

August 16, 2018

VIA ELECTRONIC SUBMISSION

COMMENTS OF THE NAAQS IMPLEMENTATION COALITION ON THE UNITED STATES ENVIRONMENTAL PROTECTION AGENCY’S PROPOSAL ENTITLED “STRENGTHENING TRANSPARENCY IN REGULATORY SCIENCE”

**83 FED. REG. 18768 (APRIL 30, 2018)
DOCKET NO. EPA-HQ-OA-2018-0259**

The National Ambient Air Quality Standards (“NAAQS”) Implementation Coalition submits these comments to the Environmental Protection Agency (“EPA” or “Agency”) on its proposal entitled “Strengthening Transparency in Regulatory Science” (“Transparency Proposal”). The NAAQS Implementation Coalition is comprised of trade associations, companies, and other entities who confront challenges in permitting and operating facilities under increasingly-stringent NAAQS.¹

COMMENTS

Our members, and the companies they represent, have a proven record of working with states and regional EPA offices on implementing emissions reduction strategies to attain NAAQS. However, with NAAQS now at levels near or even below background concentrations, demonstration requirements for Clean Air Act permits often exceed the limits of current tools and policies for NAAQS implementation. This makes it increasingly difficult for companies, even in areas that attain NAAQS, to obtain the necessary approvals for new, state-of-the-art projects that create jobs and bring much needed tax revenue to local communities. This is not a coherent approach to NAAQS, and is certainly not what Congress intended of permitting for attainment areas. Rather, the Clean Air Act is clear that Prevention of Significant Deterioration (“PSD”) permitting should “insure that economic growth will occur in a manner consistent with the preservation of existing clean air resources.”²

¹ In light of our area of focus, these comments focus solely on the Transparency Proposal’s implications for air regulations.

² Clean Air Act §160(3), 42 U.S.C. § 7470(3).

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Overly-stringent NAAQS not only strain the limited feasible and cost effective control options for their implementation, they also leave EPA with little margin for error in setting future standards that, as the Supreme Court requires, are sufficient to protect public health, but no more so than necessary.³ Without a more transparent process, EPA is more likely to set NAAQS that fail to provide objective public benefit. While inaccurate assumptions in both setting and implementing NAAQS could be more readily tolerated under prior, less stringent standards, recent, more-stringent standards have eroded that capacity to absorb biases and flawed inputs.

Addressing this new reality of setting and implementing NAAQS starts with an inherently forward-looking review process that assesses science and policy in a rigorous and holistic manner. The Transparency Proposal fosters such an open-source approach to pivotal regulatory science, one that enables the public to comment more meaningfully on the dose response data and models underlying NAAQS review. This will lead to a more effective NAAQS process that still meets the Clean Air Act’s mandate to protect public health.

We support the Transparency Proposal in principle because its open process supports a more cohesive approach to NAAQS development and implementation. However, we recommend that the Transparency Proposal be further clarified to enhance safeguards of private, sensitive, and confidential information, tailor its requirements to appropriate rulemakings, and provide an exemption process that robustly assesses studies without excluding them from the rulemaking process. We also encourage EPA to further develop transparent methodologies for use in future research either performed or funded, or both, by the Agency.

I. The Transparency Proposal Would Enhance the Public’s Ability to Provide Meaningful Comments During NAAQS Review.

The Transparency Proposal, when finalized, can enhance public input into the rulemaking process, resulting in better air regulations. According to EPA, the Transparency Proposal is intended to ensure that the data underlying significant regulations “are available in a manner sufficient for independent validation[.]”⁴ thereby “better informing the public” and “enhancing the public’s ability to understand and meaningfully participate in the regulatory process.”⁵

³ See *Whitman v. Amer. Trucking Assoc.*, 531 U.S. 457, 473 (2001).

⁴ 83 Fed. Reg. at 18,773 (Proposed 40 C.F.R. § 30.1).

⁵ *Id.* at 18,769.

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The Transparency Proposal builds upon transparency principles advanced by the previous Administration. President Obama noted in an Executive Branch-wide memorandum issued on the second day of his presidency that “[t]ransparency promotes accountability and provides information for citizens about what their Government is doing.”⁶ Shortly thereafter, then-EPA Administrator Lisa Jackson issued her own memorandum to EPA employees stating that “[t]he American people will not trust us to protect their health or their environment if they do not trust us to be transparent and inclusive in our decision-making.”⁷

The Transparency Proposal moves these general concepts to the specific – shedding light not just on the decision-making process, but also on the information influencing those decisions. As the Transparency Proposal explains, “When EPA develops significant regulations using public resources, including regulations for which the public is likely to bear the cost of compliance, EPA should ensure that the data and models underlying scientific studies that are pivotal to the regulatory action are available to the public.”⁸

In this way, the Transparency Proposal increases replicability and verification in the scientific process, thereby allowing the testing of critical methodological assumptions and mitigating biases in key studies that inform significant regulations. It recognizes that transparency can be more than simply maximizing disclosure, but rather a means by which studies are contextualized to enhance public participation in the notice-and-comment process critical to effective rulemaking.

II. EPA is Authorized by Congress to Promulgate Internal Housekeeping Regulations Like the Transparency Proposal.

The Transparency Proposal relies upon authority under various environmental statutes, including Clean Air Act sections 103 and 301(a).⁹ EPA solicits comment on whether additional or alternative sources of authority are an appropriate basis for the Transparency Proposal.¹⁰

⁶ Memorandum from President Obama to the Heads of Executive Departments and Agencies, Transparency and Open Government 1, Jan. 21, 2009.

⁷ Memorandum from EPA Adm’n. Lisa Jackson to All EPA Employees, Transparency in EPA’s Operations 1, Apr. 23, 2009.

⁸ 83 Fed. Reg. at 18,768.

⁹ *Id.* at 18,769.

¹⁰ *Id.* at 18,771.

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In addition to those statutes cited in the Transparency Proposal, we note EPA’s authority under 5 U.S.C. § 301. More commonly known as the “Federal Housekeeping Statute,” this provision authorizes the “head of an Executive department”¹¹ to “prescribe regulations for the government of his department, the conduct of its employees, the distribution and performance of its business, and the custody, use, and preservation of its records, papers, and property.”¹²

The Federal Housekeeping Statute authorizes the Transparency Proposal – a regulation for the government of EPA and the performance of its business – on a general basis, similar to how the environmental statutes cited by EPA do so specifically. As seen in the Federal Housekeeping Statute, Congress expected that regulations like the Transparency Proposal would be so commonplace within agencies that it provided a general federal government-wide authorization for their promulgation. We recommend EPA to consider the Federal Housekeeping Statute as additional support for the Transparency Proposal.

III. EPA Should Clarify that the Transparency Proposal Does not Assert Authority Under the Law to Disclose Private, Sensitive, and Confidential Information.

EPA must balance the Transparency Proposal’s sound policy goals with the Agency’s legal obligation to be a good steward of private, sensitive, and confidential information. We do not read the Transparency Proposal as compromising these responsibilities. However, EPA can further clarify the Transparency Proposal’s information protections by explicitly stating that regulations arising from the Transparency Proposal do not assert authority under the law to disclose private, sensitive, and confidential information.

Pivotal regulatory science often relies on aggregated health information subject to various legal protections. For example, the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”) and its related Privacy Rule¹³ place restrictions on the use and disclosure of certain protected health information (“PHI”). Those collecting PHI and compiling it into the databases used by researchers for dose response data and models are

¹¹ EPA is technically not an “Executive department” within the meaning of 5 U.S.C. § 301. *See* 5 U.S.C. § 101 (defining “Executive departments”). However, the Department of Justice has concluded that the EPA Administrator has the same “housekeeping” authority under EPA’s organic statute. Dep’t. of Justice, Office of Legal Counsel, *Authority of the Environmental Protection Agency to Hold Employees Liable for Negligent Loss, Damage, or Destruction of Government Personal Property*, 32 OPINIONS OF THE OFFICE OF LEGAL COUNSEL 79, 81-83 (May 28, 2008) available at: <https://www.justice.gov/file/482166/download>.

¹² 5 U.S.C. § 301 (emphasis added).

¹³ 45 C.F.R. Part 160 and Part 164, Subparts A and E.

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frequently “covered entities” under HIPAA. Such covered entities are required, through non-disclosure agreements or other mechanisms, to condition researchers’ access to these databases on HIPAA and Privacy Rule requirements. Thus, HIPAA and the Privacy Rule can ultimately restrict the disclosure of dose response data and models, including PHI. However, as discussed below, neither HIPAA nor the Privacy Rule place a blanket prohibition on releasing such dose response data and models when PHI is de-identified.

EPA also faces direct restrictions on the disclosure of proprietary information and trade secrets. Protections of such information are widely recognized throughout the law. Either by statute or under common law, all 50 states have laws protecting proprietary information.¹⁴

At the federal level, Exemption 4 of the Freedom of Information Act (“FOIA”) exempts government agencies from being compelled to disclose “trade secrets and commercial or financial information obtained from a person [that is] privileged or confidential.”¹⁵ Federal agencies, including EPA, are not merely protected from mandatory disclosure of proprietary information under FOIA. Unless otherwise authorized by law, they are prohibited under “an extraordinarily broadly worded criminal statute”¹⁶ from discretionary disclosures of such information. Specifically, 18 U.S.C. § 1905, commonly known as the “Trade Secrets Act,” prohibits employees of the federal government from disclosing “in any manner or to any extent not authorized by law” trade secrets and other types of proprietary information received in the course of federal employment. Violating the Trade Secrets Act is punishable by a fine and up to one year in prison, as well as mandatory removal from office.

Agency actions that disclose information in violation of the Trade Secrets Act can be challenged as “contrary to law” under the Administrative Procedure Act.¹⁷ Furthermore, the Supreme Court unanimously ruled in *Chrysler Corp. v. Brown* that agency regulations compelling disclosure of trade secrets and proprietary information are not “authorized by law” under the Trade Secrets Act unless such disclosure is “reasonably within the contemplation” of “statutory grants of authority.”¹⁸ As Justice Marshall summarized in his concurrence, “[i]n

¹⁴ Chris Montville, *Reforming the Law of Proprietary Information*, 56 DUKE L.J. 1159, 1162 (2007).

¹⁵ 5 U.S.C. § 552(b)(4).

¹⁶ DEP’T. OF JUSTICE, GUIDE TO THE FREEDOM OF INFORMATION ACT 354 (2009) *available at*: https://www.justice.gov/sites/default/files/oip/legacy/2014/07/23/exemption4_0.pdf#_PAGE92.

¹⁷ *McDonnell Douglas Corp. v. Widnall*, 57 F.3d 1162, 1164 (1995).

¹⁸ *Chrysler Corp. v. Brown*, 441 U.S. 281, 306 (1979) (emphasis in original). Notably, *Chrysler* specifically examined the Federal Housekeeping Statute, finding that language in the statute stating that it “does not authorize withholding information from the public or limiting the availability of records to the public” does not specifically grant authority to disclose information protected by the Trade Secrets Act. *Id.* at 309-316. As

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imposing the authorization requirement of [the Trade Secrets Act], Congress obviously meant to allow only those disclosures contemplated by congressional action. Otherwise, the agencies Congress intended to control could create their own exceptions to [the Trade Secrets Act] by promulgating valid disclosure regulations.”¹⁹ In other words, agencies cannot create their own exemptions to the Trade Secrets Act. Rather, they must look to Congress for authority to disclose trade secrets and proprietary information.

Limits on agency disclosure of trade secrets and other proprietary information under the Trade Secrets Act are widely acknowledged throughout the federal government, including in the context of environmental regulations. For example, the Bureau of Land Management (“BLM”) noted in 2013 that it “lacks statutory authority to exclude hydraulic fracturing chemicals by regulation from the scope of the Trade Secrets Act” and that even the “assertion that more information provided to the public would assist the BLM in its statutory duties does not render disclosure of operators’ trade secrets ‘authorized by law.’”²⁰

We do not believe that EPA’s intends the Transparency Proposal to override restrictions on the disclosure of private, sensitive, and confidential information, whether PHI, trade secret or proprietary information, or in any other form. Indeed, the Transparency Proposal does the opposite by providing a process to exempt dose response data and models containing such information from its requirements. Additionally, the Transparency Proposal does not explicitly claim new authority under existing environmental statutes to disclose protected sensitive and confidential information. We do not read either of the Clean Air Act provisions cited in the Transparency Proposal nor any other provision of the Clean Air Act as providing such statutory authority.

Instead, we understand the Transparency Proposal as seeking to provide the public with information that contextualizes pivotal regulatory science so comments on significant regulatory decisions can be more meaningful, while still protecting private, sensitive, and confidential information. EPA can clarify this position by explicitly stating that any final regulations arising from the Transparency Proposal do not assert authorization under the law to disclose protected sensitive or confidential information, and that any such claim must be independently based on a statutory grant of authority from Congress.

such, reliance on the Federal Housekeeping Statute for authorization of the Transparency Proposal would not grant EPA authority to override Trade Secrets Act protections.

¹⁹ *Id.* at 320.

²⁰ Oil and Gas; Hydraulic Fracturing on Federal and Indian Lands; Proposed Rule, 78 Fed. Reg. 31,636, 31,660 (May 24, 2013).

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IV. EPA Should Further Detail How the Transparency Proposal will be Applied.

The Transparency Proposal would subject dose response data and models to a high standard of robustness, exceeding that of even the traditional peer review process. While this is a sensible approach where the costs and benefits of a decision are substantial, such rigor is not necessarily practical in all circumstances. Rather, the Transparency Proposal should be tailored according to the type and scope of regulatory decision involved, and its exemption process should allow for varying outcomes, as explained below.

a. The Transparency Proposal is Not, and Does Not Need to be, an Exclusionary Rule.

Public discourse concerning the Transparency Proposal has been marked by presumption rather than a careful review of its actual requirements. Some have mischaracterized the Transparency Proposal as an exclusionary rule that would bar EPA from considering studies where underlying information cannot be made public. Yet, a plain reading of the Transparency Proposal's specific regulatory language shows no such requirement.

Under the Transparency Proposal, EPA is to "clearly identify" all studies relied upon in any final agency action, and "should make all such studies available to the public to the extent practicable."²¹ Where a regulatory action is determined to be "significant" by the Office of Management and Budget,²² EPA is to "ensure" that dose response data and models²³ underlying pivotal regulatory science²⁴ "are publicly available in a manner sufficient for independent validation."²⁵ The Administrator has authority to grant exemptions to these requirements "on a case-by-case basis" where, among other reasons, compliance "is not feasible . . . in a fashion that is consistent with law, protects privacy, confidentiality, confidential business information, and is sensitive to national and homeland security."

²¹ 83 Fed. Reg. at 18,773 (Proposed 40 C.F.R. § 30.4).

²² 83 Fed. Reg. at 18,773 (Proposed 40 C.F.R. § 30.2).

²³ *Id.* ("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.")

²⁴ *Id.* ("Pivotal regulatory science means the specific scientific studies or analyses that drive the requirements and/or quantitative analysis of EPA final significant regulatory decisions.")

²⁵ 83 Fed. Reg. 18,773 (Proposed 40 C.F.R. § 30.5).

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To paraphrase, the Transparency Proposal states that: (1) EPA should generally release regulatory science where practicable; (2) EPA shall ensure certain information underlying studies cited in significant rulemaking is made publicly available; and, (3) the Administrator has authority to exempt studies cited in significant rulemakings containing certain information, including that which is private, sensitive, or confidential, from these requirements. These are reasonable steps to improve the evidentiary basis for EPA's regulatory policies and improve regulatory outcomes by targeting resources to where they can achieve the largest benefits.²⁶

It would be unsound policy for EPA to summarily exclude science from regulatory consideration – and the Transparency Proposal does not do so. To the contrary, it presumes proactive management of private, sensitive, or confidential information and only requires disclosure of dose response data and models in appropriate circumstances. Rather than rigidly excluding important studies, the Transparency Proposal provides a flexible, case-by-case exemption process.

The Transparency Proposal is not, and does not need to be, an exclusionary rule in order to accomplish its underlying goal of informing public discourse on significant regulations. It can be implemented to protect private, sensitive, or confidential information while still seeking maximum possible transparency.

Public release of all dose response data and models is obviously the preferred method of complying with the Transparency Proposal. While this may be difficult, the challenges are not insurmountable. The presence of private, sensitive, or confidential information does not necessarily make disclosure of dose response data and models impossible.

Some contend that HIPAA, through the Privacy Rule, automatically requires complete redaction of all data elements related to PHI, rendering the disclosed dataset unusable for further analysis. However, this assumption focuses only on the Privacy Rule's "Safe Harbor Method," which generally requires that all covered PHI be eliminated regardless of de-identification.²⁷ It does not address the Privacy Rule's other compliance mechanism, the "Expert Determination Method," which allows for release of data elements related to PHI where an expert using generally accepted methods has de-identified the information.²⁸ As

²⁶ Susan E. Dudley, *Public Interest Comment on the Environmental Protection Agency's Proposed Rule Strengthening Transparency in Regulatory Science*, GEO. WASH. U. REGULATORY STUDIES CTR., Docket No. EPA-HQ-OA-2018-0259-0555, May 18, 2018.

²⁷ 45 C.F.R. § 164.514(b)(2).

²⁸ *Id.* at (b)(1).

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EPA notes, federal agencies have developed tools and methods to de-identify private information for a variety of disciplines, including PHI redaction.²⁹ Wherever possible, EPA should work to de-identify PHI so that usable dose response data and models can be made public through the Privacy Rule's Expert Determination Method.

Where private, sensitive, or confidential information cannot be de-identified, dose response data and models could still be subject to independent verification. In these cases, EPA should facilitate review of the dose response data and models by a diverse group of experts subject to HIPAA-compliant non-disclosure agreements, similar to those signed by the researchers who created the sensitive datasets. While not providing full public review of the information, this approach can still allow for significant replicability and verification, balancing the Transparency Proposal's goals with privacy needs.

Even where confidential or sensitive information cannot be de-identified or where a discrete group of outside experts cannot review dose response data and models, pivotal regulatory science need not be excluded. Rather, EPA could qualify discussion of such a study with a statement to the effect that "due to sensitive underlying dose response data and models, the robustness of this study's results could not be subjected to outside replicability and verification." While the study would remain in a rulemaking's record, the Administrator would be free to consider uncertainties in the study arising from the lack of external review when making regulatory decisions. Administrators have taken similar methodological considerations into account when weighting studies in past NAAQS reviews.³⁰

b. The Transparency Proposal Should be Tailored to Appropriate Situations.

Making dose response data and models publicly available for replication and verification through de-identification or other processes could be resource-intensive. For this and other reasons, the Transparency Proposal is appropriately focused on pivotal regulatory science involved in significant regulatory actions resulting in substantial costs. Because of the unique characteristics of air rules, the Transparency Proposal's high standard of

²⁹ 83 Fed. Reg. at 18,771.

³⁰ See e.g., National Ambient Air Quality Standards for Ozone, 80 Fed. Reg. 65,292, 65,326 (explaining that then Adm'n. McCarthy's "determination to attach *less weight* to the epidemiologic-based risk estimates reflected her *consideration of key uncertainties*, including the heterogeneity in effect estimates between locations, the potential for exposure measurement errors, and uncertainty in the interpretation of the shape of concentration-response functions for O₃ concentrations in the lower portions of ambient distributions.") (emphasis added).

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robustness is particularly appropriate to significant regulatory actions under to the Clean Air Act.

Air is the most constant of regulated environmental media, surrounding us at all times. Its ubiquity can quickly magnify even small projected incremental benefits exponentially. On the one hand then, air regulations can be a source of significant public health improvement. On the other hand, this amplification effect can cause small initial miscalculations to dramatically skew cost-benefit analysis.

This issue is particularly crucial in light of the federal government’s reliance on air benefits to support regulatory activity. Over the last decade, benefits claimed under air rules have accounted for over 95% of benefits associated with EPA rules and 80% of the benefits for all rules across the federal government.³¹

Air regulations do not come without a cost. Indeed, 70% of monetized costs under federal regulations come from EPA air rules.³² Many believe that these estimates do not capture the total cost of compliance. As a practical matter, these costs have far-reaching effects on society. Air regulations not only require large facilities to install emission control equipment, but can even determine the consumer products that companies sell.³³ They can also influence whether new facilities are located in the United States or abroad.

The scientific replicability and verification provided by the Transparency Proposal are uniquely important to studies influencing EPA’s calculations of both the benefits and costs of air regulations. Air regulations are the most likely to incur substantial costs (and benefits), and are therefore most appropriate for the Transparency Proposal’s high standard of robustness. EPA should implement the Transparency Proposal in a manner well-tailored to significant regulations under the Clean Air Act.

³¹ OFFICE OF MANAGEMENT AND BUDGET, OFFICE OF INFORMATION AND REGULATORY AFFAIRS, 2017 DRAFT REPORT TO CONGRESS ON THE BENEFITS AND COSTS OF FEDERAL REGULATIONS AND AGENCY COMPLIANCE WITH THE UNFUNDED MANDATES REFORM ACT 13.

³² *Id.*

³³ See e.g., *EPA’s Proposed Ozone Rule: Potential Impacts on Manufacturing*, Hearing Before the H. Subcomm. on Energy and Power and Subcomm. on Commerce, Manufacturing, and Trade, H. Comm. on Energy and Commerce, 114th Cong., June 16, 2015 (testimony of Stacey-Ann Taylor, Dir., Product Stewardship, Henry Co.) (noting that while the company manufactures 1,200 products, in certain parts of the country, only half are sold due to ozone restrictions).

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V. EPA Should Build “Transparency by Design” into its Research Requirements.

Rather than employing after-the-fact de-identification protocols, it would be far easier to achieve the Transparency Proposal’s replicability and verification goals if transparency were incorporated into studies from the outset. EPA should go beyond the Transparency Proposal to develop methods that encourage transparency early in studies’ development.

EPA should borrow from the well-known privacy policy, “privacy by design,” which calls for privacy to be taken into account throughout an entire developmental process. Building on this concept, EPA could incorporate “transparency by design” requirements into its research grants by conditioning funding on accounting for transparency throughout studies’ lifecycles. EPA could conduct further research on “transparency by design” protocols, such as anonymous coding methods, to be incorporated in these requirements. Such forward-looking planning can most efficiently accomplish the Transparency Proposal’s goal of better informing public comments in significant EPA rulemakings.

CONCLUSION

The Transparency Proposal would increase replicability and verification in the scientific process, thereby testing critical methodological assumptions and mitigating biases in key studies upon which the Agency relies in developing regulations. It recognizes that transparency can go beyond simply maximizing disclosure, to better contextualizing studies through replicability and verification. In doing so, the public can more meaningfully take part in the notice-and-comment processes for significant EPA rulemakings. As EPA advances the Transparency Proposal, it should implement these sound policy goals in concert with its obligations to protect private, sensitive, and confidential information. The NAAQS Implementation Coalition appreciates EPA’s efforts on the Transparency Proposal as well as this opportunity to present its views on the topic.

Sincerely,

A handwritten signature in blue ink that reads "Joseph C. Stanko, Jr." The signature is written in a cursive, flowing style.

Joseph C. Stanko, Jr.
*Counsel for the
NAAQS Implementation Coalition*