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Environmental Protection Agency
1200 Pennsylvania Ave., NW.
Washington, D.C. 20460

Re: **Proposed Rule: Strengthening Transparency in Regulatory Science; April 30, 2018; 83 Fed. Reg. 18,768; Docket ID: EPA–HQ–OA–2018–0259**

The American Petroleum Institute (API) offers the following comments on the Environmental Protection Agency's (EPA) proposed rule: Strengthening Transparency in Regulatory Science.

API is the only national trade association representing all facets of the oil and natural gas industry, which supports 10.3 million U.S. jobs and nearly 8 percent of the U.S. economy. API's more than 620 members include large integrated companies, as well as exploration and production, refining, marketing, pipeline, and marine businesses, and service and supply firms. They provide most of the nation's energy and are backed by a growing grassroots movement of more than 40 million Americans. As science is used in developing policy and regulations, how it is handled can have an impact on all aspects of API member operations.

The members of API are dedicated to continuous efforts to improve the compatibility of their operations with the environment while economically developing energy resources and supplying high quality products and services to consumers. Our members recognize their responsibility to work with the public, the government, and others to develop and to use natural resources in an environmentally sound manner while protecting the health and safety of our employees and the public.

API supports the use of sound science as a critical component in public policy. To the extent possible, and consistent with the protection of other compelling interests such as privacy, trade secrets, intellectual property, and other confidentiality protections, data and analysis used in establishing and evaluating environmental, health, welfare and economic impacts should be transparent and reproducible and available as early as possible in the rulemaking process. Transparency and reproducibility should also apply to underlying data and information, such as environmental and economic impact data and models that are utilized to predict costs, benefits, market impacts and/or environmental and health effects of specific regulatory interventions.

API members are aware there are some obstacles to full transparency and reproducibility and are committed to working with other stakeholders to develop practices that maximize science transparency while preserving existing confidentiality strictures.

As EPA goes about this rulemaking API suggests that regulatory decisions based on science should rely upon the following principles:

- Openness in science and related findings underpinning laws, regulations, standards and guidance documents.
    - This is especially true for government-funded research and science but should include all policy-relevant studies.
- Reproducibility of research and associated findings including fully-annotated data, methodologies, model inputs, code and other critical information that supports the conclusions of research should be available to the public.
- Inclusion of clear requirements and a well-documented process are critical to ensure that the data underlying decision-making are publicly available in a manner sufficient for independent validation to the degree practicable.
    - Privacy concerns are important, but advances in encryption technology and blinding of data make it possible to enhance transparency while ensuring privacy as necessary to comply with the law.
- Protection for confidential business information (CBI) used in regulatory processes and support Agency actions.
    - This protection for CBI may need to be maintained even for certain data that are submitted to EPA to influence rulemakings.
    - Protections for proprietary information or CBI should not be weakened, though results of Agency analyses of this information could potentially be made available. Any such available results should be transparent as to the identification and selection of the key data, and the interpretation of that key data.
- Explicitly addressing and highlighting uncertainties in data, models and analyses when utilizing those studies in decision-making.
    - This is particularly important when models are used to quantify benefits of an action at levels at or below existing standards or background concentrations of a regulated substance.
- Broad application of these principles to information used to inform policy decisions, including scientific, economic and environmental impact data and models that are designed to predict health and environment impacts, costs, benefits, and/or market impacts of specific regulatory interventions on complex economic or environmental systems.
- Engaging stakeholders, as early as possible, in the decision-making process to ensure application of data transparency principles for studies to be included and to address

how studies that have not been reproduced or that are non-reproducible will be considered in the process.

    - For studies that are high quality and are regarded by EPA as the best available data for regulatory use though proprietary, contain CBI, raise privacy concerns or otherwise do not meet the transparency requirements, identify the recourse for stakeholders to ensure that they can independently discern that regulatory decisions are indeed based on sound science.

- Application of these principles, as early as possible, in the pre-rulemaking stage as technical support documents are prepared.

Again, API appreciates the opportunity to provide these comments. If you have any questions about these comments, please contact Ted Steichen of my staff or me. Ted can be reached at (202) 682-8568 or steichent@api.org.

Sincerely,

/s/

Howard J. Feldman

Comments on the

U. S. Environmental Protection Agency's

Proposed Rule

Strengthening Transparency in Regulatory Science

Docket ID: EPA–HQ–OA–2018–0259

April 30, 2018

83 Fed. Reg. 18,768

Submitted by the

American Petroleum Institute

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In responding to the U. S. Environmental Protection Agency's (EPA) Proposed Rule: Strengthening Transparency in Regulatory Science, the American Petroleum Institute (API) provides comment on those areas solicited, grouped by topic.

The topics include: Authority, Scope, Complications, Implementation, Dose-Response Studies, and Peer Review.

I. Authority

A. Additional or Alternative Sources

EPA solicits comment on whether additional or alternative sources of authority are appropriate bases for this proposed regulation. (pg. 18,771).

EPA's statement concerning its legal authority could be enhanced by reference to statutory provisions that require it to rely on "accurate," "useful," or "best" data. For example, section 108(a)(2) requires that the Administrator issue air quality criteria that "accurately reflect the latest scientific knowledge useful in indicating the kind and extent of all identifiable effects on public health and welfare . . .." 42 U.S.C. § 7408(a)(2). Similarly, section 304 of the Clean Water Act requires water quality criteria that "accurately reflect [] the latest scientific knowledge . . .." 33 U.S.C. § 1314(a)(1). The Safe Drinking Water Act requires the Administrator to assess risk using "the best available, peer-reviewed science and supporting studies conducted in accordance with sound and objective scientific practices." 42 U.S.C. § 300g-1(b)(3)(A). Increasing the transparency of regulatory science and ensuring that it is reproducible helps in evaluating its accuracy and usefulness.

Furthermore, making data and methods underlying regulatory decisions publicly available is not new. Guidelines issued by both the Office of Management and Budget (OMB) and EPA implementing the Information Quality Act (IQA), Treasury and General Government Appropriations Act for Fiscal Year 2001, § 515, P.L. No. 106-554, 114 Stat. 2763 (Dec. 21, 2001), emphasize the importance of reproducibility in assessing the quality and utility of data used in making regulatory decisions. It appears the OMB's IQA guidelines recognize that the reproducibility of underlying science helps to ensure the integrity of agency decisions and explain that, "[m]aking the data and methods publicly available will assist in determining whether analytic results are reproducible." 67 Fed. Reg. 8452, 8460 (Feb. 22, 2002) (OMB IQA Guidelines).

EPA's IQA guideline[1] states: "A higher degree of transparency about data and methods will facilitate the reproducibility of such information by qualitied third parties, to an acceptable degree of imprecision. . .. It is important that analytic results for influential information have a higher degree of transparency regarding (1) the source of the data used, (2) the various assumptions employed, (3) the analytic methods applied, and (4) the statistical procedures employed."

[1] EPA, Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency. Pg. 21 (Oct. 2002, as amended June 24, 2004 & May 13, 2005) (EPA IQA Guidelines).

EPA should also consider replacing some of the citations it provides for its legal authority with others that might be more relevant. For example, the Agency may want to cite 42 U.S.C. § 6981, on research, instead of 42 U.S.C. § 6979, which concerns "Labor standards." In addition, section 115 of CERCLA, 42 U.S.C. § 9615, which authorizes regulations, might be a more appropriate citation than section 116 of that Act, 42 U.S.C. § 9616, which specifies schedules for assessment and evaluation of facilities subject to the Act's requirements.

B. Other Regulatory or Policy Vehicles

EPA solicits comment on whether alternative or additional regulatory or other policy vehicles are appropriate to establish and implement these policies, and whether further regulatory or other policy vehicles at the programmatic or statutory level would be appropriate as alternative or additional steps the agency may take to further the policies articulated in Section II. (pg. 18,771).

The regulatory language that EPA proposes provides general requirements that apply to the Agency's use of science under the many statutes that it implements. The generality of the proposed regulations may be a function of the diverse purposes of those statutes Specifically, some of these statutes focus on the introduction of new substances into the marketplace (e.g., FIFRA and TSCA), while others primarily concern regulation of emissions or releases to (e.g., CAA and CWA), or removal from (e.g., CERCLA), the environment. The scientific analyses required for these different programs and the sources of the scientific information underlying those analyses differ. The Agency should consider supplementing the general language that it has proposed with statutory specific regulations. A statutory-specific rulemaking would provide greater certainty going forward.

II. Scope – What the Rule Covers

A. Apply to Other Stages of Rulemaking

EPA solicits comment on whether and to what extent these requirements, or other provisions and policies, should apply to other stages of the rulemaking process, including proposed rules, as well as to other types of agency actions and promulgations, such as guidance. (pg. 18,771).

These requirements should not be limited to final regulations. In fact, the scope should be expanded to cover other agency actions and promulgations such as guidance, where appropriate. It is critical to make data accessible as early as possible; in most cases, this should be done immediately following the publication of studies which the agencies believe could be "pivotal regulatory science". At minimum this rule should apply to pre-rulemaking activities (*e.g.*, during the planning and/or assessment stages of a NAAQS cycle, EPA should indicate on which studies it plans to rely). EPA also consider applying these requirements for EPA's Integrated Risk Information System (IRIS) and other assessments that are not agency actions but are often relied on for such actions. EPA should assess new studies on a routine basis to ensure that adequate time is available for independent review of these studies, as necessary, and to minimize delays in the rulemaking process.

B. Narrow or Broad

EPA also solicits comment on whether a narrower scope of coverage would be appropriate, such as only final regulations that are determined to be "major" under the Congressional Review Act, or "economically significant" under EO 12866. (pg. 18,771).

In general, EPA should strive for transparency to the degree possible for any studies used as "pivotal regulatory science" including those utilizing dose-response models. That said, API understands that there is a balance needed between a desire for transparency and the resources needed to achieve that transparency.

While an economic trigger is a key criterion that should be used to underpin this rulemaking, there are other critical times when the Agency should apply this rule. For example, agency actions that raise novel legal or policy issues should also fall into the scope of this rule. Often, agency actions which raise novel legal or policy issues have broader implications for subsequent agency actions including rulemakings. Thus, API supports EPA's proposal for this rulemaking to be triggered by agency actions determined to be 'significant regulatory actions' pursuant to E.O. 12866,"[2] with one minor change. The $100 million trigger may be too high to use in this rulemaking. A review of the historical rules under E.O. 12866 found that the majority were major regulatory actions and those were primarily those NAAQS regulations.[3] Instead, EPA should lower the $100 million trigger to provide increased transparency to other EPA programs.

C. Beyond Significant under EO 12866

The Agency also seeks comment on whether other agency actions, beyond significant final regulatory actions under EO 12866, should be included, such as site-specific permitting actions or non-binding regulatory determinations. (pg. 18,771).

EPA should strive for transparency for any dose-response models used as pivotal regulatory science. That said, there is a balance needed between a desire for transparency and the resources that such transparency may require. While an economic trigger is a key criterion that should be used to underpin this rulemaking,

[2] E.O. 12866 defines a "significant regulatory action" as any regulatory action that is likely to result in a rule that may:

- 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;
- Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;
- Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or
- Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in this Executive order.

[3] Specifically, from FY 2007 through FY 2016, Federal agencies published 36,255 final rules in the Federal Register. OMB reviewed 2,670 of these final rules under Executive Order 12866. Of these OMB-reviewed rules, 609 are considered major rules, primarily as a result of their anticipated impact on the economy (i.e., an impact of $100 million in at least one year). Many major rules are budgetary transfer rules, and may not impose a significant private mandate, thus no additional analyses have been performed. (OIRA 2017 Draft Report to Congress on the Benefits and Costs of Federal Regulations)

there are other critical reasons, such as rulemakings that raise novel legal or policy issues, which should also fall into the scope of this rule.

D. Definitions

EPA solicits comment on the definitions of "pivotal regulatory science," and "dose response data and models" and how to implement such definitions. (pg. 18,771).

API concurs with the general definition of "pivotal regulatory science" in the Proposed Rule:

> Pivotal regulatory science is the studies, models, and analyses that drive the magnitude of the benefit-cost calculation, the level of a standard, or point-of-departure from which a reference value is calculated. In other words, they are critical to the calculation of a final regulatory standard or level, or to the quantified costs, benefits, risks and other impacts on which a final regulation is based.

The definition of "pivotal regulatory science" could be further clarified to include examples that illustrate situations in which the definition would and would not apply. Examples where the rule would apply should include:

- Studies cited as the basis for Causal or Likely Causal determinations in a NAAQS Integrated Science Assessment, if they are not part of a generalized weight-of-evidence approach that incorporates a broader literature base;
- Studies EPA uses for its mortality or morbidity projections in a NAAQS Health Risk and Exposure Assessment, or the specification of a definitive concentration-response function upon which projections are based; and
- Studies EPA cites as a basis for quantifying a NAAQS.

API concurs with the general definition of "dose-response data and models"[4] in the Proposed Rule:

> "Dose-response data and models" are 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.

Discussion of the term should include the structure of the data (*e.g.*, data dictionary, variable list, de-identification measures) and sufficient detail regarding the model (*e.g.*, sample program codes or commands).

EPA should include a clear definition of a dose-response (or for the NAAQS, concentration-response) study. Otherwise, any study with a single coefficient from a linear model could reasonably be categorized as a "dose-response" study.

[4] Note that it is, important to document the weakness of linear extrapolation to zero being the "default" and also highlight the uncertainty of the results and establishing as a point of policy some lower bound other than zero unless zero is a provable limit.

Suggested elements of a definition could include that a study to be classified as a dose-response study, when:

- The study assesses/examines a broad class of parametric, non-parametric, and flexible concentration-response models (e.g., linear, superliner, sublinear, quadratic, threshold, spline) that incorporate a robust set of potential confounding variables (including co-pollutants) and confounding factors;
- Results from all models are shown in a supplement or separate report; and
- Selection of the most valid model among those examined is based on robust and well-defined statistical criteria, e.g., Akaike information criterion (AIC).

When identifying and describing the dose and response parameters, EPA should require the following to be reported:

- The magnitude, frequency, and duration over which the dose applies;
- The biological basis for the observed effect and the dose at which it was observed (e.g. mode of action);
- Scientific rationale for adjusting the dose using uncertainty factors to convert an animal dose to a human-equivalent dose, or adjustment for magnitude, frequency, duration, or human subpopulations;
- Scientific rationale for using any biomarkers as a surrogate for exposure;
- Assumptions made to estimate internal or external doses (e.g. personal exposure); and
- Description of the biological response and whether it is adaptive or adverse and the scientific rationale for the determination.

E. Applicability of Disclosure Requirements

EPA also requests comment on whether the disclosure requirements applicable to dose response data and models in the proposed rule should be expanded to cover other types of data and information, such as for example economic and environmental impact data and models that are designed to predict the costs, benefits, market impacts and/or environmental effects of specific regulatory interventions on complex economic or environmental systems. (pg. 18,772).

As stated in our general comments above, sound science should be a critical component in public policy in all parts of the rulemaking process. Such transparency and reproducibility should be extended to include all underlying information and analyses, such as economic and environmental impact data and models that are designed to predict costs, benefits, market impacts and/or environmental and health effects of specific regulatory interventions on complex economic or environmental systems. That said, API understands that this is a focused rulemaking effort and may not be the appropriate mechanism to address other types of data and information. If EPA decides not to address other types of data and information in this rulemaking, EPA is strongly encouraged to address those in a subsequent rulemaking.

F. Increasing Access Regulation

EPA is soliciting public comment on a proposed regulation designed to provide a mechanism to increase access to dose response data and models underlying pivotal regulatory science in a manner consistent with statutory requirements for protection of privacy and confidentiality of research participants, protection of proprietary data and confidential business information, and other compelling interests. (pg. 18,770).

A number of peer-reviewed scientific journals strive to promote data transparency and research reproducibility by requiring or encouraging authors to make underlying analytical datasets available at online data repositories. Similarly, EPA should consider adopting, adapting or setting up new online data repositories dedicated to the storage and access of the analytical datasets relied on in setting regulatory standards.

EPA should clearly define data processing/scrambling/analytical measures that are deemed sufficient for protection of privacy and confidentiality of study participants, protection of proprietary data and confidential business information, and other compelling interests. For example, EPA could consider whether certain analytical processes can be compartmentalized to allow further de-identification of the participants and better protection of the privacy information.

III. Scope – Exemptions

A. Criteria

EPA also seeks comments on which criteria the Agency should use to base any exceptions, including whether case-by-case exceptions may be appropriate. (pg. 18,771).

EPA should seek to minimize the use of exceptions to the extent feasible within this rulemaking, but API understands that there will be some situations in which exceptions are needed. Regardless of the criteria used, it is critical that EPA provide a robust and transparent explanation in the Federal Register that explains in detail why the data and models in question cannot be made publicly available. That said, API understands that EPA does not control all data and models for the studies it may wish to utilize as pivotal regulatory science. In those cases, EPA should not provide an exemption simply because a third-party does not agree to make the data and models publicly available and does not have a valid reason (e.g. CBI, privacy, etc.) to prevent their release.

In those cases, EPA should make every attempt to make as much of the data and models available for independent review as possible. Even if the dose-response data and models *per se* cannot be made publicly available, it may be possible for the results and analyses of this information to be made publicly available. Any such available results should be transparent as to the identification and selection of the key data, and the interpretation of those key data, in supporting the Agency's decision.

B. Other Actions or Categories

The agency requests comment on whether these exemptions are appropriate, and on whether there are other situations in which specific significant regulatory actions, or specific categories of significant regulatory actions should be exempted. (pg. 18.772).

The exemptions described in the rule and under *OMB's Information Quality Bulletin for Peer Review* to ensure compliance with privacy and national security laws and regulations are appropriate. EPA should handle these exemptions in a similar manner to the case-by-case exceptions for studies: EPA should provide a robust and transparent explanation in the Federal Register early in the rulemaking process to explain why the provisions of this rule do not apply to the rulemaking in question (e.g. which laws would be in conflict). That said, the exemption for "promptness" under *OMB's Information Quality Bulletin for Peer Review* is appropriate for an exemption except during the implementation after the effective date of

this regulation. This rule will initiate a significant change in the way EPA manages pivotal regulatory science and some time will be needed to set up new processes and systems to ensure internal compliance. EPA should identify in any rule finalized during the implementation window which dose-response studies used as pivotal regulatory science have not been made publicly available and release a schedule for making those studies available. Once those processes and systems are set up, EPA should be evaluating new dose-response studies well in advance of any rulemaking activities such that exemptions for "promptness" should not be needed.

C. When Reaffirming

EPA also requests comment on whether certain categories of regulations should be excluded from coverage, such as those that merely reaffirm an existing standard, or some other category. (pg. 18,777).

EPA should not exclude any category of regulation from this rulemaking. EPA specifically includes a regulation that "merely reaffirms an existing standard" as an example of one type of regulation it is considering excluding from this rule. This example is extremely concerning because it would be inappropriate to reaffirm an existing standard without first reaffirming the underlying science. If the underlying science was based on pivotal regulatory studies which have not been made publicly available, there would be no way to know if the standard was set correctly. That said, the check to determine if an agency action is a "significant regulatory action" should ensure that agency resources are not used on activities with low impact on the public and stakeholders. EPA should consider the potential cost savings from a rulemaking when determining if the provisions of this rule should apply. A standard based on pivotal regulatory science that was not made publicly available, which has ongoing or upcoming economically significant costs, should be subject to this rule.

1. Applicable to Individual Actions

EPA requests comment on whether the provisions of the proposed rule should apply to individual party adjudications, enforcement activities, or permit proceedings when EPA determines that these provisions are practical and appropriate and that the actions are scientifically or technically novel or likely to have precedent-setting influence on future actions. EPA seeks comment on whether the Agency should apply the provisions of the proposed rule to these actions or to specific types of actions within these categories.

EPA should apply this rule to any agency actions (including individual party adjudications, enforcement activities, or permit proceedings) that are scientifically or technically novel or likely to have precedent-setting influence on future rulemakings. Science and technology are broadly applicable and that EPA's interpretation and use of particular science and technology in one part of EPA has the potential to influence the interpretation and use of science and technology in another part of EPA. Previously EPA has identified the broad applicability of science and technology along with the need for harmonized and consistent interpretation and use of science and technology throughout EPA, as suggested by the availability of guidelines and guidance that are applicable Agency-wide. This broad applicability and need for harmonization and consistency is further indicated by the Agency's solicitation of scientific advice from the National Academies and external EPA review panels on scientific and technological matters. Thus, a case can be made that EPA has already identified that actions that are "scientifically or technically novel" should apply to "individual party adjudications, enforcement activities, or permit proceedings."

D. Balancing Copywrite and Confidential Business Information

EPA seeks comment on how to balance appropriate protection for copyrighted or confidential business information, including where protected by law, with requirements for increased transparency of pivotal regulatory science. (pg. 18,771).

EPA should solicit input from EPA Offices (such as the Office of Pesticide Programs) or other federal agencies (such as FDA) that rely heavily on copyrighted information, proprietary studies, and confidential business information (CBI) for strategies to balance these concerns with transparency. For example, EPA Offices (e.g. Pesticides) that rely heavily on proprietary studies/CBI apparently have already devised mechanisms that balance protection with transparency of pivotal regulatory science. One mechanism is Data Evaluation Records (DERs) that summarize proprietary studies.[5] Another is human health risk assessments that integrate findings in DERs such that stakeholders can assess the impact of a particular endpoint (e.g. health effect) in a particular study (pivotal regulatory science) on the overall risk assessment. Both DERs and risk assessments have been made available in the docket or by other means. While not as transparent as making the underlying data and models fully available, sufficiently detailed DERs and risk assessments are arguably as detailed and transparent as many health studies and risk assessments published in the peer-reviewed scientific literature. Regarding copyright protection, a potential alternative for copyrighted works that use data that are federally funded may be to solicit from the authors the raw data (which often isn't copyrighted) that were used to produce the copyrighted work. These raw data, along with EPA's analysis of these raw data, could then be made publicly available.

E. Promulgation and Implementation Approaches

EPA solicits comment on this proposal and how it can best be promulgated and implemented in light of existing law and prior Federal policies that already require increasing public access to data and influential scientific information used to inform federal regulation. (pg. 18,768).

The implementation of this proposal should consider existing law concerning protection of influential scientific information, including the IQA and EPA IQA Guidelines and OMB IQA Guidelines discussed above. Furthermore, EPA should follow 2 C.F.R. § 200.315(d) (2017), regarding EPA's right to "obtain, reproduce, publish or otherwise use" data produced under a Federal award."

IV. Scope – Retrospective Review

A. Inadvertent Introduced Bias

EPA seeks comment on how the prospective or retrospective application of the provisions for dose response data and models or pivotal regulatory science could inadvertently introduce bias regarding the timeliness and quality of the scientific information available. (pg. 18,772).

In general, if the right processes and systems are in place to manage the public sharing of dose-response studies, then no unintended bias will occur for any prospective application of this rule. In recognition of the challenge this may present, EPA should consider a process ensuring that new dose-response studies are identified and assessed when they are completed and not wait until the rulemaking process begins. The NAAQS process is an example where EPA could develop a continual review process. Continual

[5] (https://www.epa.gov/pesticide-registration/oecd-data-evaluation-record-templates).

assessment of new dose-response studies to determine if they have the potential to be pivotal regulatory science is key to ensuring that this rule does not cause bias or otherwise slow the rulemaking process. This will allow enough time for independent verification to be completed prior to the rulemaking process, thus minimizing unnecessary delays.

Regarding retrospective application, if EPA does not ensure that data and models from past dose-response studies are made publicly available when reviewing a previously finalized rule or creating a new rule, EPA could be giving the same weight to studies that may not have the same level of quality or veracity. This could bias the rulemaking decisions toward results which do not represent the best available science. Therefore, the Agency should release underlying data from older studies including methodologies so that strength and weaknesses of these data sets can be identified and that bias toward lower quality studies can be identified and constrained going forward.

B. Applicability to the Previous Record

EPA seeks comment on the effective date of a rule. EPA seeks comment on the manner in which this proposed rule should apply to that previous record. (pg. 18,772).

In general, EPA need not perform a retrospective review of all past final regulations to ensure compliance with this rule when this rule is published. That said, many of EPA's past rules may have been based on dose-response studies that have not been independently verified. The Agency will need to balance the need for transparency and independent verification with the available EPA resources. At a minimum, API believes that this rule should apply to any rule in the ANPRM or proposed rule phase as of the effective date of this regulation and that enough time is available prior to any statutory or court-ordered deadlines to make public all data and models from dose-response studies. If there are instances when EPA cannot apply this rule, then the Agency should identify in the final rule which dose-response studies used as pivotal regulatory science have not been made publicly available and a schedule for making those studies available.

C. Applying to Dose Response Data and Models

EPA also solicits comments on whether and how the proposed rule should apply to dose response data and models underlying pivotal regulatory science if those data and models were developed prior to the effective date. (pg. 18,772).

EPA should make the data and models from dose-response studies available as early as possible in the rulemaking process (either at the ANPRM or proposed rule stages) when a rule is being developed or reviewed by the Agency, for example the periodic review of the NAAQS. This approach should apply to dose-response studies even if they were developed prior to the effective date of this rule.

V. Complications

EPA seeks comment on how to address a circumstance in which EPA has a statutory requirement to make a determination for which scientific information publicly available in a manner sufficient for independent validation does not exist. (pg. 18772).

EPA should solicit input from EPA Offices (such as the Office of Pesticide Programs) and other federal agencies (such as FDA) that rely heavily on proprietary studies, many of which are not published in the peer-reviewed scientific literature and for which the data have historically not been available to the public for independent validations to make a determination as required by statute. As described above, EPA's Office of Pesticide Programs relies heavily on proprietary studies/CBI and apparently has devised mechanisms that balance protection with transparency of pivotal regulatory science and the public's right to now. One mechanism is Data Evaluation Records (DERs) that summarize proprietary studies.[6] The other is human health risk assessments that integrate findings in DERs such that stakeholders can assess the impact of a particular endpoint (e.g. health effect) in a particular study ("pivotal regulatory science") on the overall risk assessment. Both DERs and risk assessments have been made available on the docket or by other means. While this is not as transparent as making the underlying studies fully available, sufficiently detailed DERs and risk assessments are arguably as detailed and transparent as many health studies and risk assessments published in the peer-reviewed scientific literature.

VI. Implementation – Protection of Information

A. Platform Options

*EPA also solicits suggestions for a platform that would enable the Agency to implement the provisions of this proposal related to increasing public access to EPA-funded data. (pg. 18,772**).***

Various government agencies, such as the Centers for Disease Control and Prevention (CDC), the Centers for Medicare & Medicaid Services (CMS) and the U.S. Census Bureau maintain online databases and data repositories to allow public data access or restricted access to identifiable data. For example, the U.S. Census Bureau maintains American FactFinder,[7]an interactive online data tool, to allow public access to statistics data from the Economic Census, the American Community Survey, and the 2010 Census. CDC and CMS both provide restricted and secured access to health data that contain potentially identifiable and privacy information, such as name, residential address, vital status, birth date, and disease diagnosis.[8]

Of course, EPA also maintains various online databases to allow public access to data that do not contain identifiable or confidential information. For example, the Air Quality System (AQS) at EPA contains nationwide monitoring data on ambient air pollutants.[9]

EPA should study these systems and adopt, adapt or set up new online data repositories similar to those that already exist that allow public access to data on which agency actions rely that do not contain personal or confidential information. EPA could also implement additional background screening processes and security measures for access to data that may contain identifiable or proprietary information, similar to those employed by CDC and CMS for access to research identifiable data.

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[6] (https://www.epa.gov/pesticide-registration/oecd-data-evaluation-record-templates).
[7] https://factfinder.census.gov/.
[8] https://www.cdc.gov/rdc/; https://www.cms.gov/Research-Statistics-Data-and-Systems/CMS-Information-Technology/AccesstoDataApplication/index.html.
[9] https://www.epa.gov/aqs

B. Methodologies and Technologies

*EPA also seeks comment on methodologies and technologies designed to provide protected access to identifiable and sensitive data, such as individual health data, and on commenters experience with the use of such methodologies and technologies and their strengths and limitations. (pg. 18,772)***.**

As discussed above, multiple government agencies provide restricted and secured access to data that contain privacy or confidential information. EPA should seek inter-agency advice and technical support on this matter; other government agencies, such as CDC and CMS, provide restricted and secured access to research identifiable data.

VII. Implementation – General

A. Requirements in Cooperative Agreements and Grants

EPA also solicits comment on how to incorporate stronger data and model access requirements into the terms and conditions of cooperative agreements and grants. (pg. 18,771).

EPA should clearly stipulate in cooperative agreements and grant terms that data used by researchers receiving funding from EPA must be made publicly available to the extent possible after consultation with EPA. EPA should also require as part of the cooperative agreement or grant that the data be placed into EPA's designated system to allow access to the underlying data and models.

B. Certain Activities to Exempt

EPA solicits comment on the effects of this proposed rule on individual EPA programs, including whether certain activities are appropriate to be excepted or if other requirements would affect implementation. (pg. 18,771).

The scope of this proposed rule should be broad and apply to all individual EPA programs where the impact warrants.

C. Phase In

EPA solicit its comments on whether the Agency should seek to phase-in the requirements for certain significant regulatory actions or seek to prioritize specific actions. (pg. 18,772).

This rule should apply to all significant regulatory actions promulgated after the effective date of the rule as discussed above in IV.B. If a phase-in is desired, another approach would be to prioritize implementation of this rule for any significant regulatory actions related to establishment, review, and/or revision of NAAQS. Subsequently, the Agency could then apply this to other programs on a set schedule laid out in the final rule.

D. Additional Challenges

EPA also seeks comment on any additional implementation challenges not discussed in this notice that commenters may be aware of as well as suggestions for addressing them. (pg. 18,772).

EPA should assign designated personnel and allocate sufficient funds to facilitate data access. In addition, EPA should ensure that data access occurs early enough in the rulemaking process so that the public has sufficient time to analyze the data.

VIII. Implementation – Linear Dose-Response models

A. When Risk Below a Standard

If and when use of these models to determine risk below an existing or proposed standard (health-based threshold) are appropriate? (pg. 18,770)).

With respect to Dose–Response Models (DRM), those which are mathematical expressions fitted to scientific data that characterize the relationship between dose and response:

- Documentation: EPA should require documentation of the choices made at each step of the process and to include a scientific rationale for the selected approach. Key steps requiring this documentation and rationale include:
    - Data selection: determine the response to be modelled and select appropriate data;
    - Model selection: choose the type of model to be applied to the data;
    - Statistical linkage: state the assumptions about the distributions that describe the response; and
    - Parameter estimation: estimate of the model parameters using the above statistics.
- Implementation: use the estimated model parameters and the model formula to predict response/dose as needed and may be used to:
    - Define levels of exposure at which the response measurement is assumed to be virtually unchanged relative to the control measurement;
    - Identify a dose with a known level of response at or slightly below the observable range; and
    - The model(s) may be used to find the dose associated with a negligible (e.g. 1 in a million) response over control.
- Evaluation: EPA should examine the sensitivity of the resulting predictions to the assumptions used in the analysis (e.g. model comparison, uncertainty)
    - The dose-response relationship can be linear or nonlinear in shape. A linear dose-response relationship suggests that the toxicity or adverse effect being evaluated does not have a threshold, while a nonlinear dose response relationship holds that a range of exposures from zero to some finite value can be tolerated.[10]
- On Extrapolation Considerations: EPA should require the documentation of the methods used and scientific justification for those methods, as well as a need to document potential alternative interpretations of extrapolations and nature of the dose-response curve (e.g. threshold, no-threshold, supralinear, etc.).

[10] See EPA's Risk Characterization Handbook. https://www.epa.gov/risk/conducting-human-health-risk-assessment#tab-3 for more information

- Epidemiological Data Considerations: EPA should require that any assumptions, uncertainties, and scientific rationales be documented. Examples of these uncertainties and assumptions include, but are not limited to:
    - The lack of valid semi-quantitative or quantitative estimates of exposure (as a surrogate for dose, as dose is rarely available in observational studies) for each individual studied;
    - Systematic errors or study bias may result in spurious causal associations between an estimated exposure and the occurrence of disease;
    - Due to the lack of complete exposure information, historical estimates may be incorrectly extrapolated back in time. Depending on the direction and degree of all study biases, an observed dose-response may not reflect the true underlying dose-response relationship;
    - Epidemiological studies often suffer from low statistical power due to limited numbers of observed events for relatively rare diseases such as specific cancers. Effects at the lowest estimated doses, where risks are anticipated to be low as well, may be impossible to distinguish from background incidence. This may also preclude differentiating a linear dose-response from a threshold dose-response function; and
    - Statistical/analytical challenges, including: the impact of that random error in the exposure measurement can have on the assessment of the shape of the dose-response curve, assumptions on the shape of the dose-response curve and the use of parametric statistics, and problems elucidating possible non-linearity of exposure-response in epidemiological studies.

- For Reporting Dose-Response: EPA should require documentation of any dose or concentration-response assessment for those health effects where the evidence is sufficient to conclude that a causal relationship exists or where the evidence is sufficient to conclude that a causal relationship is at least as likely as not, but not sufficient to conclude that a causal relationship exists:
    - A sensitivity analysis should be conducted to determine the robustness of the concentration-curves; and
    - It is recommended to include a discussion of all models that fit the data equally well (i.e. where there is no statistically significant difference in quality of fit), including threshold and non-threshold models, when there are alternative procedures having significant biological plausibility, the assessments using these alternative procedures should be document any information on the uncertainties in the assessment.

IX. Peer Review

API offers the following additional comment regarding Peer Review:

Peer review and access to data by the reviewers are critical aspects of applying sound science to the regulatory process. EPA should consider updating and utilizing its own peer-review policy in addition to that provided in the peer-reviewed scientific literature (please see US EPA Peer Review Handbook, 4th

Edition. Science and Technology Policy Council. October 2015. EPA/100/B-15/001). For proprietary data/CBI that are submitted to EPA to support new chemical registrations and other regulatory actions, EPA has full data access from which to conduct its own peer reviews in accordance with its own policy. Data from other sources to be used in regulatory decision making should be available such that EPA can comply with its own peer review policy.