THE GEORGE WASHINGTON UNIVERSITY

WASHINGTON, DC

Public Interest Comment[1] on

The Environmental Protection Agency's Proposed Rule

Strengthening Transparency in Regulatory Science

Docket ID No. EPA-HQ-OA-2018-0259; FRL-9977-40-ORD
RIN: 2080-AA14

May 18, 2018

Susan E. Dudley, Director[2]

The George Washington University Regulatory Studies Center

The George Washington University Regulatory Studies Center improves regulatory policy through research, education, and outreach. As part of its mission, the Center conducts careful and independent analyses to assess rulemaking proposals from the perspective of the public interest. This comment on the Environmental Protection Agency's proposed rule to strengthen the transparency of its regulatory science does not represent the views of any particular affected party or special interest, but is designed to evaluate the effect of the proposal on the reliability of the scientific information underlying EPA's regulatory decisions.

Introduction

In this proposal, EPA aims to strengthen the transparency of the science it considers "pivotal" to its significant regulatory actions by ensuring that "the data and models underlying the science is publicly available in a manner sufficient for validation and analysis." It cites existing authorities and policies, but acknowledges, "EPA has not previously implemented these policies and guidance in a robust and consistent manner."

[1] This comment reflects the views of the author and does not represent an official position of the GW Regulatory Studies Center or the George Washington University. The Center's policy on research integrity is http://regulatorystudies.columbian.gwu.edu/policy-research-integrity.

[2] Director, the George Washington University Regulatory Studies Center and Distinguished Professor of Practice in the Trachtenberg School of Public Policy and Public Administration.

The rule would not directly regulate non-governmental entities, but instead would require "EPA to ensure that the regulatory science underlying its actions is publicly available in a manner sufficient for independent validation."[3] The preamble says the policy is "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."[4] In the long run, through this rule, EPA aims "to change agency culture and practices regarding data access so that the scientific justification for regulatory actions is truly available for validation and analysis."[5]

The proposal defines "*dose response data and models"* as those "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."[6] "*Pivotal regulatory science"* refers to "specific scientific studies or analyses that drive the requirements and/or quantitative analysis of EPA final significant regulatory decisions."[7] "*Regulatory decisions"* are limited to "significant regulatory actions" as defined in Executive Order 12866.[8] *"Regulatory science* means scientific information, including assessments, models, criteria documents, and regulatory impact analyses, that provide the basis for EPA final significant regulatory decisions," and *research data* is used as "defined in Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards."[9]

The rule would require EPA to:

1. Clearly identify all regulatory science it relied on in selecting a regulatory action and make those studies available to the public "to the extent practicable."[10]
2. Consistent with laws and sensitive to privacy, confidentiality, and national and homeland security, "ensure that *dose response data and models* underlying *pivotal regulatory science* are publicly available in a manner sufficient for independent validation."[11]
3. "Describe and document any assumptions and methods used," including the scientific basis for those assumptions, as well as analysis "showing the sensitivity of the modeled results to alternative assumptions."[12]

[3] Proposed §30.1. 83 FR 18773
[4] 83 FR 18770
[5] 83 FR 18770
[6] Proposed §30.2. 83 FR 18773
[7] Proposed §30.2. 83 FR 18773
[8] Proposed §30.2. 83 FR 18773
[9] Proposed §30.2. 83 FR 18773
[10] Proposed §30.4. 83 FR 18773
[11] Proposed §30.5. 83 FR 18773
[12] Proposed §30.6. 83 FR 18774

4. "Give explicit consideration to high quality studies" that may challenge existing default assumptions including "parametric dose-response or concentration-response models; a robust set of potential confounding variables; nonparametric models that incorporate fewer assumptions; various threshold models across the dose or exposure range; and models that investigate factors that might account for spatial heterogeneity."[13]
5. "Conduct independent peer review on all *pivotal regulatory science* used to justify *regulatory decisions,"* consistent with existing peer review requirements and exemptions.[14]

It is unusual for an agency to provide guidelines such as these through a rulemaking rather than internal guidance; however, the transparency of this rulemaking approach is consistent with the goals of the proposal, and the robustness and legitimacy of any final policy will be enhanced if it is supported by the record the agency develops as it solicits public comment.[15] A 30-day comment period may not provide enough time for constructive input on key issues, however, and a May 12, 2018 memorandum from a working group of EPA's Science Advisory Board (SAB) argues that this "action merits further review by the SAB."[16]

EPA also seeks comment on its legal authority for the rulemaking, and the appropriateness of the proposed policies to regulatory decisions developed pursuant to its various statutory mandates. This is important, but this comment will leave those issues to others and focus on the intrinsic merits of the proposal.

Merits of the Proposed Rule

1) EPA will clearly identify and make publicly available the studies and science relied on for significant regulatory actions.

When the Office of Information and Regulatory Affairs (OIRA) tallies up the total benefits and costs of all federal regulations each year, EPA's regulations always comprise the bulk of those figures. In OIRA's most recent draft report, for example, EPA's estimated annual benefits of the regulations it issued between fiscal years 2007 and 2017 ranged from $196 billion to $707

[13] Proposed §30.6. 83 FR 18774

[14] Proposed §30.7. 83 FR 18774

[15] Establishing agency administrative practices and procedures via rulemaking is not unprecedented. For example, without legislative mandate, the U.S. Food and Drug Administration used informal rulemaking to codify its Good Guidance Practices. 65 FR 56477, September 19, 2000.

[16] Alison Cullen, Chair, SAB Work Group on EPA Planned Actions for SAB Consideration of the Underlying Science, Memorandum to Members of the Chartered SAB and SAB Liaisons "Preparations for Chartered Science Advisory Board (SAB) Discussions of Proposed Rule: Strengthening Transparency in Regulatory Science RIN (2080-AA14)" May 12, 2018. https://yosemite.epa.gov/sab/sabproduct.nsf/E21FFAE956B548258525828C00808BB7/$File/WkGrp_memo_2080-AA14_final_05132018.pdf

billion, constituting 68% to 78% of all the regulatory benefits agencies estimated during that 10-year window. OIRA reported corresponding cost estimates for those EPA rules of $54 billion to $65 billion per year, which comprise between 57% and 69% of all the rules OIRA reviewed during that period.[17]

Given the significance of these estimates, documenting and making available for public review the underlying science supporting them is essential. EPA estimates that its National Ambient Air Quality Standards (NAAQS), for example, are among the most beneficial regulations issued. In setting NAAQS, EPA is statutorily proscribed from considering the costs of meeting standards, but it must evaluate available data on health and welfare impacts in presenting alternatives for the administrator to consider. EPA's formulation and presentation of the studies and data necessarily involve judgments about which studies to consider and which to exclude, but these decisions and their rationale are often not transparent.[18] Increasing transparency regarding which science it considered; how it weighted and combined individual studies; what competing theories were included, etc. would allow broader review and analysis, and improve the rigor of regulatory decisions.[19]

EPA's proposal to clearly identify available studies and make them available for public review is not only important for ensuring decisions are supported by the best information, but also consistent with policies on scientific integrity espoused by previous administrations. OMB's 2002 Information Quality Guidelines directed agencies to make publicly available "peer-reviewed studies known to the [agency] that support, are directly relevant to, or fail to support any estimate of [risk] effects and the methodology used to reconcile inconsistencies in the scientific data."[20] In 2009, President Obama issued a memorandum to agencies that encouraged "transparency in the preparation, identification, and use of scientific and technological information in policymaking," and affirmed that "scientific and technological information … should ordinarily be made available to the public."[21]

---

[17] 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." February 23, 2018. https://www.whitehouse.gov/wp-content/uploads/2017/12/draft_2017_cost_benefit_report.pdf

[18] Susan Dudley and Marcus Peacock. "Improving Regulatory Science: A Case Study of the National Ambient Air Quality Standards," with Marcus Peacock. *Supreme Court Economic Review*. (forthcoming) Working paper https://regulatorystudies.columbian.gwu.edu/improving-regulatory-science-case-study-national-ambient-air-quality-standards 2017.

[19] Susan Dudley and George Gray. "Improving the Use of Science to Inform Environmental Regulation," in *Institutions and Incentives in Regulatory Science,* Lexington Books, Jason Johnston ed. (2012)

[20] Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies (2002), 67 Fed. Reg. 8452 (Feb. 22, 2002). https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/assets/OMB/inforeg/iqg_oct2002.pdf

[21] Barrack Obama, "Memorandum for the Heads of Executive Department and Agencies on Scientific Integrity." Mar. 9, 2009. https://obamawhitehouse.archives.gov/the-press-office/memorandum-heads-executive-departments-and-agencies-3-9-09

2) EPA will make dose response data and models underlying pivotal regulatory science publicly available for independent validation.

The selection of the model used to estimate responses to different exposures to contaminants can have significant impacts on estimated regulatory benefits. In 2007, OIRA and the Office of Science and Technology Policy (OSTP) observed in a memorandum to agency heads on risk assessment that a "high degree of transparency with respect to data, assumptions, and methods will increase the credibility of the risk analysis, and will allow interested individuals, internal and external to the agency, to understand better the technical basis of the analysis."[22]

In 2010, OSTP directed agencies to develop policies to "facilitate the free flow of scientific and technical information, consistent with privacy and classification standards." In a memorandum to department and agency heads, President Obama's science advisor John Holdren stated:

> Open communication among scientists and engineers, and between these experts and the public, accelerates scientific and technological advancement, strengthens the economy, educates the Nation, and enhances democracy. Consistent with the Administration's Open Government Initiative, agencies should expand and promote access to scientific and technological information by making it available online in open formats. Where appropriate, this should include data and models underlying regulatory proposals and policy decisions.[23]

In a 2013 memorandum, OSTP directed all Executive Departments with greater than $100 million in yearly research and development expenditures to prepare plans for improving the public's access to the results of that research. EPA did not publish a plan to comply with the OSTP directive until November 29, 2016, years after many other agencies had begun to implement their plans.[24,25]

EPA's proposal to make the data and models underlying its pivotal regulatory science pubic is also consistent with developments in scholarly journals. In recent years, scientific publishing has

---

[22] Susan Dudley and Sharon Hays, "Memorandum for the Heads of Executive Department and Agencies: Updated Principles for Risk Analysis." September 19, 2007. https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/memoranda/2007/m07-24.pdf

[23] John P. Holdren. "Scientific Integrity," OSTP Director Memorandum for the Heads of Executive Departments and Agencies. December 17, 2010. https://obamawhitehouse.archives.gov/sites/default/files/microsites/ostp/scientific-integrity-memo-12172010.pdf

[24] Environmental Protection Agency, Plan to Increase Access to Results of EPA-Funded Scientific Research. November 29, 2016. https://www.epa.gov/sites/production/files/2016-12/documents/epascientificresearchtransperancyplan.pdf

[25] Federal STI Managers Group (CENDI), "Implementation of Public Access Programs in Federal Agencies," https://cendi.gov/projects/Public_Access_Plans_US_Fed_Agencies.html

focused more on the sharing of data and experimental transparency.[26] Indeed, disclosure of underlying data and computer code has become standard among the more prestigious scientific and technical journals, which allow for data sharing agreements when personally identifiable information prevents public disclosure. These disclosure policies appear to improve the reproducibility of the results of published papers.[27]

In 2013, for example, the journal *Nature* took steps to ensure it reported "key methodological details and encourage[d] authors to be transparent by including the raw data used in their studies." While recognizing that experimental studies vary, the editors concluded that variation does not preclude "a full report of how a study was designed, conducted and analysed that will allow reviewers and readers to adequately interpret and build on the results."[28]

The journal *Science* has also undertaken "initiatives to increase transparency and promote reproducibility in the published research literature... Connected to that progress, and an essential element to its success, an additional focus will be on making data more open, easier to access, more discoverable, and more thoroughly documented."[29]

EPA's proposal states that it would consider information to be "'publicly available in a manner sufficient for independent validation' when it includes the information necessary for the public to understand, assess, and replicate findings." This emphasis on replicability can encourage challenge and validation that is so important to the scientific method.[30] It is consistent with OMB's 2002 Information Quality Guidelines, which require that significant information disseminated to the public be "capable of being substantially reproduced, subject to an acceptable degree of imprecision."[31]

As the *Science* editors observe, "When the greatest number of creative and insightful minds can find, access, and understand the essential features that led to the collection of a data set, the data reach their highest potential."[32]

---

[26] Joel Achenbach, "The new scientific revolution: Reproducibility at last." Washington Post. January 27, 2015.

[27] Lutter, Randall and Zorn, David (2016). Reinforcing Reproducibility: What Role for the Federal Government? Regulation, Winter 2015–16, 15–16. https://object.cato.org/sites/cato.org/files/serials/files/regulation/2015/12/regulation-v38n4-8_4.pdf#page=10.

[28] Editors, "Reducing our Irreproducibility," *Nature.* Vol 496, p. 398. April 25, 2013.

[29] *Science* 2 January 2015: Vol. 347 no. 6217 p. 7

[30] Dudley and Peacock, 2017.

[31] OMB 2002, p. 8460

[32] *Science*, January 2015.

3) EPA will describe and document its assumptions and methods and show how sensitive modeled results are to those and alternative assumptions.

This requirement comports with recommendations from various sources. For example, in a recent article, 19 regulatory analysis experts warned:

> Analyses that do not provide information on how sensitive the primary estimate is to assumptions, data, and models, and the range of outcomes possible under reasonable alternative analytic assumptions should raise questions. Sensitivity analysis examines different "what if" scenarios to see how changes in key assumptions (or combinations of assumptions) influence estimated outcomes. Because many uncertain factors determine the impact of any regulation, one should look for a convincing justification regarding which uncertain parameters have the most consequential effects on outcomes, and a sensitivity analysis that varies these factors over a reasonable range to gauge their effects on the rule's net benefits.[33]

In 2010, OSTP directed agencies to communicate scientific and technological findings to the public "by including a clear explication of underlying assumptions; accurate contextualization of uncertainties, and a description of the probabilities associated with both optimistic and pessimistic projections, including best-case and worst-case scenarios where appropriate."[34]

This is important, because, as Dudley and Peacock explain, "scientists will never have complete information to predict outcomes with certainty, so analysts rely on what the [National Research Council][35] calls 'risk assessment policy'—assumptions, judgments, and rules of thumb—to guide the use of scientific information in analyses that inform policy in the face of uncertainty."[36] The Institute of Medicine observed in 2013:

> Uncertainty is inherent in the scientific information upon which health risk estimates are based. Uncertainties enter the health risk assessment process at

---

[33] Dudley, S., Belzer, R., Blomquist, G., Brennan, T., Carrigan, C., Cordes, J., Cox, L.A., Fraas, A., Graham, J., Gray, G., Hammitt, J., Krutilla, K., Linquiti, P., Lutter, R., Mannix, B., Shapiro, S., Smith, A., Viscusi, W.K., Zerbe, R. (2017). Consumer's Guide to Regulatory Impact Analysis: Ten Tips for Being an Informed Policymaker. *Journal of Benefit-Cost Analysis, 8*(2), 187-204. doi:10.1017/bca.2017.11. https://www.cambridge.org/core/services/aop-cambridge-core/content/view/FAF984595B822A70495621AEA7EF7DEB/S2194588817000112a.pdf/consumers_guide_to_regulatory_impact_analysis_ten_tips_for_being_an_informed_policymaker.pdf

[34] Holdren 2010.

[35] National Research Council and the Committee on the Institutional Means for Assessment of Risks to Public Health. *Risk Assessment in the Federal Government: Managing the Process*. 1983. Washington D.C.: National Academies Press, p. 3.

[36] Dudley and Peacock. 2017.

> every step and can be caused by the potential confounders in observational studies, by extrapolation from animal studies to human studies, by extrapolation from high to low dose exposures, by inter-individual variability, and by modeling the relationships between concentrations, human exposures, and human health responses and evaluating the effect of interventions or risk control options on public health risk.[37]

Assumptions and judgments made in each of these steps get embedded in predictions of health risk under different policy options. Intentionally or not, they can bias the ultimate advice provided to decision-makers and the public. Documenting those assumptions and estimating how sensitive predicted outcomes are to them and alternative assumptions and judgments could greatly improve the transparency and quality of EPA's decisions.

Gray and Cohen suggest:

> Fundamentally, the EPA should replace risk values that are built on science-policy assumptions with risk estimates that acknowledge underlying uncertainties. For instance, the agency could follow the example of the Intergovernmental Panel on Climate Change and report a range of risks that correspond to different models. Users would then be able to see whether a value is sufficiently precise to support a particular course of action.[38]

They recognize that policymakers will face more difficult choices when faced with a range of reasonable estimates but argue "that is how it should be."

> The EPA's definitive values are illusions: they conceal uncertainty that cannot be resolved scientifically. Bringing conflicting value judgements into the open will enable honest debate and improve public health.[39]

4) EPA will explicitly consider high quality studies that offer new dose-response information that may allow the agency to move away from default assumptions.

In estimating adverse effects of exposure to many pollutants (especially potential carcinogens, but also fine particles), EPA's default dose-response function is assumed to be linear within the range of exposures under consideration. Both theory and observation suggest that thresholds

---

[37] Board on Population Health and Public Health Practice; Institute of Medicine. *Environmental Decisions in the Face of Uncertainty*, Committee on Decision Making Under Uncertainty, 2013. http://www.nap.edu/catalog.php?record_id=12568

[38] George Gray and Jason Cohen. "Rethink Chemical Risk Assessment." *Nature*. September 2012; 489. p. 28.

[39] Gray and Cohen, p. 28.

exist below which further reductions in exposure do not yield changes in mortality response, however more accurate dose-response functions are elusive.[40] The default linear, no threshold assumption is convenient in that it allows EPA to estimate incremental health improvements in proportion to estimated reductions in exposure; but, if it is inaccurate, it can lead to under or over estimates of risks at relevant exposure levels, and to a misallocation of resources.

EPA's proposed commitment to consider research that can help clarify the effect of low-dose exposure to key pollutants would not only improve short term policy outcomes, but it would also provide incentives for researchers to devote attention and resources to exploring and reducing this key uncertainty. As the 19 regulatory experts observe, "if expected outcomes hinge on the value assumed for a particular uncertain variable, it might be appropriate to gather more information regarding that variable prior to making a decision,[41] or to ask what policies would generate the information necessary to reduce that uncertainty.[42,,43]

5) EPA will conduct independent peer review on all pivotal regulatory science used to justify regulatory decisions.

Peer review is a fundamental component of the scientific process. Concerns over the extent and rigor of review of important scientific analyses led OMB in 2004 to issue a memorandum establishing guidelines for the use of external peer review at all federal agencies and departments.[44] EPA's proposed approach is consistent with those guidelines, and the exemptions therein.

When engaging experts in peer review, EPA should consider the recommendations of recent interdisciplinary efforts regarding scientific advisory panels. Such advisors can provide a necessary and valuable source of information and peer review for agency science, but care should be taken in both the composition of the panels and the charges they are given.

An important 2012 Keystone Center report offers a series of recommendations on "the composition of committees that are empaneled to review the science behind a regulatory

---

[40] See, for example Texas Commission on Environmental Quality, "$PM_{2.5}$ Standards may be set Lower than Scientifically Justifiable," noting that "extrapolations [to current exposure levels] can be contrary to the basic principles of toxicology where the biological threshold (a level below which no effect is apparent) is a key concept." http://www.tceq.texas.gov/assets/public/comm_exec/pubs/pd/020/2013/Outlook-Mar-2013-x.pdf

[41] Office of Management and Budget (OMB) (2003). Circular A-4, Regulatory Analysis. September 17, 2003. Cited in Dudley et al, 2017.

[42] Michael Greenstone (2009). Toward a Culture of Persistent Regulatory Experimentation and Evaluation. In David Moss and John Cisternino (Eds.), *New Perspectives on Regulation* (pp. 111–125). Cambridge: The Tobin Project. Cited in Dudley et al 2017.

[43] Dudley et al, 2017. *Journal of Benefit-Cost Analysis*. p. 196.

[44] U.S. Office of Management and Budget. 2004. *Information Quality Bulletin for Peer Review*. http://www.whitehouse.gov/sites/default/files/omb/memoranda/fy2005/m05-03.pdf

decision."[45] Acknowledging the importance of choosing panelists that "have the knowledge, training, and experience needed to address the charge to the panel,"[46] it encouraged agencies "to recognize that all potential panelists will have conscious and unconscious biases." It recommended, "because biases exist, an agency should strive to engage a wide range of perspectives of qualified scientific experts."[47]

Both the Keystone group and a group convened by the Bipartisan Policy Center in 2009 recommend that scientific peer reviewers restrict their advice to matters of science, and not be asked to recommend regulatory policies. EPA's Clean Air Scientific Advisory Committee (CASAC), for example, is tasked with advising on policy choices, which creates incentives to present policy views as scientific recommendations.[48,49] When drafting charge questions for individual peer reviewers and scientific advisory committees, EPA should be careful to solicit their scientific expertise without encouraging them to blur the lines between scientific expertise and policy judgment.[50] As both the BPC and Keystone reports emphasized, the questions posed to experts "should be clearly articulated, and 'explicitly differentiate, to the extent possible, between questions that involve scientific judgments and questions that involve judgments about economics, ethics, and other matters of policy.'"[51]

Applications of the Proposed Policies to Existing Regulatory Science

When possible, EPA should apply the new guidelines to existing regulations and the regulatory science that supports them.[52] This may not always be feasible, especially for regulatory science

---

[45] The Keystone Center. Research Integrity Roundtable. *Improving the Use of Science in Regulatory Decision Making: Dealing with Conflict of Interest and Bias in Scientific Advisory Panels, and Improving Systematic Scientific Reviews*. Washington (DC): The Keystone Center; 2012: p. 4. https://www.keystone.org/images/keystone-center/spp documents/Health/Research%20Integrity%20Rountable%20Report.pdf

[46] Keystone, 2012. p. 14

[47] Keystone, 2012. p. 15

[48] Dudley and Peacock, 2017.

[49] See, for instance, the recommendation of former CASAC member Morton Lippman regarding changing the Clean Air Act. Lippman noted "CASAC's role must be limited to highlighting the issues at the science-policy interface and the scientific knowledge that informs these issues." Dr. Morton Lippman. "Comments on the NAAQS Review Process." 2006, at A-22. http://yosemite.epa.gov/sab/sabproduct.nsf/WebCASAC/Vanessa%20Memo_03-16-06/$File/sabso-casac_memo_and_comments.pdf

[50] See Dudley and Peacock, 2017. Several former CASAC officials encouraged EPA to be clearer in its charge questions to distinguish between science and policy. Environmental Protection Agency Clean Air Scientific Advisory Committee (CASAC). CASAC Input on EPA's revised NAAQS Review Process; 2006 March. http://yosemite.epa.gov/sab/sabproduct.nsf/WebCASAC/NewNAAQSProcess?OpenDocument

[51] The Keystone Center, 2012: 8. (Internal citation to BPC at 5.)

[52] 83 FR 18772

that was developed under conditions that would limit disclosure, and EPA should develop clear criteria for the types of research that would be eligible for exemptions to its transparency policy.

Nevertheless, EPA has an opportunity, when conducting retrospective evaluation of regulatory impacts (as required by Executive Orders 13563 and 13771), to reexamine the studies, data, models and assumptions that generated ex-ante estimates of regulatory benefits and costs. Such retrospective review can provide data that either corroborates or raises questions about the assumptions on which previous estimates were based. As such, ensuring transparency and opportunities for independent analysis and evaluation could be particularly valuable in retrospective review, not only for decisions regarding continuation of existing policies, but also for improving the quality of the science used to design new policies.[53]

For regulatory programs, like the NAAQS, that periodically review and update standards based on a record that has been built over decades, application of the proposed transparency and integrity procedures to that record, when feasible, could allow a broader group of experts access to pivotal regulatory science, including data, models, and assumptions. Such review would be consistent with EPA's statutory mandate for review under the Clean Air Act, and allow EPA to make future decisions on better data.

Protecting Privacy and Confidentiality

EPA acknowledges concerns that increased transparency and public access to data may risk exposing confidential or private information, but it points to practices at other federal agencies and in scientific publishing that can ensure confidential or personally-identifiable information is not disclosed. Lutter and Zorn review some of these practices and conclude that, depending on the situation and sensitivity of the information, a range of measures is available to share data in a way that allows access for replication and validation purposes while protecting personally identifiable information.[54]

The SAB working group memo raises concerns that "for studies already completed or underway, the participation of human subjects is undertaken according to terms approved by the cognizant IRB" (institutional review board) which may constrain data sharing.[55] Input from the SAB and public comments may elucidate specific concerns, as well as methods EPA can use to address them.

---

[53] Susan E. Dudley 2017. Retrospective Evaluation of Chemical Regulations. Environmental Working Paper No. 118, Organisation for Economic Co-operation and Development. http://dx.doi.org/10.1787/368e41d7-en.

[54] Randall Lutter and David Zorn, "On the Benefits and Costs of Public Access to Data Used to Support Federal Policy Making," Mercatus Working Paper, George Mason University. September 2016. https://www.mercatus.org/system/files/Mercatus-Lutter-Public-Access-Data-v3.pdf

[55] Cullen, 2018.

Conclusion

Regulations aimed at addressing public health and environmental risks depend heavily on scientific information. Regulatory impact analyses often hinge on assessments of risk that necessarily involve assumptions and judgments but often generate precise-sounding predictions that hide not only considerable uncertainty about the actual risk, but hidden policy judgements.[56] A lack of transparency surrounding these judgments harms the credibility of scientific advice and results in poorer policy decisions.

Former EPA scientist Robert T. Lackey cautions against what he calls "normative science":

> Science should be objective and based on the best information available. Too often, however, scientific information presented to the public and decision-makers is infused with hidden policy preferences. Such science is termed normative, and it is a corruption of the practice of good science. Normative science is defined as "information that is developed, presented or interpreted based on an assumed, usually unstated, preference for a particular policy choice."[57]

EPA's proposal to strengthen the transparency of its regulatory science includes reasonable steps that could improve the evidential basis for its regulatory policies, and thus improve regulatory outcomes by targeting resources to where they can achieve the largest benefits. As President Obama's science advisor observed, "open communication among scientists and engineers, and between these experts and the public, accelerates scientific and technological advancement, strengthens the economy, educates the Nation, and enhances democracy."[58]

The requirements proposed here are not a radical departure from existing guidelines. For example, since 2004, OMB has directed agencies to issue information quality guidelines to, among other things, ensure the objectivity of information, including "a high degree of transparency about data and methods to facilitate the reproducibility of such information by qualified third parties."[59] President Obama in 2011 encouraged an "open exchange of information and perspectives among State, local, and tribal officials, experts in relevant disciplines, affected stakeholders in the private sector, and the public as a whole, …including relevant scientific and technical findings."[60]

---

[56] Dudley and Peacock, 2017. p. 36.

[57] Robert T. Lackey, "Normative Science." *Terra Magazine*. Oregon State University. 2013;8(2).

[58] Holdren memo, 2010.

[59] U.S. Office of Management and Budget. 2002. "Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies." 67 FR 8452

[60] Barrack Obama. Executive Order 13563. "Improving Regulation and Regulatory Review." 76 FR 3822 January 18, 2011.

Greater transparency in the studies, models, assumptions, and risk assessment policy choices used in regulatory decisions could encourage more open, constructive debate on those choices.[61] The scientific method depends on falsifiable hypotheses, data gathering, replication, dissent, and challenge, to ensure objective analysis and to minimize bias in the interpretation of results.[62] Greater transparency is an essential step in improving scientific integrity. Clearer explanations regarding the policy rationales for choosing one set of assumptions or models over another would encourage more openness and constructive discussion about science and policy, improving the ultimate policy decision and engendering greater acceptance of that policy choice.[63]

[61] Open Data Initiative https://www.whitehouse.gov/open

[62] Dudley and Peacock, 2017. p. 37.

[63] Dudley and Gray, 2012.