatory science” and combining the definitions of “pivotal science” and “pivotal regulatory science” under the single term “pivotal science” in 40 CFR 30.2. The EPA is responding to comments on both terms together.

Some commenters noted that the scope of studies that could be considered “pivotal science” was unclear but appeared broad. Some commenters argued that since properly conducted science reviews the entire body of scientific evidence, nearly any study evaluated could be considered “pivotal science.” The EPA’s SAB suggested that the Agency clarify whether “pivotal science”

refers to all the hazard characterization and dose-response models that the EPA evaluates and captures in its analysis (Ref. 27). Other commenters asserted that if the EPA interprets “pivotal science” broadly to include all studies involved in the development of significant regulatory actions or influential scientific information, implementing this rule would be infeasible.

As discussed in Section III.B of this preamble, the EPA finds merit in comments that the proposed definition for “pivotal science” appeared too broad to feasibly implement in this rule. Because of the EPA’s commitment to basing its decisions on sound science, the EPA may review several hundred or thousands of scientific studies in the development of significant regulatory actions or influential scientific information. As such, the EPA agrees that determining data availability for all the studies EPA considers in significant regulatory actions and influential scientific information may be infeasible at this time. Future statute-specific rulemakings may be more expansive as the EPA continues to make incremental progress toward maximizing transparency.

Further, although this rulemaking does not require reanalysis of a study’s underlying data, the EPA finds that limiting the scope of “pivotal science” will still provide meaningful and impactful opportunity for reanalysis. Lewandowsky et al. (2020) evaluated the cost-effectiveness of reanalysis studies under various scenarios and concluded that reanalysis studies are most cost-effective when they are focused on studies of the greatest interest to the scientific community (in this study, the number of citations was a surrogate for interest) (Ref. 38). This finding is consistent with results in other studies that found and encouraged narrowing the focus of attempted reanalysis studies to those studies of greater significance (Refs. 37, 39, 40, 41).

In this final rule, rather than considering all studies that support the assessment of the relationship of a dose or exposure of a pollutant, contaminant, or substance to the magnitude of a

predicted health or environmental impact as “pivotal science,” the EPA is balancing transparency and feasibility by focusing on those studies that inform the quantitative relationship between the dose or exposure of a pollutant, contaminant, or substance and an effect. Thus, “pivotal science” includes only those studies that are integral to characterizing dose-response relationships (e.g., identifying candidate PODs). These are the studies that drive the requirements or quantitative analyses of EPA significant regulatory actions or influential scientific information. Although this rule takes an incremental approach and therefore does not include studies informing the dose-response modeling (e.g., benchmark response selection), studies identifying data for toxicokinetic adjustments, or studies informing the selection of uncertainty factors do not drive the requirements or quantitative analyses of EPA significant regulatory actions or influential scientific information. Future statute-specific rulemakings may interpret “pivotal science” more broadly.

This clarified definition of “pivotal science” in the final rule is also responsive to the SAB’s comments that pivotal science should be more focused (Ref. 27). Consistent with the intent of this rulemaking, the EPA intends to clearly identify the studies considered pivotal in the documentation at the proposed rule stage for significant regulatory actions and when influential scientific information is disseminated for peer review.

Some commenters also expressed confusion regarding how “pivotal science” relates to “best available science.” One commenter recommended that if this rulemaking is intended to alter the EPA’s definition and use of the best available science, the EPA should issue further guidance for public comment. To be clear, this rulemaking is not intended to modify the Agency’s interpretations of “best available science.” The EPA will continue to consider all peer-reviewed science, consistent with existing study quality assessment factors and corresponding statutory

mandates. The EPA will then identify and consider “pivotal science in accordance with the provisions of this rule,” unless the implementation of the rule conflicts with statutory requirements and associated implementing regulations.

6. *Publicly available.* In the 2018 proposed rule, the EPA used the term “publicly available,” but did not propose a definition at 40 CFR 30.2 or describe it in the preamble to the 2018 proposed rule. Some commenters on the 2018 proposed rule asked the EPA to explain what it meant by the term. In the 2020 SNPRM, the EPA proposed a definition for “publicly available” at 40 CFR 30.2.

One commenter stated that the proposed definition was vague because it did not make clear whether the study data itself would proactively be made available to members of the public by data holders in government sources, media sources, or other online sources. The definition is not intended to describe the mechanism for making the information available (i.e., whether the information is made available proactively or is made available upon request). Rather, the definition describes whether, given the nature of the information, it can be, must be, or is already generally available (i.e., where the information can be made lawfully available from government records, is required to be made available by government law or regulation, or is information that is widely available to the general public).

Another commenter requested that the EPA consider data and models to be publicly available when they are available through restricted access when the data includes CBI, proprietary data, or PII that cannot be sufficiently de-identified to protect the data subjects. The EPA disagrees with the commenter. The plain meaning of “publicly available” does not include availability through restricted access to data that includes CBI or PII because there are laws that preclude the disclosure of CBI or PII to those not authorized for its access. Thus, the general public cannot

access the un-sanitized CBI data or non-anonymized PII data in a manner that will allow for independent validation through reanalysis. If the public cannot access such data, it is not publicly available.

Several commenters contended that the proposed definition of “publicly available” would introduce a bias favoring industry data submitted to the EPA. They asserted that industry-generated studies submitted to the EPA pursuant to FIFRA would be considered publicly available because they could be obtained by the public in response to a Freedom of Information Act (FOIA) request. However, this does not mean that these are immediately or easily available to the public. Some commenters cited the EPA’s *Freedom of Information Act Annual Report Fiscal Year 2019* (2020), which lists a median response time for “expedited processing” of FOIA requests by the EPA as 493 days (Ref. 42). The EPA finds that such comments have merit and is modifying the definition in the final rule to add the following at the end of the definition: ““the public must be able to access the information on the date of publication of the proposed rule for the significant regulatory action or dissemination of the draft influential scientific information for public review and comment.”

7. *Research data.* Proposed 40 CFR 30.2 in the 2018 proposed rule included a definition of “research data.” In the 2020 SNPRM, the EPA deleted the proposed definition of “research data.” While one commenter on the 2020 SNPRM noted that the exclusions in the proposed definition of “research data” of trade secrets and personal and medical information were not incorporated into the proposed definition of “data,” commenters did not request that the EPA maintain a definition of “research data.” The EPA is not including a definition of “research data” in this final rule given that it is finalizing the definition of “data.”

8. *Significant regulatory actions.* In the 2018 proposed rule, the EPA defined the term

“regulatory decisions” as final regulations determined to be significant regulatory actions under Executive Order (E.O.) 12866, *Regulatory Planning and Review*. Some commenters stated that the use of regulatory decisions was confusing given that the term was only intended to apply to a subset of regulations. The EPA agrees with these comments, and to clarify the definition, the Agency is changing the term from “regulatory decisions” to “significant regulatory actions” in the final rule.

9. *Science that serves as the basis for informing a significant regulatory action.* In the 2018 proposed rule, the EPA proposed to define the term “regulatory science.” A number of commenters expressed confusion over both the meaning and scope of this proposed term. One commenter noted that other federal agencies have defined “regulatory science.” For example, the U.S. Food and Drug Administration (FDA) has described “regulatory science” as “the science of developing new tools, standards, and approaches to assess the safety, efficacy, quality, and performance of all FDA-regulated products” (Ref. 43). This commenter suggested that a simplified definition would be “regulatory science consists of the scientific segment of the regulatory process.” The EPA acknowledges that the term “regulatory science” may be confusing because it suggests either that the term refers to a scientific discipline of regulatory decision-making (akin to FDA’s description), or that the EPA considers some science inherently regulatory. Neither of these interpretations reflects the Agency’s intent in defining this term. The EPA considers the breadth of scientific evidence in its rulemakings; while this scientific evidence informs policy decisions, the EPA’s consideration of the science does not make it “regulatory science.” To reflect this fact, in the final rule the EPA is changing the proposed term “regulatory science” to “science that serves as the basis for informing a significant regulatory action.”

In the 2018 proposed rule, the EPA defined regulatory science as “scientific information, including assessments, models, criteria documents, and regulatory impact analyses, that provide the basis for EPA final significant regulatory actions.” Several commenters claimed that this definition was vague and without discernable meaning. The EPA disagrees with the assertion that the proposed definition was without meaning, but in response to comments is altering the final definition to increase clarity. For example, the EPA notes that the proposed definition for “regulatory science” combined both general categories of scientific information, such as assessments and models, with specific examples of EPA scientific products, such as criteria documents and regulatory impact analyses. The EPA acknowledges that this may increase confusion and is therefore limiting the final definition to general categories. As such, the EPA is altering the definition of “science that serves as the basis for informing a significant regulatory action” in 40 CFR 30.2 to mean “studies, analyses, models, and assessments of a body of evidence that provide the basis for EPA significant regulatory actions.” Examples of models include those used in regulatory impact analyses. Examples of assessments of a body of evidence include risk assessments, hazard identifications, Integrated Risk Information System (IRIS) assessments, and criteria documents.

Other commenters expressed confusion over the scope of what constitutes science that serves as the basis for informing a final significant regulatory action, as defined in the proposed rule. One commenter asserted that the phrase “provides the basis” means that science that serves as the basis for informing a final significant regulatory action could be all the science considered, relied upon, and included in the administrative record of a rulemaking by the EPA. The EPA agrees with this and clarifies in the final rule that the scope of science that serves as the basis for informing a significant regulatory action is equivalent to the science included in the public

docket as part of a rulemaking, but not all of that body of science would typically be considered “pivotal science.”

D. Applicability of the rule

In the 2018 proposed rulemaking, the EPA proposed to apply the requirements of this rulemaking on significant regulatory decisions. The EPA then solicited comment on whether the requirements of this rulemaking should apply to (1) other stages of the rulemaking process; (2) a narrower scope of coverage; and (3) certain categories of regulatory actions, such as individual party adjudications, enforcement activities, or permit proceedings or other agency actions. In the 2020 SNPRM, the EPA proposed to expand the applicability of this rulemaking to include influential scientific information.

The EPA received significant comment on the proposed applicability of this rulemaking to significant regulatory decisions and influential scientific information. Some commenters supported the proposed applicability, while other commenters disagreed with it.

A few commenters addressed the potential for expansion or narrowing of the scope of the rule to include other actions in addition to final significant regulatory decisions and influential scientific information. Of the few commenters that explicitly addressed potential expansion beyond the proposed rulemaking, a majority focused on recommendations to include the science underlying Integrated Science Assessments (ISAs) and IRIS assessments. A few commenters expressed support to expand the proposed rulemaking to include one or more of the following: TSCA risk evaluations; CERCLA remedial actions; RCRA corrective actions; as well as assessments and actions under the CWA. Additional comments recommended expansion of the scope of the proposed rulemaking to include enforcement and permitting actions, as well as agency guidance documents. Some commenters supported applying the requirements of this

rulemaking to proposed rules and advance notices of proposed rulemakings. Other commenters specifically opposed expanding the proposed rulemaking to include the aforementioned actions. Additionally, some commenters recommended narrowing the scope to only rulemakings subject to the Congressional Review Act or economically significant regulatory actions under E.O. 12866 (i.e., those rules that “have an annual effect on the economy of \$100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities”).

Some of the assessments that commenters suggested should be subject to the requirements of this rulemaking are categorized as influential scientific information. The EPA notes that many assessments categorized as influential scientific information support rulemakings and other actions under several environmental statutes that the EPA administers. For example, the ISA for lead and the IRIS assessment for trichloroethylene have been used in a variety of actions (including those that are not significant regulatory actions) under TSCA, RCRA, and the CAA. IRIS assessments are routinely used under the CAA, RCRA, and CERCLA. By finalizing the scope rule to include influential scientific information, the Agency is applying the applicability of the rule to an important category of scientific assessments that influence a wide range of EPA regulatory actions.

The EPA sees no need to include the proposed rule stage of final significant regulatory actions in the regulatory text because as a practical matter proposed rules must comply with this final rule before being finalized. As a general matter, the EPA does not introduce the studies and analyses it relies on for a rulemaking at the final rule stage. The scientific basis for a rulemaking is provided for public review and comment in the public docket when the proposed rule is issued

or, if subsequently added to the docket, through a separate opportunity for public comment. Advance notices of proposed rulemakings are not consistent with the purpose of this rule, given their preliminary nature and frequent focus on soliciting comments on a regulatory issue or approach.

Transparency is important in ensuring that the decisions the EPA makes are based on sound science. The EPA is finalizing the applicability of this rule to significant regulatory actions and influential scientific information because of the potential broad impact of these actions and assessments on American lives and livelihoods. The EPA is not applying this rulemaking to permit proceedings, site-specific actions, or enforcement actions because these actions are typically focused on individual regulated entities.

E. Availability of dose-response data

In the 2018 proposed rule, the EPA proposed to require at 40 CFR 30.5 that “[w]hen promulgating final 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.” The EPA received a large number of comments stating that the approach in the 2018 proposed rule would likely preclude the use of valid data and models from consideration as pivotal science. The comments indicated that the proposed requirement to ensure data and models are publicly available in a manner sufficient for independent validation would prevent the use of data and models that include CBI, proprietary data, and PII that cannot be sufficiently de-identified to protect the data subjects, as well as many older studies. In response to such comments, in the 2020 SNPRM, the EPA proposed a modified version of the 2018 proposed regulatory text at 40 CFR 30.5. Proposed 40 CFR 30.5 would allow agency consideration of studies with restricted 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 were to be used as pivotal regulatory science or pivotal science. In the 2020 SNPRM, the EPA also proposed an alternative. Under the alternative 40 CFR 30.5 proposal, when promulgating significant regulatory decisions or developing influential scientific information, the Agency would, 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 the 2020 SNPRM, the Agency proposed that in developing the final significant regulatory decision or influential scientific information, the EPA would identify those studies that were given greater consideration and provide a short description of why and how greater consideration was given.

A few commenters contended that 40 CFR 30.5 as proposed in the 2018 proposed rule was superior to proposed 40 CFR 30.5 in the 2020 SNPRM and the alternative proposed 40 CFR 30.5 in the 2020 SNPRM. The commenters asserted that privacy or confidentiality should not have priority over transparency. They further asserted that the approaches in the 2020 SNPRM would impose substantial limits on the effect of the rule since privacy, confidentiality, and restricted access are all concepts and practices that inhibit full transparency.

Some commenters supported the categorical approach taken in proposed 40 CFR 30.5 in the 2020 SNPRM in which pivotal science would need to be available for independent validation. A few commenters suggested that it be expanded to apply to all studies, not only those that are pivotal science. Other commenters contended the proposed 2020 SNPRM approach was flawed because it would exclude from consideration valid scientific studies for which the underlying

data at the stage required by this regulation are unavailable, regardless of whether the studies have been peer reviewed or would be considered part of the “best available science” under the environmental statutes that EPA administers that require the use of “best available science.” These commenters stated that such a categorical exclusion is inconsistent with current scientific standards and the requirements of the environmental statutes that the EPA administers. Other commenters noted that there are a variety of reasons, including the age of a study, why the underlying data at the stage required by this rulemaking would not be available, publicly or otherwise, for independent validation.

Some commenters supported and other commenters opposed alternate proposed 40 CFR 30.5 in which the Agency would, all else being equal, give greater consideration to studies where the underlying data and models are available in a manner sufficient for independent validation. Some commenters stated that this was a reasonable way to consider transparency because studies would be assessed on a case-by-case basis and valid studies would not be categorically excluded. Other commenters did not support alternate proposed 40 CFR 30.5 because they contended there is no scientific justification for a rule that directs the EPA to selectively give greater consideration to certain studies over others based on data availability.

Upon consideration of the comments, the EPA agrees that it is important not to categorically exclude any study because the data underlying a study at the stage required by this rulemaking may not be available for independent validation. Therefore, the EPA is not finalizing the primary proposal in the 2020 SNPRM that would have categorically required that for studies to be considered pivotal science, the underlying data would need to be available for independent validation. However, given that transparency is an important aspect of EPA’s regulatory actions and assessments, it should be an important consideration in how the Agency considers pivotal

science. As described in 40 CFR 30.5 of the final rule, the EPA will rely on the highest quality, most relevant studies available in determining the potential for hazard due to exposure to a pollutant, contaminant, or substance. Where there is convincing and well substantiated evidence to support a relationship between exposure and effect, the EPA will identify those studies—based on the exposure situation being addressed, the quality of the studies, the reporting adequacy, and the relevance of the endpoints—that would inform a dose-response assessment for those effect endpoints. From that subset, the specific dose-response studies or analyses that drive the requirements or quantitative analyses of an EPA significant regulatory action or influential scientific information will be identified as pivotal science.

Further, the EPA is finalizing the approach that gives greater consideration to pivotal science whose underlying dose-response data are publicly available or available through restricted access. Restricted or tiered access in this final rule means that the underlying dose-response data are available through a data sharing mechanism, such as through an agreement with the originating author or institution, access to a refined or redacted dataset that anonymizes the more sensitive portions of the analyzable dataset, a restricted access data repository or secure data enclave, or some other mechanism (e.g., Data Use Agreements) that allows a qualified subject matter expert access to enough data to support independent validation while still protecting sensitive information.

Some commenters argued that the EPA did not sufficiently explain how it will identify “pivotal science.” For example, one commenter stated that the EPA did not explained what it means for a study to “underly” [sic] influential scientific information or to “drive the requirements” of final significant regulatory actions. Some commenters on the 2018 proposed rule asked for the EPA to clarify in what stage of the review process the Agency would identify

pivotal science. In the 2020 SNPRM, the EPA explained, “under this [proposed] 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.” In response to the 2020 SNPRM, one commenter suggested the EPA provide a transparent explanation of how and why studies are determined to be pivotal science over others. A commenter also argued that if the EPA interprets “pivotal science” narrowly (i.e., not as all the studies included in the weight of evidence), this would introduce risk of selecting “pivotal science” in a biased manner without sufficient accountability. Another commenter recommended that the EPA establish criteria for designating studies as pivotal science.

The EPA disagrees with the proposition that designating a set of key studies as “pivotal science” will necessarily be biased or without accountability. The EPA follows an objective, unbiased process for identifying and evaluating scientific studies and already identifies key or pivotal studies in some of its actions (e.g., IRIS assessments). The EPA intends to issue implementation guidelines and statute-specific rulemakings that will further describe these criteria and how the EPA will identify pivotal science in its assessments and rulemakings. In general, the EPA will rely on the highest quality, most relevant studies available in determining the potential for hazard due to exposure to a pollutant, contaminant, or substance. Where there is convincing and well substantiated evidence to support a relationship between exposure and effect, the EPA will identify a subset of those studies based on the exposure situation being addressed, the quality of the studies, the reporting adequacy, and the relevance of the endpoints that would inform a dose-response assessment for those effect endpoints and drive the

requirements and/or quantitative analyses of an EPA final significant regulatory action or influential scientific information will be identified as pivotal science.

Further, the EPA intends to promulgate regulations under the environmental statutes that the EPA administers to further clarify how the Agency will apply the definition of “pivotal science” in specific programs authorized under those statutes (e.g., CAA, CWA, SDWA, RCRA, FIFRA, TSCA, EPCRA). The specific criteria for determining “pivotal science” may necessarily be specific to the authorizing statute, as well as the significant regulatory action or the influential scientific information. The EPA intends to explain in each significant regulatory action and for influential scientific information how the pivotal studies were identified.

In response to comments on the meaning of “drive the requirements and/or quantitative analysis,” these are the studies that are integral to quantitatively characterizing dose-response relationships for the toxicity endpoints that underlie the requirements or analyses of EPA significant regulatory actions or influential scientific information. The EPA may further interpret the meaning of “drive,” and describe the process for designating key studies as pivotal science in subsequent implementation guidelines and/or statute-specific rulemakings.

Some commenters stated that the EPA did not explain what was meant by “other things being equal.” Some of these commenters requested clarity on what factors in addition to transparency would be considered. Some specific suggestions from commenters include that EPA should give consideration to quality studies that evaluate a range of models, that are scientifically sound for the intended use, and that have study “characteristics (e.g., sample size, confidence intervals of results, or overall methods validity) [that] may compensate for any lack of full transparency.” In consideration of these and other public comments, the EPA developed additional factors that clarify specific technical factors that it may consider in balancing study quality and data

availability. Although the EPA is prioritizing transparency in pivotal science, the Agency also recognizes that there will be instances where the underlying dose-response data of pivotal science is unavailable for independent validation. In order to ensure that the Agency maintains a strong scientific basis for its decision-making, the availability of underlying dose-response data should be considered as long as other significant technical considerations can provide some level of certainty or confirmation of a study's conclusions, importance, and applicability, even in the absence of maximum transparency. Though EPA's list of factors herein is not exhaustive or exclusive, the EPA has identified several factors in 40 CFR 30.5(d) that balance some of the important technical considerations the EPA will consider in addition to data availability and that are particularly relevant to the stage of the analysis where dose-response data are used. These factors are intended to assist the EPA in determining the consideration to afford to pivotal science with underlying dose-response data that are not available for independent validation. The final rule requirements and the consideration of these factors apply to any data used in characterizing the relationship between the amount of dose or exposure to a pollutant, contaminant, or substance and an effect, regardless of the direction of that effect. Because study quality factors (including soundness, applicability and utility, clarity and completeness, uncertainty and variability, and evaluation and review) would have already been evaluated at an earlier stage in the assessment process (see 40 CFR 30.5(b)), the EPA envisions that at the stage of the evaluation that utilizes the factors described in 40 CFR 30.5(d), the studies to be evaluated would generally be of the highest quality available.

Some of the factors in 40 CFR 30.5(d) are intended to be evaluated for pivotal science with underlying data that are not available for independent validation relative to pivotal science with underlying data that are available for independent validation. For example, when assessing

studies, the EPA may determine that greater consideration should be given to a study with underlying data that are unavailable for independent validation when that study is of higher quality compared to a medium-quality study with underlying data that are available for independent validation (factor 1), the conclusions of the significant regulatory action or influential scientific information are or are not highly sensitive to the exclusion of the study for which the underlying data are not available for independent validation (factor 3), the study with data unavailable for independent validation was better fit for the purpose of the EPA assessment (factor 4), or the results of the study for which the underlying data are not available are supported by other scientific evidence, such as mechanistic data (factor 6).

Importantly, the factors in 40 CFR 30.5(d) do not apply to other stages in the assessment process (although they are relevant to determining whether to grant an exemption under 40 CFR 30.7, as further explained below). For example, the consideration for exposures that were conducted at more environmentally relevant exposure concentrations (factor 5) does not suggest that epidemiological studies will automatically be given greater weight than laboratory studies. The EPA will continue to use established guidelines for identifying and integrating evidence and will use the factors in 40 CFR 30.5(d) only when evaluating the data availability requirements of this rule (or when determining whether to grant an exemption under 40 CFR 30.7, as further explained below). In addition, not all of these factors will be applicable to all studies or assessments. For example, some pollutants, chemicals, or substances may have unique scientific considerations (factor 7), such as the valence state of a metal compound or endogenous contributions to internal concentrations, that may not be relevant for other pollutants, chemicals, or substances. Therefore, the weight afforded to each factor by the EPA may vary by assessment, and how those factors were considered will be documented in the assessment. If two studies, one

with and one without available data and are relatively equal with respect to the study quality factors in 40 CFR 30.5(b), the study where the underlying data is available will be given greater consideration and the weight of the other study will be based on an assessment of the factors in 40 CFR 30.5(d). In this way, the EPA will balance the importance of transparency with the need to maintain a strong scientific basis for its assessments.

This final rule requires the consideration of the factors in 40 CFR 30.5(d) when assessing pivotal studies for which the dose-response data are not available for independent validation. The EPA may adapt these factors in upcoming statute-specific rulemakings, as appropriate, for significant regulatory actions under the different environmental statutes that the EPA administers. How scientific information is to be considered varies among the different environmental statutes and sometimes within an individual statute. Interpretation of the assessment factors will be tailored to the specific circumstances and the specific environmental statutes.

Some commenters asserted that the 2018 proposed rule and the 2020 SNPRM failed to explain how historical data, which may have been collected under different policies and procedures, will be treated. These commenters noted that underlying dose-response data may have been lost for older studies due to record retention schedules. Some commenters also contended that a significant amount of work would be required to locate, curate, and retrospectively make datasets available for public access.

The EPA intends to determine the extent of the consideration that should be given to pivotal studies lacking available data on a case-by-case basis. The EPA will consider the circumstances specific to each such study when it applies the factors listed in 40 CFR 30.5(d) to that study. The age of the data is not a consideration under 40 CFR 30.5(d), but could be the basis for an 40 CFR

30.7 exemption request.

Some commenters stated that the EPA should not have the rulemaking apply retrospectively to studies given the potential difficulty accessing, reviewing, and making data available that were not originally intended to be disseminated, as would be required by this rulemaking. These commenters requested that the EPA apply the rulemaking provisions only to data and models underlying studies generated after the promulgation of this rule.

This final rule applies prospectively to significant regulatory actions and influential scientific information and has no retrospective effect on existing (i.e., completed) significant regulatory actions or influential scientific information. For future, significant regulatory actions and influential scientific information, the final rule applies equally to all dose-response data underlying studies used as pivotal science, regardless of when the study or the data was created. Scientific transparency is important regardless of the age of the study or the dose-response data.

Some commenters contended that a substantial amount of work would be required in order to make data underlying studies available for independent validation, but that the EPA has not identified a responsible party for this work, nor has it made clear the timelines, electronic data sharing mechanisms, or how public reporting of such availability would be achieved, archived, and maintained over time. The EPA would like to emphasize that this final rule does not impose requirements on any entity outside of the EPA. This is a rule of internal procedures and does not direct or require any outside entity or the EPA to establish data sharing mechanisms. Further, the final rule does not require the EPA to collect, store, or publicly disseminate dose-response data underlying pivotal science.

Some commenters asserted that reproducing findings across similar studies is more informative than reanalyzing the data from a single study. Such commenters noted that

confidence in the study findings is best gained when different groups are studying the same thing or are conducting similar studies. They asserted that the study results could then be averaged, compared, and further analyzed. One commenter noted that the ability to reanalyze the data from a study with very poor scientific quality does not strengthen the quality of the study.

Commenters contended that reproducing studies (i.e., producing something that is very similar to that research, but it is in a different medium or context) is generally viewed as a more informative and resource efficient approach to validation of research than reanalyzing the data of a particular study. Some commenters contended that reanalysis of the data and models underlying studies is not how to determine the quality of a study; rather, there are other key aspects of studies that are integral to assessing the quality of a study.

Other commenters supported the proposed requirement for independent validation by reanalysis of data and models underlying studies because they believe this is key to determining whether the science is accurate and of high quality. Some commenters contended that by reanalyzing the underlying data and models, independent researchers can evaluate the myriad of choices and assumptions the original researchers have made regarding the data and statistical models and the potential introduction of any sources of bias.

While the availability of dose-response data underlying a study in a manner sufficient for independent validation is an important component of determining the level of consideration to afford a study, the EPA agrees that availability by itself is not sufficient to determine study quality. As explained in 40 CFR 30.5(b), the EPA will use existing factors (including soundness, applicability and utility, clarity and completeness, uncertainty and variability, and evaluation and review) to evaluate study quality. Subsequently, after identifying the highest quality, most relevant studies that would inform a dose-response assessment and identifying the availability of

pivotal science, the EPA would consider the additional applicable factors in 40 CFR 30.5(d) when determining the level of consideration to give pivotal science where the underlying dose-response data are not available for independent validation. Further, although the EPA agrees with commenters that meaningful insights can be obtained through similar studies in different media or context, the EPA continues to find that independent validation of the study findings and conclusions driving the EPA's dose-response assessments would provide important information. As detailed in Section III.A.1 of this preamble, there is scientific support for the usefulness of reanalyzing data, and the EPA finds this to be especially true for data that drive the quantitative requirements or analyses of EPA significant regulatory actions or influential scientific information. Implementation of this rule will increase transparency and, thus, the opportunity for independent subject matter experts to validate pivotal science, and as the dose-response data are better understood the public will, if they so choose, be able to more effectively comment, engage, and hold the EPA accountable during the development of future significant regulatory actions and influential scientific information.

F. Proposed 40 CFR 30.6

In the 2018 proposed rule, the EPA proposed requirements at 40 CFR 30.6 specific to dose-response data and models. These proposed requirements directed the EPA to describe and document the assumptions and methods it used; to evaluate the appropriateness of using default assumptions, including assumptions of a linear, no threshold dose-response; to explain the scientific basis for each model assumption used; and to show the sensitivity of the modeled results to alternative assumptions. These proposed requirements also directed the EPA to give explicit consideration to high quality studies that explore a broad class of parametric dose-response models, non-parametric models that incorporate fewer assumptions, various threshold

models, and models that investigate factors that might account for spatial heterogeneity.

The EPA received significant comment on the 2018 proposed rule regarding the proposed 40 CFR 30.6 requirement that the EPA evaluate the appropriateness of using default assumptions, “including assumptions of a linear, no threshold dose-response.” The vast majority of commenters asserted that the EPA should not focus the requirement to evaluate the appropriateness of using default assumptions specifically on linear, no threshold dose-response. In the 2020 SNPRM, in response to these comments, the EPA proposed a variation of the regulatory text which did not include the phrase “including assumptions of a linear, no threshold dose-response,” because this could imply that the regulation is specific to those particular assumptions.

The EPA also received significant comment on the 2018 proposed rule about the proposed 40 CFR 30.6 requirement to clearly explain the scientific basis for each model assumption used and to present analyses showing the sensitivity of the modeled results to alternative assumptions. Most commenters contended that such a requirement would be overly burdensome and unnecessary. They recommended that the EPA should present sensitivity analyses only on the most significant assumptions.

Considering these comments, in the 2020 SNPRM, the EPA clarified that the use of the terms “model assumptions,” “assumptions” and “models” in the proposed regulatory text at 40 CFR 30.6 apply to the critical assumptions that drive the model’s analytic results, not to each assumption used in the model. The EPA’s proposed revision of the 40 CFR 30.6 regulatory text reflected this clarification.

After considering comments on both the 2018 proposed rule and the 2020 SNPRM, the EPA has determined that this rule should apply to dose-response data rather than dose-response data

and models. Given the specificity of 40 CFR 30.6 to dose-response data and models, and in particular dose-response models, the EPA is not finalizing 40 CFR 30.6. The EPA is adapting one provision of 40 CFR 30.6 as a factor in 40 CFR 30.5 in determining the consideration to afford pivotal science for which the dose-response data are not available for independent validation. Specifically, the EPA is finalizing as a factor in 40 CFR 30.5 the consideration that the EPA would give to high quality studies that explore a broad class of parametric dose-response models, non-parametric models that incorporate fewer assumptions, various threshold models, and models that investigate factors that might account for spatial heterogeneity.

Further, because the EPA is not finalizing any part of the provision that is specific to assumptions and methods associated with dose-response models, comments on the proposed requirements related to these issues are moot. However, while the EPA is not finalizing the provisions in 40 CFR 30.6 that include the term uncertainty, the EPA is responding to these comments because the term uncertainty is used in 40 CFR 30.5. The EPA is also responding to comments on the proposed 40 CFR 30.6 provision incorporated as part of 40 CFR 30.5.

Some commenters contended that the EPA's use of the term "uncertainty" at 40 CFR 30.6 is vague. A few other commenters contended that the EPA should include specific requirements in 40 CFR 30.6 as to the scope of an analysis of uncertainty. The EPA disagrees with the suggestion that the term "uncertainty" is vague or that there is significant ambiguity about what should be in the scope of a characterization of uncertainty. The characterization of uncertainty is a key factor in the assessments that the EPA conducts. It is a component of various EPA guidelines (e.g., *Framework for Human Health Risk Assessment to Inform Decision Making*, Ref. 36) that the EPA relies upon in conducting its assessments. The scope of the uncertainty analyses that the EPA conducts necessarily varies across assessments and actions. The intent of this

regulation is not to force uncertainty analyses into a one-size-fits-all approach, as that is not practical, good policy, or good science. Thus, a regulation of internal procedures, such as this one, does not require a regulatory definition for a term that is already a key component of current EPA practices and guidelines and EPA's assessment process.

Several commenters contended that the proposed 40 CFR 30.6 requirement that the EPA give explicit consideration to high quality studies that explore a broad range of parametric dose-response or concentration-response models and to non-parametric models that incorporate fewer assumptions could force the EPA into situations in which it applies dose-response model(s) that are not appropriate for the data being assessed. The EPA notes that the final regulatory text in 40 CFR 30.5 does not require that a specific type of dose-response model be applied to a particular situation. Rather, in determining the consideration to afford pivotal science for which the dose-response data are not available for independent validation, the EPA will evaluate, as appropriate, the extent to which the study considered a broad range 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.

G. Administrator's exemption

In the 2018 proposed rule, the EPA proposed that the Administrator could grant case-by-case exemptions to the requirements in proposed 40 CFR part 30 when compliance with those requirements is impracticable (proposed 40 CFR 30.9). In the 2020 SNPRM, the EPA modified proposed 40 CFR 30.9 to be consistent with other changes proposed in the 2020 SNPRM, such that the Administrator could grant case-by-case exemptions to the requirements in proposed 40

CFR part 30 under specific conditions for which compliance with the requirements in proposed 40 CFR part 30 is impracticable.

Some commenters supported the Administrator's exemption provision in proposed 40 CFR 30.9 while others opposed it. Commenters expressing support for the exemption provision noted that exemptions may be needed to account for lawful and reasonable restrictions on underlying data and models. Commenters expressing opposition to the exemption provision raised concerns about the Administrator granting exemptions from the requirements in proposed 40 CFR part 30. These commenters contended that the Administrator may lack the scientific expertise to make the appropriate exemption decisions and that the Administrator, as a political appointee, could be biased. Some public commenters recommended that the exemption process require formal consultation with EPA career scientists, the EPA's SAB, or another Agency advisory committee.

The EPA also received comment on the following proposed conditions under which the Administrator could grant an exception in the 2020 SNPRM: technological barriers render sharing of the data or models infeasible; the development of the data or model was completed or updated before the effective date of the final rule; or making the data and models available would conflict with laws governing privacy, confidentiality, CBI, or national security. Some commenters supported the condition that would allow the Administrator to grant an exemption based on the age of a study, noting that older studies may not have been conducted with the intention of providing access to underlying data and models for independent validation, particularly at the stage of data and models proposed in the 2020 SNPRM. Other commenters opposed this condition, contending that exempting studies based on the age of the study is unnecessary and undermines the goal of increasing transparency in the development of

regulatory decisions. Some commenters noted it may be prohibitively expensive for researchers to make their data and models available.

The EPA finds that these comments have merit, in part. The Agency agrees with retaining the Administrator's exemption provision because there are conditions under which compliance with the requirements in 40 CFR part 30 might be impracticable. For example, the underlying dose-response data for some studies, particularly older studies, may not be readily publicly available because of the technological barriers to data sharing (e.g., differences in data storage devices or data retention practices) that existed when they were developed. As a result, the EPA is finalizing the Administrator's exemption provision as proposed in the 2020 SNPRM, with additional conditions described here. Due to other changes described in this preamble, the Administrator's exemption provision, which was previously in 40 CFR 30.9 in the 2018 proposed rule and the 2020 SNPRM, is now 40 CFR 30.7 in the final rule.

The EPA does not agree with the comments regarding the role of the Administrator in determining whether to grant an exemption and finds that the Administrator is the appropriate decision maker in this context. To ensure that the Administrator's decision is appropriately transparent, in the final rule the EPA has included a provision in 40 CFR 30.7 that requires the Agency to document the rationale for any exemptions granted by the Administrator in the significant regulatory action or influential scientific information. This documentation would typically be provided as part of the proposed rulemaking, given that it would be part of the decision concerning what is the pivotal science for the rule. Regardless of what is provided in the proposed rule stage of the rulemaking, the final rulemaking will provide clear documentation.

Some commenters and the EPA's SAB (Ref. 27) also requested that the EPA include criteria that the Administrator will consider when determining whether to grant exemptions from the

requirements in 40 CFR part 30. The EPA finds that these comments have merit and is including additional criteria in 30 CFR 30.7 that may be used by the Administrator when he or she is determining whether greater consideration should be afforded to pivotal science for which the underlying dose-response data are not available in a manner sufficient for independent validation. As a result, the Administrator may also determine that greater consideration is warranted when a third party has independently validated the underlying dose-response data through reanalysis or when the EPA's evaluation of the factors in 40 CFR 30.5(d) indicate that full consideration of the pivotal science is justified.

To assist the Administrator in determining whether to grant an exemption, the EPA program or Region responsible for the significant regulatory action or influential scientific information and public commenters can provide input when the Administrator is considering an exemption. The EPA will document the rationale for the Administrator's exemption in the significant regulatory action or influential scientific information. The EPA is confident that the above criteria provide sufficient clarity and boundaries for the Administrator to consider when granting an exemption under 40 CFR 30.7.

H. Peer review

In the 2018 proposed rule and the 2020 SNPRM, the EPA proposed to require independent peer review on pivotal regulatory science and pivotal science. The EPA also proposed to require that the Agency ask peer reviewers to opine on the strengths and weaknesses of the EPA's justifications for the assumptions used in models.

Some commenters on the 2018 proposed rule and 2020 SNPRM specifically asked why the EPA would need to peer review health and scientific studies and scientific literature that had already undergone independent peer review. They stated that the EPA failed to explain why

existing peer review requirements and mechanisms are insufficient. Such commenters also noted that in addition to being duplicative and unnecessary, the proposed requirement would cause unnecessary delays in the EPA actions and would result in increased costs for the Agency. One commenter noted that the EPA already has policies in place for peer review and referred to the EPA's Peer Review Handbook (Ref. 44). Another commenter stated that, while it is certainly best practice to consider only science that has been independently peer reviewed when making regulatory decisions, that does not necessitate independent peer review by the EPA. The commenter noted that most scientific bodies and publications – including *Nature*, *Science*, the Bipartisan Policy Center, and *Proceedings of the National Academy of Sciences* – employ some of the most robust peer review practices and that they already apply to the types of studies which the proposed rule would require the EPA to peer review anew. Some commenters also stated that the proposed peer review requirements specific to assumptions used in models suggest that the 40 CFR 30.7 regulatory text would require that the EPA conduct peer review of the proposed Agency action itself, rather than of the science underlying that action. One of the commenters contended that it is entirely unclear how peer review could be applied to EPA's reasoning itself, rather than the pivotal science supporting the regulatory decision.

The EPA finds that these comments have merit, in part. However, in this rule, the EPA is not changing the pre-existing requirements of the OMB Final Information Quality Bulletin for Peer Review (Ref 8). The preamble of the Bulletin states that “the intensity of peer review is highly variable across journals” and “prior peer review and publication is not by itself sufficient grounds for determining that no further review is necessary” (Ref. 8). Peer review does not typically include reanalysis of the underlying data (i.e., the proper stage of data where the data that are ready to be analyzed to extract relevant information) and, thus, peer review is not

considered a replacement for the data availability requirements of this rule.

The EPA is, therefore, finalizing the language at 40 CFR 30.6 (formerly 40 CFR 30.7 in the 2018 proposed rule and the 2020 SNPRM) to clarify that the Agency will evaluate whether or not to initiate peer review, consistent with the OMB Final Information Quality Bulletin for Peer Review (Ref. 8) and the EPA's Peer Review Handbook (Ref. 44), of individual studies identified as pivotal science if the studies have already undergone journal peer review. If the Agency conducts peer review on pivotal science, the EPA shall ask peer reviewers to articulate the strengths and weaknesses of the justification for the assumptions applied in analyzing dose-response data and the implications of those assumptions for the results.

I. Changes to 40 CFR 30.4 "What requirements apply to EPA's use of studies in significant regulatory actions?"

In the 2018 proposed rule, the EPA proposed to require at 40 CFR 30.4 that "EPA shall clearly identify all studies (or other regulatory science) relied upon when it takes any final action. The EPA should make all such studies available to the public to the extent practicable." Some commenters expressed concern that proposed 40 CFR 30.4 would permit the Agency to exclude valid studies from consideration on the basis of the availability of underlying data or models. Another commenter noted that this section would apply to any final agency action, rather than regulatory decisions. In response to these comments, the EPA notes that this section does not require the EPA to exclude studies from consideration when developing final significant regulatory actions either on the basis of the availability of underlying data or models, or depending on the practicability of making these studies available to the public.

The EPA agrees with the commenter that the scope of 40 CFR 30.4 should be limited to significant regulatory actions, which are defined in 40 CFR 30.2 as "final regulations determined

to be ‘significant regulatory actions’ by the Office of Management and Budget pursuant to Executive Order 12866.” The EPA is finalizing additional changes to the title and body of 40 CFR 30.4 by using terms defined in 40 CFR 30.2. In the title of 40 CFR 30.4, the EPA is replacing “taking final action” with “significant regulatory actions” to improve clarity and specificity, since the latter term is defined. In the body of 40 CFR 30.4, the EPA is replacing “all studies (or other regulatory science) relied upon when it takes any final agency action” with “science that serves as the basis for informing a significant regulatory action” to improve specificity, since the latter language is defined; replacing “should” with “shall;” “studies” with “science that serves as the basis for informing a significant regulatory action” to improve specificity, since the latter term is defined; and “available to the public” with “publicly available” to improve specificity, since the latter term is defined. Together, these changes are meant to clarify that the requirements of 40 CFR 30.4 are consistent with the EPA’s existing practice of making science that serves as the basis for informing a significant regulatory action available in the public docket as part of the rulemaking.

J. Benefits and costs

In the 2018 proposed rule, as part of its E.O. 12866 and E.O. 13563 reviews, the EPA stated that the benefits of the proposal justify the costs. The EPA’s rationale was that the rule would facilitate expanded data sharing and exploration of key data sets, improve the ability to independently validate analyses underlying significant regulatory actions, and would be implemented in a cost-effective way. The 2020 SNPRM did not provide additional characterizations of benefits and costs. A number of commenters noted that the EPA did not provide an economic assessment to support the Agency’s benefit-cost claims. Commenters also noted that the EPA did not characterize costs to the Agency, including administrative costs to

ascertain the public availability of underlying data, costs for additional analyses required, and costs to ensure that PII and CBI are not disclosed. Other commenters noted that the EPA had not adequately explained the benefits of this rule, including enabling increased secondary analyses by third party researchers.

The EPA agrees that neither the 2018 proposed rule nor the 2020 SNPRM included a characterization of costs to the Agency. The EPA emphasizes that this is a rule of internal procedure promulgated under the EPA's housekeeping authority. However, the EPA has identified some incremental costs that the Agency may incur as a result of this final rule. As stated in Section III.A.2 of this preamble, the EPA will continue its current practice of conducting extensive review of scientific studies during the development of significant regulatory actions and influential scientific information. The additional procedures required by this rule apply only to pivotal science, which is a subset of the total number of studies that the EPA would evaluate. Given the costs of the current robust process for identifying and reviewing scientific studies and documentation that are existing Agency practice, as well as that the determination of dose-response data availability is limited to pivotal science underlying significant regulatory actions and influential scientific information, the EPA anticipates that the incremental costs of this rule will be small. The Agency may also incur other administrative costs to perform analyses and evaluations to support activities such as exemption decisions made by the Administrator, and documenting these or other decisions made pursuant to the requirements of the final rule. Again, the Agency anticipates that the incremental costs for these activities will be small relative to current administrative costs for developing significant regulatory actions or influential scientific information. Finally, this final rule does not require the EPA to disclose or host data, but to determine if dose-response data are available and to give

greater consideration to those studies for which such data are available. Hence, this rule does not impose costs on the EPA or any other party to make data available, including costs to ensure that PII and CBI are not disclosed. The Agency may opt, at its discretion, to incur the costs associated with making data available when it is in the public interest to do so, but that will be decided on a case-by-case basis and is not a requirement of the final rule.

The EPA also agrees that the benefits of the rule were not fully characterized in the 2018 proposed rule or the 2020 SNPRM. The EPA emphasizes, however, that this is a rule of internal procedure promulgated under the EPA's housekeeping authority. As discussed in Section III.A.1 of this preamble, the main benefits of this rule spring from greater transparency in significant regulatory actions and influential scientific information. By placing greater emphasis on the availability of dose-response data underlying pivotal science, the rule will allow for greater scientific scrutiny as EPA decision makers are developing significant regulatory actions and influential scientific information and increases the likelihood that any errors will be identified and corrected. Greater transparency is also inherently valuable as a principle of good government and provides benefits to the public at large, including reducing the risk of errors in EPA analyses and in the science such analyses rely upon. The ability for independent subject matter experts to validate pivotal science will facilitate more effective comment and engagement with the public during development of future significant regulatory actions and influential scientific information.

Some commenters further argued that the EPA failed to account for costs external to the EPA as consequence of this rule, including costs to third party researchers and their institutions to make their raw data available and protect PII/CBI through data-masking, de-identification, or deposition in public data repositories. The EPA disagrees with the argument that this rule would impose costs on third-party researchers. This is a rule of internal procedure that does not impose

requirements on any party other than the EPA. This rule imposes no costs on researchers or their institutions, and the EPA will consider and evaluate all relevant and appropriate science in its significant regulatory actions and influential scientific information. The EPA recognizes that researchers and other third parties may voluntarily consider the EPA's position on data availability, as described in this rule, as they make their own decisions about how to conduct research and the extent to which they make data and models available. Researchers may choose to make more data and models available, but the EPA recognizes that these parties will weigh their own benefits and costs and make choices that they deem appropriate.

Some commenters argued the 2018 proposed rule and the 2020 SNPRM would impose costs on third parties because it would prohibit the EPA from using necessary science where the underlying data and models are not publicly available, which would prevent the EPA from meeting its statutory obligations and performing its mission of protecting human health and the environment. Some commenters also contended that the proposed rule requirements would impose costs to the public by delaying EPA regulatory actions that protect human health and the environment.

As described earlier, the EPA acknowledges and agrees with commenters that there may be pivotal science where the underlying data are not publicly available or available through restricted access. The final rule is limited to dose-response data and, as no studies are categorically excluded from consideration, the EPA will continue to rely on the full body of the highest quality, most relevant studies available in determining the potential for hazard due to exposure to a pollutant, contaminant, or substance. Consistent with the requirements of this rule, the EPA will identify a subset of those studies based on the exposure situation being addressed, the quality of the studies, the reporting adequacy, and the relevance of the endpoints that would

inform a dose-response assessment, and will give greater consideration to pivotal science for which the underlying dose-response data are available. The EPA disagrees with commenters that the requirements of this rule will result in any meaningful delay in promulgating regulations. While this final rule requires the Agency to evaluate the availability of dose-response data for pivotal science, the incremental burden to the Agency to carry out these requirements is expected to be small given (1) the extensive scientific review the EPA already conducts regularly and (2) that the requirement is limited to pivotal science (i.e., typically a small, though highly important, subset of the studies the EPA would review). Further, with this final rule, the EPA is maintaining language in 40 CFR 30.3 stating that the statutes that the EPA administers, or their implementing regulations, will control in the event of any conflicts with the requirements of this rule. The Agency will continue to comply with and abide by the requirements in those statutes and implementing regulations, including regulatory deadlines.

K. Proposed 40 CFR 30.8 “How is EPA to account for cost under this subpart?”

In 2018, the EPA proposed in 40 CFR 30.8 that “EPA shall implement the provisions of this subpart in a manner that minimizes costs.” A number of commenters argued that this statement was vague and that the 2018 proposed rule neither explained what costs this rule would incur, nor how they would be minimized. One commenter further raised concern that, in order to minimize costs, proposed 40 CFR 30.8 may require the EPA to exclude valid data from consideration rather than take potentially expensive steps to protect CBI, proprietary data, and PII. Still other commenters interpreted proposed 40 CFR 30.8 as requiring the EPA to base its final significant regulatory actions and influential scientific information on cost. Commenters expressed concern that this would be at the exclusion of considerations such as the best available science and public health. A commenter further argued that the EPA does not have the statutory

authority to base its assessment of science on cost without consideration of public health and environmental costs and benefits and privacy-related costs and benefits, and that doing so would be irrational and arbitrary.

As explained in Section III.J of this preamble, this rule of internal procedure is anticipated to incur small incremental costs related to the additional review of data availability, as compared to the Agency's existing costs for extensive review and documentation as part of the development of significant regulatory actions and influential scientific information. In consideration of the public comments, however, the EPA is not finalizing proposed 40 CFR 30.8 "How is EPA to account for cost under this subpart?" This rule is not intended to require the EPA to exclude valid data from consideration on the basis of cost, nor interpret the EPA's statutory authority to consider costs in significant regulatory actions or influential scientific information. Given the EPA's existing commitment to fulfill its duties in a cost-effective manner, the EPA has determined not to finalize proposed 40 CFR 30.8.

IV. 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.

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44. U.S. EPA. (2015). Peer Review Handbook, 4th Edition. (EPA/100/B-15/001). Washington, DC: U.S. Environmental Protection Agency. *Available at* https://www.epa.gov/sites/production/files/2020-08/documents/epa_peer_review_handbook_4th_edition.pdf.

V. Statutory and Executive Orders 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. The EPA does not anticipate that this rulemaking will have an economic impact on regulated entities.

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

This action is not subject to Executive Order 13771 because this final rule is a rulemaking of agency organization, procedure, or practice.

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” within the meaning of Executive Order 13211. It is not likely to have a significant adverse effect on the supply, distribution or use of energy, and it has not otherwise been designated as a significant energy action by the

Administrator of the Office of Information and Regulatory Affairs (OIRA).

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.

L. Congressional Review Act (CRA)

This rule is exempt from the CRA because it is a rule of agency organization, procedure or practice that does not substantially affect the rights or obligations of non-agency parties.

List of Subjects in 40 CFR Part 30

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

Andrew Wheeler, Administrator.

For the reasons set forth in the preamble, the EPA is adding 40 CFR part 30 to read as follows:

**PART 30—TRANSPARENCY IN SIGNIFICANT REGULATORY ACTIONS AND
INFLUENTIAL SCIENTIFIC INFORMATION**

1. Add part 30 to read as follows:

**PART 30— TRANSPARENCY IN SIGNIFICANT REGULATORY ACTIONS AND
INFLUENTIAL SCIENTIFIC INFORMATION**

Sec.

30.1 What is the purpose of this part?

30.2 What definitions apply to this part?

30.3 How do the provisions of this part apply?

**30.4 What requirements apply to the EPA’s use of studies in significant
regulatory actions?**

**30.5 What requirements apply to the EPA’s use of dose-response data underlying
pivotal science?**

30.6 What role does independent peer review have in this part?

30.7 May the EPA Administrator grant exemptions to this part?

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

§ 30.1 What is the purpose of this part?

This part directs the EPA to give greater consideration to pivotal science when the underlying dose-response data are available in a manner sufficient for independent validation.

§ 30.2 What definitions apply to this part?

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.

Dose-response data means the data used to characterize the quantitative relationship between

the amount of dose or exposure to a pollutant, contaminant, or substance and an effect.

Independent validation means the reanalysis of study dose-response data by subject matter experts who have not contributed to the development of the study to evaluate whether results similar to those reported in the study are produced.

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.

Pivotal science means the specific dose-response studies or analyses that drive the requirements or quantitative analyses of EPA significant regulatory actions or 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. The public must be able to access the information on the date of publication of the proposed rule (or, as appropriate, a supplemental notice of proposed rulemaking, or notice of availability) for the significant regulatory action or on the date of dissemination of the draft influential scientific information for public review and comment.

Reanalyze means to analyze exactly the same dose-response data to determine whether a similar result emerges from the analysis by using the same methods, statistical software, models, or statistical methodologies that were used to analyze the dose-response data, as well as to assess potential analytical errors and variability in the underlying assumptions of the original analysis.

Science that serves as the basis for informing a significant regulatory action means studies, analyses, models, and assessments of a body of evidence that provide the basis for EPA

significant regulatory actions.

Significant regulatory actions means final regulations determined to be “significant regulatory actions” by the Office of Management and Budget pursuant to Executive Order 12866.

§ 30.3 How do the provisions of this part apply?

The provisions of this part apply to science that serves as the basis for informing a significant regulatory action or influential scientific information, as well as to dose-response data underlying pivotal science, regardless of the source of funding or identity of the party conducting the science. The provisions of this part apply to significant regulatory actions for which a proposed rule was published in the Federal Register after **[INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER]** and influential scientific information submitted for peer review after **[INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

The provisions of this part do not apply to physical objects (like laboratory samples), drafts, and preliminary analyses, and influential scientific information or pivotal science that meet one or more of the exemptions identified in Section IX of the OMB Final Information Quality Bulletin for Peer Review. In the event the procedures outlined in this part conflict with statutes the 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, site-specific actions, or permit proceedings.

§ 30.4 What requirements apply to the EPA’s use of studies in significant regulatory actions?

The EPA shall clearly identify the science that serves as the basis for informing a significant

regulatory action. The EPA shall make all such science that serves as the basis for informing a significant regulatory action publicly available to the extent permitted by law.

§ 30.5 What requirements apply to the EPA's use of dose-response data underlying pivotal science?

(a) When promulgating a significant regulatory action or developing influential scientific information that relies on dose-response data, the Agency shall follow best practices to evaluate potential links between exposure to a pollutant, contaminant, or substance and the effect and the nature of the dose-response relationship.

(b) The EPA will use the following factors to assess the quality of studies identified in the systematic review: soundness, applicability and utility, clarity and completeness, uncertainty and variability, and evaluation and review. The EPA will rely on the highest quality, most relevant studies in determining the potential for hazard due to exposure to a pollutant, contaminant, or substance. Where there is convincing and well-substantiated evidence of a relationship between exposure and effect, the EPA will identify those studies based on the exposure situation being addressed, the quality of the studies, the reporting adequacy, and the relevance of the endpoints that would inform a dose-response assessment for those effect endpoints. From that subset, the specific dose-response studies or analyses that drive the requirements, quantitative analyses, or both of an EPA significant regulatory action or influential scientific information will be identified as pivotal science.

(c) The EPA shall give greater consideration to pivotal science where the underlying dose-response data are publicly available in a manner sufficient for independent validation. The Agency shall also give greater consideration to pivotal science based on dose-response data that include confidential business information, proprietary information or personally identifiable

information if these data are available through restricted access in a manner sufficient for independent validation. For pivotal science where there is no access to dose-response data, or access is limited, the Agency may still consider these studies but will give them lesser consideration unless the Administrator grants an exemption under 40 CFR 30.7. The Agency will identify the pivotal science that was given lesser consideration and provide a short description of why lesser consideration was given.

(d) In determining the degree of consideration to afford pivotal science for which the dose-response data are not available for independent validation, the EPA shall consider the following factors and any other relevant factors, as applicable:

- (1) The quality of the study relative to other studies for which the dose-response data are available;
- (2) The extent to which there are other studies for which the dose-response data are available;
- (3) The sensitivity of the conclusions in the significant regulatory action or influential scientific information based on the use of the study;
- (4) The extent to which the study is fit for the purpose or intended use relative to other pivotal science for which the dose-response data are available;
- (5) The use of exposures or doses in a range and duration that is relevant for the intended use and that minimizes the need for extrapolations;
- (6) The extent to which the study is supported by other scientific evidence;
- (7) The extent to which the study accounted for unique scientific considerations;
- (8) The extent to which the study minimizes the use of defaults and assumptions, uses appropriate and strong statistical methods, and includes a robust representation of

uncertainty and confidence intervals; and

- (9) The study's consideration of a broad range 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.

(e) The EPA shall also describe critical assumptions and methods used in its dose-response assessment and shall characterize the variability and uncertainty of the assessment. The EPA shall evaluate the appropriateness of using default assumptions on a case-by-case basis. The EPA shall clearly explain the scientific basis for critical assumptions used in the dose-response assessment that the EPA relied on for the significant regulatory action or influential scientific information.

(f) Where the Agency is making dose-response data 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 security. Dose-response data is considered "publicly available in a manner sufficient for independent validation" when it includes the information necessary for the public to understand, assess, and reanalyze findings and may include, for example:

- (1) Data (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.

(g) The provisions of this section apply to dose-response data underlying studies that are

pivotal science, regardless of who funded or conducted the studies. 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 security is not possible.

§ 30.6 What role does independent peer review have in this part?

The EPA shall conduct independent peer review consistent with the requirements of the OMB Final Information Quality Bulletin for Peer Review and the exemptions described therein. The EPA will evaluate whether or not to conduct additional peer review of individual studies identified as pivotal science if the studies have already undergone journal peer review. Because transparency in pivotal science includes addressing issues associated with assumptions used in analyzing dose-response data, the EPA shall ask peer reviewers to articulate the strengths and weaknesses of the justification for the assumptions applied and the implications of those assumptions for the results.

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

The Administrator may grant an exemption to this part for a study on a case-by-case basis if he or she determines that greater consideration is warranted because:

- (1) Technological or other barriers render sharing of the dose-response data infeasible;
- (2) The development of the dose-response data was completed or updated before **[INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER]**;
- (3) Making the dose-response data available would conflict with laws and regulations governing privacy, confidentiality, confidential business information, or national security;
- (4) A third-party has conducted independent validation of the study's underlying dose-

response data through reanalysis; or

- (5) The factors used in determining the consideration to afford to the pivotal science indicate full consideration is justified.

When making a decision to grant an exemption, the Administrator may consider input from EPA staff and public commenters. The EPA shall document the rationale for exemptions granted by the Administrator in the significant regulatory action or influential scientific information.