Draft Department of Defense Comments on

Proposed Rule: Strengthening Transparency in Regulatory Science

EPA–HQ–OA–2018–0259

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Comment No.	**Section**	**Pages**	**Proposed Rule Text**	**Comment**
1.	I.B. What action is the Agency taking?	83 FR 18769	The proposed regulation provides that, for the science pivotal to its significant regulatory actions, EPA will ensure that the data and models underlying the science is publicly available in a manner sufficient for validation and analysis. In this notice, EPA solicits comment on this proposal and how it can best be implemented in light of existing law and prior statements of policy that have called for increasing public access to data and influential scientific information used to inform federal regulation.	It is appropriate to limit application of the rule to only "major" regulatory actions as defined in the Congressional Review Act. For regulations with lower cost thresholds EPA may wish to consider issuing similar policy. While we agree that public access to information is very important, we do not believe that failure of the Agency to obtain a publication's underlying data from an author external to the Agency should negate its use. As we note below, it is improbable that EPA will be able to obtain underlying data from all authors, this should not impede the use of otherwise high-quality studies.
2.	I.C. What is the Agency's authority for taking this action?	83 FR 18769	The Agency proposes to take this action under authority of the statutes it administers, including provisions providing general authority to promulgate regulations necessary to carry out the Agency's functions under these statutes and provisions specifically addressing the Agency's conducting of and reliance on scientific activity to inform those functions, including Clean Air Act sections 103, 301(a), 42 U.S.C. 7403, 7601(a); Clean Water Act sections 104, 501, 33 U.S.C. 1254, 1361; Safe Drinking Water Act sections 1442, 1450(a)(1), 42 U.S.C. 300j–1, 300j–9(a)(1); Resource Conservation and Recovery Act sections 2002(a)(1), 7009, 42 U.S.C. 6912(a)(1), 6979;	The Final Information Quality Bulletin implements the Information Quality Act (Pub L. No. 106-554, § 515, Dec. 21, 2000). This rule should reference the Information Quality Act along with the bulletin.

			Comprehensive Environmental Response, Compensation, and Liability Act (as delegated to the Administrator via Executive Order 12580) sections 115, 311, 42 U.S.C. 9616, 9660; Emergency Planning and Community Right-To-Know Act section 328, 42 U.S.C. 11048; Federal Insecticide, Fungicide, and Rodenticide Act sections 25(a)(1), 136r(a), 7 U.S.C. 136r(a), 136w; and Toxic Substances Control Act, as amended, section 10, 15 U.S.C. 2609.	
3.	II. Background	83 FR 18769	EPA should ensure that the data and models underlying scientific studies that are pivotal to the regulatory action are available to the public. This proposed rule is designed to increase transparency in the preparation, identification, and use of science in policymaking.	In many cases the EPA relies upon toxicological assessments that have already been published by the Agency. The Rule should make clear that for major or significant regulatory actions the requirements of this rule will apply at the regulatory phase regardless.
4.	II. Background	83 FR 18770	In particular, this proposal applies concepts and lessons learned from its ongoing implementation of the 2016 Plan to Increase Access to Results of EPA-Funded Scientific Research to significant regulatory decisions. The proposed rule takes into consideration the policies or recommendations of third party organizations who advocated for open science.[10] These policies are informed by the policies recently adopted by some major scientific journals,[11] spurred in some part by the ‘‘replication crisis.’’ [12]	Data and model availability may address functions that will improve analyses. 1) In the past, DoD, other interested parties, and even EPA have found places where the main text has not been updated after changes were made in the model or data used. Increased availability will facilitate and expedite corrections. 2) Within each model and data set, choices must be made. For a given parameter should a single estimate, an average, or a range of values be used? Is an existing model appropriate, or should modifications be made? No entity will use all options; data and model availability will allow interested parties to determine if alternative choices substantially change results.
5.	II. Background	83 FR 18770	With this notice, EPA is soliciting public comment on a proposed regulation designed to provide a mechanism to increase access to dose response data and models underlying pivotal regulatory science in a manner consistent with statutory requirements for protection of privacy and confidentiality of research participants, protection of proprietary data and confidential business information, and other compelling interests. The proposal takes comment on how to ensure that, over time, more of the data and models underlying the science that informs regulatory decisions (over	1) A paper cited by EPA in the Proposed Rule, Lutter and Zorn (2016) notes that only 20% of authors contacted to provide data underlying their publication actually provide it. Given this circumstance, if EPA wishes to change the culture of data access it seems that they need receive buy-in from publishers and scientists as well as change the internal EPA culture to insure requirements for data availability are met by EPA funded laboratory and epidemiological studies. 2) We recommend that models developed by EPA be constructed in R or other freeware, and the code posted with the document in which they were used. Renting or

			and above the dose response data and models underlying ‘‘pivotal regulatory science’’) is available to the public for validation[13] in a manner that honors legal and ethical obligations to reduce the risks of unauthorized disclosure and re-identification. As such this proposed regulation is designed to change agency culture and practices regarding data access so that the scientific justification for regulatory actions is truly available for validation and analysis.	buying proprietary software can impede the transparency advocated in this proposal. In addition, code availability would be very useful. 3) To insure dose-response data is available in the future the rule needs to take into consideration the cost of establishing and maintaining the electronic infrastructure necessary for obtaining and storing data and models. The cost of safeguarding integrity of the data needs to be considered as well.
6.	II. Background	83 FR 18770	In addition, this proposed regulation is designed to increase transparency of the assumptions underlying dose response models. As a case in point, there is growing empirical evidence of non-linearity in the concentration-response function for specific pollutants and health effects. The use of default models, without consideration of alternatives or model uncertainty, can obscure the scientific justification for EPA actions. To be even more transparent about these complex relationships, EPA should give appropriate consideration to high quality studies that explore: A broad class of parametric concentration response models with a robust set of potential confounding variables; nonparametric models that incorporate fewer assumptions; various threshold models across the exposure range; and spatial heterogeneity. EPA should also incorporate the concept of model uncertainty when needed as a default to optimize low dose risk estimation based on major competing models, including linear, threshold, and U-shaped, J-shaped, and bell-shaped models.	Non-linearity of dose-response functions is, at a minimum, a function of both intra-species variability and the importance of both enzymes and receptors acting through forms of the Hill function that is mathematically non-linear. Assumptions of linearity, both straight-line extrapolations and linearly proportional relationships among exposure and other risk assessment parameters are a function of known simplifications for calculations that evolved in the 1980s when data were limited, computer use expensive, and most scientists still relying on slide rules for calculations. It is now generally accepted that physiologically base pharmacokinetic and pharmacodynamics models, which are inherently non-linear, are more accurate. We believe EPA should consider a broad range of models, to include those that utilize Bayesian and data-driven approaches. Expanding the variety of dose-response models that include threshold and non-monotonically-increasing functions is important, as the data support their appropriate description of some biological functions, but should be part of guidance or EPA Guidelines, not be part of this rule. EPA may wish to provide a method for interested parties to submit papers on these issues that would be publicly available prior to workshops and other methods of discussion. This could provide EPA not only with multiple options but also with some of the strengths and weaknesses of these models. A draft of how EPA is considering use of such models, including some examples, would provide further comment that could be incorporated before guidance is final.
7.	III. Request for Comment	18771	EPA also seeks comments on which criteria the Agency should use to base any exceptions, including whether case-by-case exceptions may be appropriate.	As we note in other comments, underlying study data may be difficult to obtain from authors outside the Agency. EPA should allow exceptions for such instances.

8.	III. Request for Comment	18771	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 E.O. 12866.	We believe it is most appropriate for the rule to apply to "major regulations" as defined by the Congressional Review Act only. However, the threshold of 100M was established by Congress in 1996. Hence the threshold that would apply to this regulation should be adjusted to current and/or future year dollars as appropriate.
9.	III. Request for Comment	18771	EPA solicits comment on the definitions of "pivotal regulatory science," and "dose response data and models" and how to implement such definitions.	1) The definition of "dose response data" is not clear and should be clarified. We are unsure whether this means underlying, or "raw data" collected during a study that has not been subject to statistical analysis or whether it is data that is used by EPA in models. 2) It is not clear whether "pivotal regulatory science" means studies and analyses performed by the EPA, or those studies published by others in peer-reviewed journals that might support EPA's analysis. 3) We suggest that EPA consider that pivotal studies may also be those that determine qualitatively the weight of evidence (WOE) that a specific toxic endpoint is of relevance to human health or the species of concern. Selection of the appropriate toxic endpoint based on WOE after systematic review of the literature is as important as appropriate quantitative analysis. 4) There may be other types of models that are relied upon in regulatory actions and influence decisions. Such models might include environmental fate and transport models or bioaccumulation models. Please clarify whether the requirements of the Rule will apply to these types of models as well.
10.	III. Request for Comment	18771	EPA also solicits comment on how to incorporate stronger data and model access requirements into the terms and conditions of cooperative agreements and grants. EPA solicits comments on how it can build upon other federal agencies' policies regarding grantee and cooperator requirements for data access and data sharing. EPA also solicits suggestions for a platform that would enable the Agency to implement the provisions of this proposal related to increasing public access to EPA-funded data.	The EPA encouraged to cooperate with other federal agencies to generate common data access, management and storage standards. If the models and data are generated from government funds, require that they be publicly available on EPA's website or by request to EPA. In some cases where compelling reasons are given and publicly available, a time delay might be justified, which should also be identified.
11.	III. Request for Comment	18771	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 EPA is encouraged to cooperate with other federal agencies to generate common data access, management and storage standards. The EPA is also encouraged to participate openly with the PubChem and the NTP's databases.

			the use of such methodologies and technologies and their strengths and limitations.	The same types of legally binding documents that EPA needed to sign to obtain such data, e.g., non-disclosure agreements, would be expected to be sufficient for other parties. EPA could consider requiring data acquisition and analysis by parties independent of the stakeholder. For example, if CBI were requested by an industrial competitor, EPA might require that a non-affiliated consulting firm or academic be the entity that signs the NDA and receives the data for analysis.
12.	III. Request for Comment	18771-18772	EPA also requests comment on whether there are other compelling interests besides privacy, confidentiality, national and homeland security that may require special consideration when data is being released.	It appears as if the EPA may have overlooked the advancement of science through open publication as a compelling interest. Interests of the academic publishing sector should be considered. Additionally, the interests of scientists outside the EPA who perform studies, collect data and publish should be considered. It is not clear how scientists would know whether their data might be used for a "pivotal regulatory action" and prepare their publication packages to allow for a given study to be "validated".
13.	III. Request for Comment	18772	EPA seeks comment on the effective date of a rule as well as on whether the Agency should seek to phase-in the requirements for certain significant regulatory actions or seek to prioritize specific actions. For regulatory programs, like the National Ambient Air Quality Standards program, in which future significant regulatory actions may be based on the administrative record from previous reviews—particularly where the governing statute requires repeated review on a fixed, date-certain cycle—EPA seeks comment on the manner in which this proposed rule should apply to that previous record.	We suggest that EPA grandfather existing analyses, unless being updated or challenged. More importantly, evaluations currently in progress should be subject to these changes, else too many more chemicals will not be subject to these modifications before they are implemented.
14.	III. Request for Comment	18772	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.	Models: All new models, should be vetted separately, preferably before they were used and definitely before they are used in another analysis. Exceptions and additions to existing EPA guidance may allow for improved analyses, but the strengths and limitations of those changes should undergo the same level of review, e.g., interagency comment and public comment, as the original guidance document. When performed as part of a chemical-specific analysis, there is insufficient time and expertise available for a full discussion of the potential utility and limitations of the changes.

				Data: Recent practice has been for EPA to alter the primary data, e.g., IRIS documents convert data to percentage change from the control. Starting with the most recent documents, for which the primary data should be easily accessible, those data for all datasets that were considered sufficiently important to calculate a candidate toxicity value, should be posted on the website where the other supporting documents are available.
15.	III. Request for Comment	18772	In addition, EPA seeks comment on how the prospective or retrospective application of the provisions for dose response data and models or pivotal regulatory science could inadvertently introduce bias regarding the timeliness and quality of the scientific information available.	There may be bias against high quality studies published in the past where underlying data is not available. There may be a bias against studies published outside the USA. There may be a bias against studies performed by authors or in journal not informed by the rule. There will be a bias against proprietary models.
16.	III. Request for Comment	18772	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.	1) The Agency should clearly communicate its expectations regarding "replicability", "validation" and availability of "data" to scientists designing and publishing their studies. 2) The cost to the agency to post and maintain the integrity of data and models may be an implementation challenge.
17.	III. Request for Comment	18772	The proposed rule includes a provision allowing the Administrator to exempt significant regulatory decisions on a case-by-case basis if he or she determines that compliance is impracticable because it is not feasible to ensure that all dose response data and models underlying pivotal regulatory science are publicly available in a fashion that is consistent with law, protects privacy and confidentiality, and is sensitive to national and homeland security, or in instances where OMB' Information Quality Bulletin for Peer Review provides for an exemption (Section IX). The agency requests comment on whether these exemptions are appropriate, and on whether there are other situations in which specific significant regulatory actions, or specific categories of significant regulatory actions should be exempted.	In order to limit the potential for exempting pivotal studies that do not meet the data transparency requirements the studies in question should meet a minimal threshold of study quality.
18.	40 CFR part 30	18773	§ 30.1 What is the purpose of this subpart? This subpart directs EPA to ensure that the regulatory science underlying its actions is publicly available in a manner sufficient for independent validation.	The definition of independent validation is not clear. It is not clear if the intent is to reproduce study conclusions using underlying data, replicate entire studies, or validate the use of data extracted from published studies in a dose response model. Please present a clear definition.

19.	40 CFR part 30	18773	§ 30.2 What definitions apply to this subpart? As used in this subpart, all terms not defined herein shall have the meaning given them in the Act or in subpart A; and the following terms shall have the specific meanings given them. *Dose response data and models* means the data and models used to characterize the quantitative relationship between the amount of dose or exposure to a pollutant, contaminant, or substance and the magnitude of a predicted health or environmental impact. Such functions typically underlie pivotal regulatory science that drives the size of benefit-cost calculations, the level of a standard, and/or the points of departure from which reference values (reference doses or reference concentrations) are calculated. *Research data* means ''research data'' as that term is defined in Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards.	*Dose response data and models:* 1) As presented the definition of "dose response data and models" might be construed to include fate and transport models of pollutants, contaminants or substances since they may be used to estimate exposure. If this is not the intent, they should be made exceptions. 2) Is the intent to include ecological effects to flora and fauna as is inferred by including "environmental impacts"? If not, the definition should be revised. *Research data:* We searched 82 FR 94, 22609 and found no definition of "research data". If it is defined elsewhere please include that citation or insert a definition in the Rule.
20.	40 CFR part 30	18773-18774	§ 30.5 What requirements apply to EPA's use of dose response data and models underlying pivotal regulatory science? When promulgating significant regulatory actions, the Agency shall ensure that dose response data and models underlying pivotal regulatory science are publicly available in a manner sufficient for independent validation.	It is not clear what "independent validation" means. Clarify whether this means all the information required to replicate the entire study should be included or whether this is limited to data once generated.
21.	40 CFR part 30	18774	§ 30.6 What additional requirements pertain to the use of dose response data and models underlying pivotal regulatory science? EPA shall describe and document any assumptions and methods used, and should describe variability and uncertainty. EPA shall evaluate the appropriateness of using default assumptions, including assumptions of a linear, no-threshold dose response, on a case-by-case basis. EPA shall clearly explain the scientific basis for each model assumption used and present analyses showing the sensitivity of the modeled results to alternative assumptions. When available, EPA shall give explicit consideration to high quality studies that explore: A broad class of parametric dose-response	Suggest changing the text to read that "**In the main text of an analysis,** EPA shall describe and document any assumptions and methods used, and should **clearly present, in the main text, especially any procedure used for the first time in that type of evaluations (e.g., IRIS or TSCA) as well as presenting the results of using the standard procedure.**" In the past, this information has neither been highlighted, e.g., that is it a novel procedure, or been in an appendix, footnote, or note on a table or figure. Deviations from standard procedures and guidance are expected, especially in cases where more than the usual amounts and types of data are available. Highlighting them, providing information on how the results differ from that which would result from "standard" procedures, and requesting specific review of such changes would not only save reviewers from each trying to discover

			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.	and evaluate this information, but also provide explicit support or suggested changes to improve such changes.
22.	40 CFR part 30	18774	§ 30.10 What other requirements apply under this subpart? EPA shall implement the provisions of this section consistent with the definition of ‘‘research data’’ in Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards, exemptions in Public Law 89–487, and other applicable federal laws. Where appropriate, data sharing agreements and state-of-the-art data-masking techniques may be employed to facilitate access to information.	The EPA is encouraged to cooperate with other federal agencies to generate common data access, management and storage standards. The EPA is also encouraged to participate openly with the PubChem and the NTP’s databases.