



Environmental Data & Governance Initiative

envirodatagov.org



EnviroDGI@protonmail.com

EPA's Proposed Rule Uses the Idea of Transparency to Reduce Real Transparency and Delay Protecting Environmental and Public Health

Environmental Data & Governance Initiative (EDGI)'s Comment on the
Environmental Protection Agency (EPA) Proposed Rule: Strengthening Transparency
in Regulatory Science (Docket No. EPA-HQ-OA-2018-0259).

August 16, 2018

Comment compiled on behalf of the Environmental Data & Governance Initiative
by: Becky Mansfield, Gretchen Gehrke, Andrea Hindman, Leif Fredrickson, Lourdes
Vera, Jess Ogden, Dawn Walker

The Environmental Data and Governance Initiative (EDGI) is a network of academics, developers, and non-profit professionals that promotes evidence-based policy-making and public interest science. We document, contextualize, and analyze current changes to environmental data and governance practices through multidisciplinary and cross-professional collaborative work. We foster the stewardship and expansion of public knowledge through building participatory civic technologies and infrastructures to make data and decision-making more accessible. EDGI creates new communities of practice to enable government and industry accountability. In particular, we promote models and tools that emphasize community participation at all scales, both within EDGI and in our public-facing tools.

EDGI is comprised of over 150 members in North America residing in 19 U.S. states, including California, Colorado, District of Columbia, Florida, Illinois, Indiana, Maryland, Massachusetts, Michigan, Montana, New Jersey, New York, North Carolina, Ohio, Oklahoma, Pennsylvania, Texas, Vermont, Virginia, Washington, and Wisconsin.

Table of Contents

EPA's Proposed Rule Uses the Idea of Transparency to Reduce Real Transparency and Delay Protecting Environmental and Public Health	1
Table of Contents	2
I. INTRODUCTION	3
II. AMBIGUITY IN THE PROPOSED RULE WILL LEAD TO ARBITRARY DECISIONS	5
Which studies can be exempted from requirements for data availability?	5
Does this proposed rule supersede the Data Quality Act?	5
Does independent validation refer to analysis or entire studies?	6
Why is this proposed rule on transparency in cost-benefit analysis not transparent about the costs of the rule?	7
III. THE PROPOSED RULE WEAPONIZES THE LANGUAGE OF "TRANSPARENCY," ALLOWING THE EPA TO DISMISS EVIDENCE, PRODUCE FALSE UNCERTAINTY, AND PUT OFF REGULATION	8
Transparency requires much more than data availability	8
EPA is using the idea of transparency in bad faith to dismiss evidence and produce false uncertainty	11
IV. EPA'S FOCUS ON TRANSPARENCY IN DOSE-RESPONSE SCIENCE IS INCONSISTENT WITH ITS RECENT TURN TO SECRECY	16
V. EDGI'S ALTERNATIVE: STRENGTHEN REAL TRANSPARENCY AND ACCESSIBILITY BY INCORPORATING AND CONTEXTUALIZING THE FULL RANGE OF EVIDENCE	18
VI. CONCLUSION	21

The Environmental Data & Governance Initiative (EDGI) welcomes the opportunity to comment on the Environmental Protection Agency (EPA) Proposed Rule: Strengthening Transparency in Regulatory Science; Docket No. EPA-HQ-OA-2018-0259.

I. INTRODUCTION

The Proposed Rule “Strengthening Transparency in Regulatory Science” (STRS) would require that data and models underlying scientific studies that are pivotal to regulatory action be available to the public. The rule aims specifically to make “dose response data and models” used in regulatory decision-making available for independent validation. The proposed rule states that this requirement ensures that EPA relies on “best available science” that “enhanc[es] the public’s ability to understand and meaningfully participate in the regulatory process” [FR 18769].

In this comment, we show that transparency, best available science, and meaningful public participation are not the goal of this rule. Rather, the goal is to reduce the range of evidence that is used in regulatory decision-making and to make it harder to use scientific evidence that shows harm caused by chemical exposures. This rule will prevent deeper understanding by scientists, regulators, and the public of the risks of chemical exposures and, ultimately, will delay action to protect environmental and public health. The proposed requirement to make dose response data and models available for independent evaluation is especially compromising for interpretation of harm from hormone-like chemicals. Apart from the broader call for transparency, the implications of this rule underscore current deficiencies in chemical risk assessment and regulation that include a lack of integration of third party contributions to a chemicals’ scientific weight-of-evidence, health protective timeframes, and sensitivity to adverse health effects.

This comment presents three ways the language of transparency is disingenuous and used for obfuscation and regulatory delay rather than clarity and regulatory protection. First, ambiguity in the rule will lead to arbitrary decisions. Second, the proposed rule weaponizes the language of “transparency,” which allows EPA to dismiss evidence, produce false uncertainty, and put off regulation. Third, EPA’s

focus on transparency in dose-response science is inconsistent with its recent turn to secrecy in other situations.

In place of EPA's disingenuous transparency initiative, we suggest an alternative notion of transparency in regulatory science -- an alternative that incorporates privacy, accessibility, scientific rigor, contextualization, participation, and timeliness.

We urge Acting Administrator Wheeler to withdraw this proposed rule.

II. AMBIGUITY IN THE PROPOSED RULE WILL LEAD TO ARBITRARY DECISIONS

Even as it calls for transparency, many features of the proposed rule themselves are not transparent. Ambiguity and lack of detail lend themselves to decision-making that is arbitrary and open to influence, i.e. the opposite of transparent or based on best available science.

Which studies can be exempted from requirements for data availability?

Section 30.9 gives the EPA Administrator the power to grant exemptions to the requirements for data availability and independent peer review on a case-by-case basis. **However, the total lack of detail regarding which studies can be exempted from these requirements *makes the entire rule arbitrary.*** The proposed rule gives the Administrator the power to use some studies in regulatory decision making even if their data is not public -- but there are no rules about which studies and under what conditions. It is clear that exemptions *are* necessary to ensure the best available science is used. However, the Administrator should *not* have complete discretion. This gives the Administrator the power to make arbitrary decisions, open to a range of outside influences, about which studies to include or exclude from regulatory decision-making.

Does this proposed rule supersede the Data Quality Act?

The proposed rule notes that it is "consistent" with OMB's 2002 *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility and Integrity of Information Disseminated by Federal Agencies*. Yet, it is unclear how the rule relates to those guidelines or the Data Quality Act¹ upon which those guidelines are based. The proposed rule makes no mention of the Data Quality Act at all. It is unclear why the proposed rule is necessary given these policies or how the proposed rule would relate to them, especially given that the Data Quality Act and its associated

¹ Section 515 of Treasury and General Government Appropriations Act for Fiscal Year 2001 (Public Law 106-554). Also not addressed in the proposed rule are the Data Access Act and the 2009 "Scientific Integrity" memo.

guidelines cover much of the same ground. **Thus, it is unclear if, or why, this proposed regulation is meant to supersede existing legislation and policies.** The EPA should provide an analysis of how this rule differs from the Data Quality Act and related policies and then offer a justification for this rule in light of that analysis. Without clarity on these issues, the proposed rule appears to not only be an attempt to regulate where legislation has failed (i.e. the HONEST Act), but to use a regulation to supersede legislation that is already on the books.

Does independent validation refer to analysis or entire studies?

While the proposed rule emphasizes that data and models should be available in a manner sufficient for independent validation, the rule fails to clearly define independent validation. As a result, it is unclear if the rule applies only to replication of *analysis* or also to replication of *entire studies*. By emphasizing availability of data and models, the rule seems to be narrowly focused on replicating *analysis*, particularly as related to dose-response relationships. Yet, wording such as “using scientific information that can be independently validated” [FR 18770] can be interpreted expansively so that the rule can appear to require the ability to replicate *entire studies*, as was the intent of the failed HONEST Act. There are several problems with this. **First, if the intention *is* to require the ability to replicate entire studies, then this proposed rule is misleading; as written, it seems to be only about replicating analysis.** As a result, this proposed rule is a stealth-- not at all transparent-- way to eliminate the use of a wide swath of studies that are currently used for regulatory decision-making. For example, studies based on tragic accidents involving toxic releases provide important public health knowledge, but cannot be replicated (for more on this, see EDGI’s white paper²). **Second and more broadly, lack of clarity on this matter would allow the EPA to pick and choose, in an arbitrary manner, which studies to include or exclude in risk analysis.** This misuse of power would easily influence the findings of risk analysis.

² [Public Protections Under Threat at the EPA: Examining Safeguards and Programs That Would Have Been Blocked by H.R. 1430 — White Paper](#) (EDGI, March 2017)

Why is this proposed rule on transparency in cost-benefit analysis not transparent about the costs of the rule?

The proposed rule is justified in part in terms of costs, including minimizing the cost of regulatory compliance (mentioned in the second sentence of the rule); yet the costs of this regulation are not addressed. Costs are mentioned throughout Part IV A, on Executive Order 12866, in which EPA states that it “believes” the benefits of the proposed rule justify the costs [FR 18772]. But there is no analysis of what those costs are: EPA is not being transparent about the costs to the agency, the costs to scientists, or the overall balance of costs and benefits. Multiple aspects of the proposed rule will be costly, including its demand to make data publicly available and its metrics of ‘high quality studies’ that cover a broad range of models and doses. A hint of these costs is the \$30 million price tag for the ongoing interagency study to elucidate health outcomes resulting from exposure to a single, hormone-like chemical, bisphenol A (BPA).³ Costs such as these not only eat up scarce resources, but they also lead to selection biases regarding which studies EPA will include in risk analysis. For example, smaller organizations will likely lack the financial resources both to support such comprehensive studies and to make their data publicly available, so their studies may be excluded. Alternatively, if EPA is covering part of the cost of making data public, it may choose fewer, more general studies to include in its analyses. In short, it is troubling that a rule on transparency regarding cost-benefit analysis is not itself subject to transparency regarding its costs and the balance of costs and benefits.

³ [Bisphenol A \(BPA\) Initiatives](#), NIEHS

III. THE PROPOSED RULE WEAPONIZES THE LANGUAGE OF “TRANSPARENCY,” ALLOWING THE EPA TO DISMISS EVIDENCE, PRODUCE FALSE UNCERTAINTY, AND PUT OFF REGULATION

Whereas the previous section outlined ambiguity in the rule, this section addresses problems with the central requirements of the proposed rule: data and model availability, independent validation, and peer review. The proposed rule provides false transparency and will likely reduce reliance on best available science by eliminating important studies from consideration in risk analysis. It also wields the attractive idea of “transparency” to open regulatory science to the never-ending production of uncertainty: “independent validation” could mean continually re-analyzing data not in the name of scientific progress but in the name of denial and to justify failure to regulate. **Ultimately, this proposed rule reduces use of available evidence under the cloak of “transparency;” it weaponizes transparency as a tool for denying the harms of toxic chemicals and delaying regulations to protect public health.**

Transparency requires much more than data availability

The supposed intent of these measures is to enhance the transparency of research used to inform regulatory requirements. **Yet, the rule never addresses the wide range of measures that would be necessary to achieve true transparency for either scientists wishing to replicate results or for a broader public wishing to better understand and participate in the regulatory process.** The rule proposes just a *single* measure -- making data and models available -- and proposes a false equivalence between “transparency” and (poorly defined) independent validation.

If the EPA intends transparency in how research informs regulations, it must devote substantial resources to improving explanations of research utilized and their various caveats and not require dumps of “raw” data and algorithms without context. “Raw” data and algorithms are largely unintelligible, so this rule gives the appearance of transparency without actually enhancing science or participation. As any scientist knows, data is never just data -- it is never really “raw” because it is always shaped by techniques of sampling, collection, entry, storage, and so forth. Because the proposed rule fails to acknowledge this basic fact about scientific data,

the rule fundamentally misrepresents the practice and applications of research. This is one sense in which the proposed rule impedes meaningful public understanding and engagement.

False transparency for meaningful public participation

The requirements of this rule fail to support significant public participation, because **data and models are meaningless without explanation. Simply making them available does nothing to make them understandable or usable to the public.**

There already is a huge gap at EPA between public availability of information and meaningful accessibility and transparency. This is true not only with regard to data availability but also when *analysis* is made public without adequate explanation. Take the example of the extensive analyses underlying the National Ambient Air Quality Standards, which regulate the six criteria air pollutants. For each of these pollutants, EPA synthesizes all relevant scientific information into an Integrated Science Assessment and a Risk or Exposure Assessment and then develops a Policy Assessment based on these reviews and recommendations from an advisory council. These thorough assessments are massive documents -- together running into the thousands of pages for each of the six pollutants -- that are publicly available.

However, if the goal is public accessibility, the current system is sorely lacking. The webpage for each pollutant contains shockingly little information to help users understand and use this highly technical information. For example, the page on particulate matter contains a *single sentence* describing “What Scientific and Technical Information Supports Review of the Standards” and a handful of sentences explaining the health effects of particulate matter.⁴ EPA provides nothing between this handful of sentences and the thousands of pages in the assessments that would make this sufficient for public education and engagement. This form of “transparency” falsely equates *availability* with *accessibility*.

⁴ [Setting and Reviewing Standards to Control Particulate Matter \(PM\) Pollution](#) and [Health and Environmental Effects of Particulate Matter \(PM\)](#) (EPA websites)

The proposed rule does not address insufficiencies such as this and calls for *even less* real accessibility than the mammoth science and exposure reviews as it calls for raw data and algorithms without context. If making analyses available without context fails at transparency and public participation, then making raw data and dose-response models available without context is an even greater failure.

False transparency for scientific research

The proposed rule states that it is in keeping with data transparency requirements of major scientific journals. However, the proposal misrepresents calls for transparency by scientists, and conversely, many scientists (including prominent journal editors and the EPA's own Scientific Advisory Board) have pushed back against this rule.⁵

At the very least, transparency requires careful and explicit discussion of the data, assumptions and boundary conditions, sources of error, accuracy, precision, and statistical significance. Scientific journals also require introductory sections to orient the reader to the purpose of the study and the evidence from which the study is designed, methods sections to precisely define and describe the study design, and discussion sections to articulate results, their limitations, and their implications. Scientific journals require extensive contextualization, and to take their data transparency requirements out of context is disingenuous and damaging. **Providing raw data without context can cloak scientific research as much as providing no data; providing raw data encourages not transparency but even greater manipulation, which can be used to produce false uncertainty.**

⁵ [The E.P.A. Says It Wants Research Transparency. Scientists See an Attack on Science.](#) (New York Times, March 2018); [Re: Don't Restrict EPA's Ability to Rely on Science](#) (Letter from scientists, April 2018); [Pruitt's Own Scientist Appointees Challenge EPA Science Restrictions](#) (Inside Climate News, May 2018)

EPA is using the idea of transparency in bad faith to dismiss evidence and produce false uncertainty

Requiring full data availability is a way to limit data inclusion; i.e. in the name of full knowledge it reduces the use of existing knowledge.

A policy to limit data inclusion stalls progress to protect human health. EPA justifies the proposed rule by citing the public cost of compliance. However, dismissing evidence of adverse health outcomes from studies that do not qualify as ‘high quality’ or fail to meet the vague transparency standards put forth in this proposed rule poses a greater cost burden to the public. These costs come in the form of health consequences from preventable chemical exposures.

EPA does not have anywhere near the necessary resources to study the huge number of chemicals currently in circulation that may affect human health. These unmet demands are further exacerbated by the estimated 2,000 new chemicals that are introduced each year.⁶ Under these severe resource constraints the proposed rule agrees that third party science must be a driver, leading to the synthesis of new information that contributes to the weight-of-evidence used to make regulatory decisions. EPA’s regulatory process should aim to maximize the results of third party contributions rather than limit them. Instead, this rule uses the idea of transparency to *reduce* the range of evidence considered in regulatory decision-making. In order to use the “best available science,” the full range of studies should be included—and their data, models, and findings should be situated and contextualized in the ways we identified in the above section: “Transparency requires much more than data availability.”

⁶ [NTP 2018](#), accessed 5/22/2018

Requiring full data availability and broad application of default models encourages analyses aiming to sow false uncertainty and put off protective regulation.

In addition to eliminating evidence from the regulatory process, the proposed measures on data and model availability facilitate not transparency but the culture of science denialism, which fits with the anti-protection agendas of fossil fuel and chemical industry lobbyists. Scientific uncertainty is used not only to deny risks, but to make potential benefits of regulation uncertain and to give weight to the costs; such cost-benefit analysis justifies failure to regulate.

In particular, external “validation”—a central component of this proposed rule—can instead take the form of “deconstruction of evidence” through “data dredging”.⁷ It is possible to increase uncertainty around each data point by taking data out of context, for example isolating endpoints of a model or isolating specific data points within it. Indeed, one of the most common measures of uncertainty is the standard deviation, the calculation for which includes dividing by one less than the sample size. By reducing the sample size in question, the standard deviation will increase unless the removed data are outliers. The era of big data has demonstrated the power of massive data sets that allow interpretation beyond what could be possible in smaller studies alone in part because the relative uncertainty becomes smaller and smaller. Studies that call specific data and parts of a model into question result, both intentionally and unintentionally, not in clarifying dose-response relationships but in the endless production of uncertainty.

Additionally, counting only those studies that themselves address a wide range of models as “high quality” [FR 18774] also lends itself to manipulation and produced uncertainty. We agree that EPA should not base regulatory decisions on limited models that may fail to capture and represent the actions of many chemicals. However, requiring by default the application of all competing models to validate results of a given study, particularly dose response data, is needlessly exhaustive and seeks to remove expert judgement and biological context. It is also

⁷ Wagner and Steinzor. 2018. [Deconstructing Regulatory Science](#). *The Regulatory Review*. July, 2018.

prohibitively costly, making certainty an impossible goal. The proposed rule could allow EPA to disqualify high quality, peer-reviewed studies that generate valuable findings if they use a limited range of models or study parameters. Prioritizing model-fit in this way counteracts a health-protective timeframe, endlessly extending the timeline for determining which chemicals are safe or not. A recent example of this negligent mode of operation culminated in the court order filed August 9th, requiring EPA to finalize the ban on the pesticide chlorpyrifos.⁸ EPA's failure to protect human health should not simply boil down to the availability and 'fit' of the data. The production of uncertainty is fitting with the anti-protection agendas of the fossil fuel and chemical industry lobbyists currently appointed as Agency leadership.

Unconventional models and novel research approaches to predict adverse health outcomes are often mischaracterized as lacking transparency

The proposal states that "EPA will use... standardized test methods... and good laboratory practices (GLP) to ensure transparent, understandable, and reproducible scientific assessments" [FR 18770]. Reliance on standardized methods and GLP has been another way to limit study inclusion -- in particular studies designed to elucidate adverse effects beyond toxicity and cancer. In this way, the proposed rule and the statutory authority used to justify it perpetuate glaring negligence that omits interest in *sensitivity* among the upheld "... interests of consistency, predictability and transparency..." Proponents of GLP claim that scientific approaches outside the scope of GLP, particularly by third-party investigators, are unsound. They use this controversy to deny the existence of adverse health outcomes found using 'non-standardized methods.'

To these points, an accumulating weight-of-evidence implicates environmental chemicals that can mimic normal hormones, especially during critical windows of development. This underscores the need to conceptualize study results in ways that account for biological organization and critical developmental times of exposure.

⁸ [9th Circuit Court of Appeals, No. 17-71636](#)

Currently, GLP neglects these sensitivities. Third party studies that investigate these more sensitive pieces of biological context should be integrated in ways that add to the weight-of-evidence rather than add to uncertainty and justification for delaying regulatory decisions. Especially with regard to hormone-like chemicals, there should be more emphasis placed on the *capacity* of the models and experimental designs to detect an adverse effect if one exists. To address this deficiency in chemical regulation, EPA must use diligence to capture these sensitive intricacies that are more predictive of adverse health outcomes of interest. Reliance on limited and less sensitive models itself is a way to willfully reduce knowledge of chemical hazards and delay necessary regulation. Ultimately, regulatory efforts should focus on additional requirements for toxicity testing to adequately address adversity.

Emblematic of these deficiencies in chemical regulatory science is the Consortium Linking Academic and Regulatory Insights on Bisphenol A Toxicity (CLARITY-BPA). The program intends to 'settle' longstanding differences between guideline-driven (GLP) regulatory studies by the U.S. Food and Drug Administration (FDA) and the hypothesis-driven studies by academic third parties. The aim is to settle major controversies in interpretation of effects of hormone-like chemicals, like bisphenol A (BPA), that have been extensively linked to metabolic, reproductive and behavioral adverse susceptibilities and health outcomes. With the support of the National Toxicology Program (NTP) and the National Institute of Environmental Health Sciences of the National Institutes of Health (NIH), this program presents valuable insights that can inform integration of third party scientific contributions and better approaches to transparency and method standardization in dose response data and models underlying pivotal regulatory science. CLARITY-BPA study results, insights, and expertise are best integrated into any rule on transparency in dose response data and models, especially in the elucidation of regulatory best practices for hormone-like chemicals. Rather than peddle in false transparency, EPA should not only participate in but also incentivize collaborative efforts to address the empirical divide between guideline- and hypothesis-driven sciences.

--

In short, the proposed measures on data and model availability and use facilitate not transparency but the culture of science denialism: dismissing important

evidence and dredging data to endlessly produce false uncertainty and delay scientific advances regarding the harmful effects of chemical exposures. This false uncertainty is used to justify failure to protect environmental and public health.

IV. EPA'S FOCUS ON TRANSPARENCY IN DOSE-RESPONSE SCIENCE IS INCONSISTENT WITH ITS RECENT TURN TO SECRECY

Some brief examples include:

- As EDGI has documented, EPA has made less accessible or removed extensive information about climate change that had been available on EPA's website.⁹
- EPA has failed to provide the information necessary for independent evaluation of its decisions under TSCA, e.g. EPA's recent decision to green light a new fragrance chemical despite a range of health concerns.¹⁰
- EPA has pushed to delay releasing reports documenting harms of chemicals, e.g. formaldehyde¹¹ and Per- and Polyfluoroalkyl Substances (PFAS).¹²
- EPA has reduced opportunities for public participation by creating short comment periods and trying to circumvent public comment entirely.¹³
- EPA's procedure for implementing TSCA is designed to limit the range of information included in regulatory decisions by limiting the sorts of uses/exposures that will be analyzed.¹⁴

⁹ See for example the following reports produced by EDGI: [Missing Environmental Protection Agency Endangerment Finding Web Resources](#) (July 2017); [Assessment of Removals and Changes in Access to Resources on the EPA's "Climate and Energy Resources for State, Local, and Tribal Government" Website](#) (October 2017); [Change in Access to the EPA's "A Student's Guide to Global Climate Change" Website](#) (May 2017); [Removal from the Greening EPA Website of a Climate Change Adaptation Web Resource, Links to Resources, and Mentions of EPA's Own Greening Performance Goals](#) (Dec 2017)

¹⁰ The lack of transparency on this decisions is laid out in detail in EDF's three-part analysis: "EPA rams through its reckless review scheme for new chemicals under TSCA, your health be damned" (EDF, August 2018): [Part 1](#), [Part 2](#), [Part 3](#)

¹¹ [Sources: EPA blocks warnings on cancer-causing chemical](#) (Politico, July 2018)

¹² [Suppressed Study: The EPA Underestimated Dangers of Widespread Chemicals](#) (ProPublica, June 2018)

¹³ Heinzerling, Lisa, [The Legal Problems \(So Far\) of Trump's Deregulatory Binge](#) (October 6, 2017). Harvard Law & Policy Review, Forthcoming.

¹⁴ [The Chemical Industry Scores a Big Win at the E.P.A.](#) (New York Times, June 2018)

- EPA has drastically shifted influence away from the broader public and toward business interests, for example in private meetings and in appointments to science advisory boards.
- Especially under Scott Pruitt -- who was Administrator when this proposed rule was written and published -- EPA has been secretive, for example denying FOIAs until required to release documents by courts. Pruitt's secrecy was famous: not telling reporters where he was speaking, not letting the press into events, hiding and even changing his calendars, etc.¹⁵

The litany of ways the EPA under the current administration has been secretive and has sought to limit information and evidence of chemical harms suggests that the idea of “transparency” grows not out of commitment to openness and public participation. Rather, it is being used here strategically, in bad faith, to limit the evidence used in regulatory decision-making and to undermine moves toward protective regulations.

¹⁵ For example, [Anti-secrecy lawsuits soaring against Pruitt's EPA](#) (Politico, February 2018); [Pruitt rules EPA under a cloak of secrecy](#) (EDF, September 2017)

V. EDGI'S ALTERNATIVE: STRENGTHEN REAL TRANSPARENCY AND ACCESSIBILITY BY INCORPORATING AND CONTEXTUALIZING THE FULL RANGE OF EVIDENCE

Environmental health regulations are literally matters of life and death. Therefore, regulatory science should be guided by principles that foreground public health protection and environmental justice, both of which are central to EPA's mission. To this end, *transparency* can only be achieved through *privacy*, *accessibility*, and *scientific rigor*, which in turn require *contextualized* and *participatory* knowledge making carried out in a *timely manner*.

Privacy: Robust transparency requires not only consistency in requirements for data but also requires recognizing the right to privacy and anonymity for research participants. Researchers, particularly in the fields of epidemiology and other environmental health sciences, have navigated the narrow path of transparent yet protected data for decades; much academic environmental health research is conducted with integrity. Yet it is these fields that are the most ripe for attack from industry due to their delicate balance of protection and openness.

Accessibility: Meanwhile, industry proprietorship has been coddled by a government ensnared by business interests to such an extent that it has prevented government scientists from being able to efficiently analyze the health effects of particular compounds such as PFAS¹⁶ and glyphosate¹⁷ (both receiving public attention currently), or to investigate water quality impacts from activities like hydraulic fracturing.¹⁸ These are not only glaring examples of non-transparency, but they also drain government funding and resources. Industry proprietorship alongside agency underfunding have rendered crucial environmental health and environmental regulatory information inaccessible to the public. EDGI asserts that people have the right to know about the status of and factors influencing their

¹⁶ [The Teflon Toxin](#) (a 17-part series of articles from *The Intercept*, 2015-2018)

¹⁷ [Monsanto's EPA-Manipulating Tactics Revealed in \\$289 Million Case](#) (*Rolling Stone*, August 2018)

¹⁸ [Study of the Potential Impacts of Hydraulic Fracturing on Drinking Water Resources, Progress Report](#) (EPA/601/R-12/011, 2012)

environment and its management.¹⁹ This includes uninterrupted, public access to environmental databases and websites that are easy to navigate, providing valid and contextualized information aimed towards laypersons.

Contextualization: Proper contextualization of environmental data takes into account data provenance and the circumstances under which data has been collected and stored. Metadata should include the sample or data location, institution responsible for data collection and analysis, type of sampling conducted, time and frequency of sample or data collection, suite of parameters measured, basic assumptions, sources of error, and uncertainties. Additional information stored with the data should include the population and/or geography relevant to the study, why and how the study was executed, who funded the study, proposed studies that were rejected and the justifications, and potential values, biases, and uncertainties of the study.

Such contextualization not only addresses the public's right to know, but also improves *scientific rigor*. It does so by providing information about both the scientific and socio-political contexts of specific studies, which influence research questions and study designs. Against the false transparency of data availability, transparency through contextualization enhances everyone's ability to interpret data by taking into account the perspectives and situations that have constructed that data.

Participation: Scientific rigor, contextualization, transparency, and accessibility all can be improved through the incorporation of multiple, "third party" perspectives in study design and analyses. This means seeking ways to include -- rather than exclude -- cutting edge scientific research. It also means expanding participatory knowledge making; EDGI asserts that incorporating participant-centered values and research design will improve both scientific rigor and public health outcomes. Inclusion of only scientist or industry perspectives has resulted in regulations that exclude public health concerns. One example is the removal of the neurotoxic gas hydrogen sulfide from EPA's initial list of Hazardous Air Pollutants in 1991 despite

¹⁹ [EDGI Mission, Vision, Values](#)

evidence that low dose, chronic exposure is detrimental to human health.²⁰ Development, sharing, and stewardship of science and data with the public, including marginalized communities, will increase real transparency and accessibility while improving knowledge of the true costs and benefits of both chemicals and regulations.

Timeliness: Unlike science as the pursuit of basic knowledge, the point of regulatory science is to provide the information necessary for making timely decisions, including many that are literally matters of life and death. Therefore, regulators must be able to use a body of scientific evidence that is imperfect; they must be enabled to act even in the face of uncertainty. This is because uncertainty is inevitable: the world is complex, human error always exists, social and political bias always run through scientific studies, not all studies can be replicated, and important data (particularly about marginalized groups) often does not exist. **Transparency does not mean certainty, which is a tool for regulatory delay. Rather, transparency requires contextualizing uncertainty in order to move forward with environmental and human health protections.**

²⁰ [Initial List of Hazardous Air Pollutants with Modifications](#) (EPA website)

VI. CONCLUSION

The language of “strengthening transparency” is seductive: no one wants to be against transparency. In this case, however, transparency is not being used to identify the best science and encourage public understanding and meaningful participation, as the rule purports to do. Instead, the proposed rule uses the *idea* of transparency as a weapon to reduce public involvement, increase secrecy, dismiss and hide evidence of harms, and delay regulatory action.

The alternative is true transparency, which requires participatory science that contextualizes evidence by incorporating information about data provenance, including the scientific and political contexts within which studies are designed and executed. Rather than delaying regulatory action until all evidence has been validated-- until the elusive certainty has been achieved-- true transparency facilitates nimble and timely regulatory action guided by the twin goals of public health and environmental justice.