

Institute for
Policy Integrity
NEW YORK UNIVERSITY SCHOOL OF LAW

January 10, 2020

VIA ELECTRONIC SUBMISSION

Dr. Thomas Armitage
Designated Federal Officer (DFO)
EPA Science Advisory Board (1400R)
U.S. Environmental Protection Agency
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Re: January 2020 Meeting of the Chartered Science Advisory Board, Draft Report,
Consideration of the Scientific and Technical Basis of EPA's Proposed Rule
Strengthening Transparency in Regulatory Science

The Institute for Policy Integrity ("Policy Integrity") at New York University School of Law¹ submits the following comments to the Chartered Science Advisory Board ("SAB") regarding EPA's proposed rule, *Strengthening Transparency in Regulatory Science* and the SAB Draft Report, *Consideration of the Scientific and Technical Basis of EPA's Proposed Rule*.² This topic is on the agenda of the SAB for discussion on January 21, 2020 at 1:15pm.

Policy Integrity is a non-partisan think tank dedicated to improving the quality of government decisionmaking through advocacy and scholarship in the fields of administrative law, economics, and public policy. Our experts published a peer-reviewed critique of the scope of the proposed rule,³ and made oral comments regarding the rule at the June 2019 meeting of the SAB. In response to SAB's Draft Report, we attached the aforementioned documents and additionally write to note the following:

1. Purporting to comply with executive orders that require economic impact analysis, EPA claims that "the benefits of this proposed rule justify the costs."⁴ In reaching this

¹ This document does not purport to present New York University School of Law's views, if any.

² *Strengthening Transparency in Regulatory Science*, 83 Fed. Reg. 18768 (Apr. 30, 2018); Science Advisory Board (SAB) *Consideration of the Scientific and Technical Basis of EPA's Proposed Rule Titled Strengthening Transparency in Regulatory Science* (Oct. 16, 2019) ("Draft Report").

³ Madison Condon, Michael Livermore & Jeffrey Shrader, *Assessing the Rationale for the U.S. EPA's Proposed "Strengthening Transparency in Regulatory Science" Rule*, 14 REV. ENV. ECON. & POLICY. 1 (2020), available at <https://doi.org/10.1093/reep/rez017>.

⁴ 83 Fed. Reg. at 18,772; see Exec. Order No. 12,866, 58 Fed. Reg. 51,735 (Oct. 4, 1993); Memorandum: Implementing Executive Order 13,771, Titled "Reducing Regulation and Controlling Regulatory Costs" (Apr. 5, 2017), available at <https://www.whitehouse.gov/the-press-office/2017/04/05/memorandum->

conclusion, however, the agency both drastically underestimates the costs of compliance with the rule, and more importantly, neglects to consider how the “[e]xclusion of relevant studies... will adversely affect decision-making processes.”⁵

The Draft Report catalogs the lack of implementation details in the proposed rule and suggests a number of measures that might be taken to practically implement the rule and give the adequate notice of how to comply with its requirements. They include: establishing an office on data-sharing, funding replication studies, promulgating guidance on methods and analysis, developing tiers of public access, and conducting data reanalysis, among others. Many of these suggested measures would impose significant costs on the EPA to administer. These costs should be thoroughly assessed in good faith prior to the rule’s finalization, as required by Executive Order 12,866. As the Draft Report suggests, the EPA should seek inputs from experts in library science, data curation management, and data retention.⁶ The agency should seek advice not only to define best practices, but also to reasonably assess the expected administrative costs of implementing the rule, which are likely substantial.

2. The Draft Report does not consider alternatives to a blanket exclusion policy for studies without publicly available data. A more calibrated approach could be used by the agency, such as explicitly discounting the evidentiary value of some study types. The agency could, for example, differentially weight those studies in meta-analysis. EPA’s own review of meta-analysis techniques encourages accounting for the evidentiary value of different estimates, and federal agencies have successfully applied evidentiary weighting techniques in past rulemakings.⁷
3. The Draft Report observes that applying the proposed rule retroactively does not alter the incentive for papers that have already been published, while penalizing the agency and public by excluding potentially valuable information from the regulatory process.⁸ EPA does not assess the rule’s redundancy given that many peer-reviewed journals have already updated their data transparency policies to encourage data availability. Policy

[implementing-executive-order-13771-titled-reducing-regulation](#) (referring to Executive Order 12,866 as “the primary governing [Executive Order] regarding regulatory planning and review”).

⁵ Jeremy Berg, Philip Campbell, Veronique Kiermer, Natasha Raikhel, & Deborah Sweet, *Joint statement on EPA proposed rule and public availability of data*, 360 SCIENCE 6388 (2018) (an open response to the proposed rule by the editors-in-chief of five leading scientific journals).

⁶ Draft Report at 14.

⁷ EPA, Report of the EPA Working Group on VSL Meta-analysis, Report EE-0494, National Center for Environmental Economics (2006) (recommending the use of weighting by sample size or level of significance which would “account for differences in the uncertainty surrounding each primary estimate both within and across studies”); U.S. Food and Drug Administration, *Food Labeling: Health Claims and Label Statements; Antioxidant Vitamins and Cancer* (1992) (placing more weight on studies that met certain criteria such as the use of appropriate statistical controls, or proper storage conditions for test samples); EPA, *Economic Analysis of the EPA-Army Clean Water Rule 2015* (weighting studies by sample size).

⁸ Draft Report at 2; Timothy Vines *et al.*, *The Availability of Research Data Declines Rapidly with Article Age*, 24 CURRENT BIOLOGY, 94 (2014).

Integrity strongly supports the Draft Report’s suggestion that any finalized transparency rule only apply requirements “to information developed after the effective date.”⁹

4. The Draft Report correctly notes that the proposed rule’s lack of clarity on how exceptions to the rule will be applied is cause for concern: “Case-by-case exceptions may exacerbate concerns about inappropriate exclusion of scientifically important studies.”¹⁰ The Report may benefit from past examples where unequally applied study standards led to significantly different regulatory outcomes. In a proposed repeal of the 2015 Clean Water Rule, the EPA set an arbitrary cap on the age of studies to be considered, claiming that the “age of these [older] studies introduces uncertainty.”¹¹ Setting this age restriction excluded many of the studies that had been used by the Obama-era EPA, and resulted in a substantial diminution of the proposed benefits of the original rule. Small changes to the exclusion dates lead to large changes in estimate net benefits, opening the agency to charges of manipulating the data to reach a predetermined outcome.¹² Further, the agency applied this arbitrary exclusion only to studies used to calculate the benefits of the original Clean Water Rule, not to studies supporting estimates of costs. The proposed rule itself may be open to this type of manipulation, as it provides that exemptions from compliance may be granted “on a case-by-case basis.”¹³

Transparency in research is desirable and efforts to promote the release of data to the public are laudable. But ignoring valid and potentially valuable information in rulemaking with profound public health and economic consequences is a steep cost to pay – and it is at odds with the agency’s mandate to use the “best available” science.¹⁴ The Science Advisory Board should consider these costs, and better alternatives, in its discussion of the rule.

Respectfully,



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⁹ Draft Report at 2.

¹⁰ *Id.*

¹¹ U.S. Environmental Protection Agency & U.S. Department of the Army, Economic Analysis for the Proposed Definition of “Waters of the United States”—Recodification of Pre-Existing Rules, (2017).

¹² Jason Schwartz & Jeffrey Shrader, *Muddying the Waters: How the Trump Administration is Obscuring the Value of Wetlands Protection from the Clean Water Rule*, Institute for Policy Integrity at New York University School of Law, (2017).

¹³ 83 Fed. Reg. at 18,772.

¹⁴ Exec. Order No. 13563, 76 Fed. Reg. 3821 (Jan. 21, 2011).

Attachment:

Madison Condon, Michael Livermore & Jeffrey Shrader, *Assessing the Rationale for the U.S. EPA's Proposed "Strengthening Transparency in Regulatory Science" Rule*, 14 Rev. Env. Econ. & Policy. 1 (2020).

Comments to EPA's Science Advisory Board on Planned Actions and Their Supporting Science
Madison Condon, Legal Fellow, Institute for Policy Integrity, June 5, 2019.

Policy Brief

Assessing the Rationale for the U.S. EPA’s Proposed “Strengthening Transparency In Regulatory Science” Rule

Madison E. Condon*, Michael A. Livermore[†] and Jeffrey G. Shrader [‡]

Introduction

On April 24, 2018, the U.S. Environmental Protection Agency (EPA) issued a proposed rule, “Strengthening Transparency in Regulatory Science,” that would restrict the types of scientific studies the agency can rely on when developing future regulations ([U.S. Environmental Protection Agency 2018](#)). Most importantly, this new policy would preclude the EPA from relying on studies whose underlying data are not publicly available. The stated goal of the proposed policy is to improve the quality of the science that underlies the agency’s decisions.¹

This policy brief examines whether there are legitimate, welfare-enhancing grounds for the agency’s proposal. We find no such justifications for the proposed policy and argue that the EPA should consider an alternative path, such as offering explicit guidance on the evidentiary weight to assign to different types of studies. We conclude by arguing that there appears to be no legitimate justification for the agency to ignore large swaths of high-value research that has already been conducted, and that there are better ways to achieve the goal of scientific transparency than through the proposed rule.

The Rational Agency

Let’s assume that the EPA is a rational decision maker facing the following choice problem: for each regulation, the agency’s objective is to maximize society’s expected net benefits—that

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¹See, e.g., <https://www.federalregister.gov/d/2018-09078/p-64>.

is, the agency seeks to maximize expected well-being. Because costs and benefits are uncertain, the agency must estimate them using available information, which includes academic studies. Based on standard rational choice principles, the EPA would use all studies that include potentially valuable information to inform its analysis of the costs and benefits of a regulation (Savage 1954; Executive Order 12291). Moreover, in developing its estimates, the agency would weight each study based on its evidentiary value.²

This approach provides a framework to examine whether it makes economic sense for the EPA to exclude studies based on the public availability of their underlying data. If the availability of data increases the evidentiary value of the study—for example, by facilitating reproduction of study results³—then the agency should place a greater weight on those studies (Wicherts, Bakker, and Molenaar 2001). Nevertheless, as long as a study had *any* evidentiary value, a (rational) agency would not exclude it. This is the point emphasized in a letter responding to the proposed policy by the editors-in-chief of five leading scientific journals: “[e]xcluding relevant studies simply because they do not meet rigid transparency standards will adversely affect decision-making processes” (Berg et al. 2018).

If the EPA acts as a rational decision maker when assessing evidence, then the choice problem outlined above is similar to the challenge researchers face when carrying out meta-analysis of scientific research (Hedges and Olkin 1985). The goal of meta-analysis is to collect and analyze prior research on a question in order to draw general conclusions. Best practices for meta-analysis recommend that studies be selected for inclusion based on their relevance to the question at hand. The results in those studies are then weighted based on their evidentiary value (Hedges and Olkin 1985, chap. 14). The meta-analysis literature emphasizes that the use of improper criteria to exclude studies can result in bias (Rothstein, Sutton, and Borenstein 2005). For example, if the estimates in unpublished studies differ from estimates in published studies due to publication bias, then excluding all unpublished studies will lead to a biased sample in the meta-analysis and thus biased conclusions.

This discussion suggests that if we assume the EPA is a rational decision maker attempting to maximize well-being through individual regulatory decisions, then the agency’s proposed policy of excluding studies based on whether their underlying data are publicly available is not justified.

Rationality Failures

Alternatively, let’s assume that the EPA is not a rational decision maker but is (somewhat paradoxically) aware of its own irrationality. Under this model, the agency knows that in the future it might be tempted to irrationally rely on studies with low evidentiary value, and thus the proposed policy could be justified as a prophylactic measure, akin to a person deciding not to purchase junk food at the grocery store out of fear of overindulging at home.

There are problems with this justification for the “Strengthening Transparency in Regulatory Science” rule. First, the EPA has provided no evidence that it is subject to a

²For example, a study that has been successfully replicated would be assigned a higher evidentiary value.

³Reproduction uses the same procedures (code, methods, etc.) and the same data to obtain the same results. Replication uses the same procedures to generate and analyze new data (Bollen et al. 2015). That is, reproduction verifies that the study was performed in the way described by the researchers, while replication assesses whether the study results hold across multiple samples.

rationality failure akin to a lack of self-control in people. Indeed, a rationality failure of this type would be unexpected in an institution with the EPA’s level of sophistication. If the agency were to rely on this as the justification for its policy, some explanation for why it believes it is subject to this type of rationality failure would be warranted. Second, the EPA has not provided any guidance concerning the context that might generate this type of rationality failure.

Even if we assume that the agency could predict, but not avoid, its own future rationality failure, prohibiting reliance on an entire class of research in future regulatory decisions is a poorly tailored response. A better approach would be to establish guidelines for evidence-based decision making that include explicit criteria for assigning different evidentiary weights to different study designs. Such guidelines would bind future (irrational) decision makers without unduly restricting the information available to the agency.

An Incentive-Based Rationale

Another possible justification for the “Strengthening Transparency in Regulatory Science” rule is that it is intended to alter incentives for the research community with the goal of improving the quality of research available for future decisions (McCullough and Vinod 2003; Bernanke 2004). Assuming that researchers prefer that their work be used by government decision makers, the EPA’s proposed policy could serve as a disincentive for study designs that the agency disfavors, with future researchers who seek to influence agency decision making conforming to the requirements of the policy to avoid having their work ignored.

Although this incentive-based rationale is plausible, the EPA has not assessed the actual, dynamic effects of its proposed rule. For example, excluding research that has already been conducted has no beneficial incentive effects, yet it penalizes the agency and the public by limiting the information that is available to inform regulatory decision making (Vines et al. 2014). The effects on future research are also unlikely to be beneficial. In particular, some studies do not supply data due to ethical or privacy concerns, and agency pressure to make data more available may create costs beyond a mere administrative burden. The EPA has also not addressed the issue of the rule’s redundancy, given that many peer-reviewed journals have already updated their data transparency policies to encourage data availability.⁴ Finally, the agency fails to explain why a blanket exclusion policy would be preferred to a more carefully targeted approach, such as a policy that explicitly discounts the evidentiary value of some study types.

Disadvantages of Information Exclusion Policies: An Illustration

To illustrate the drawbacks of blanket information exclusion policies, we examine a recently proposed EPA rule to repeal the Obama-era Clean Water Rule.⁵ In the proposed repeal, the EPA set an arbitrary restriction on the age of the studies it would rely on in conducting its

⁴More than 850 journals have implemented policies in line with the Transparency and Openness Promotion Guidelines developed by the Center for Open Science (Nosek et al. 2015). These guidelines promote the sharing of data while also providing for the protection of confidential or proprietary information.

⁵The Clean Water Rule sought to clarify the jurisdictional reach of the Clean Water Act (80 Federal Register 37054).

economic analysis of the benefits of wetland protections, claiming that the “age of these [older] studies introduces uncertainty” (U.S. Environmental Protection Agency & Department of the Army 2017). Setting this age restriction excluded many of the studies that had been used by the Obama-era EPA and resulted in a substantial reduction in the estimated benefits of the original rule. However, small changes in the cutoff dates lead to large changes in the estimated net benefits, making the agency vulnerable to charges that it is “cherry picking” the data that it relies on for political purposes (Schwartz and Shrader 2017). Moreover, the EPA applied this arbitrary requirement to studies used to calculate the benefits of the original Clean Water Rule but *not* to studies used to calculate the costs, which led the agency to conclude that repealing the original rule was benefit–cost justified. The proposed “Strengthening Transparency in Regulatory Science” rule may be open to the same type of manipulation, as it allows exemptions from compliance “on a case-by-case basis.”

Conclusions

This article has argued that, if adopted, the EPA’s proposed “Strengthening Transparency in Regulatory Science” rule would exclude valid and potentially valuable information from its regulatory decisions. We urge the EPA to reconsider its proposal and focus instead on developing guidance on the evidentiary value of studies, including explicit weighting criteria that could be used in future rulemaking. Relevant factors to consider in developing such criteria might include data availability, sample size, age of the study, the use of proprietary black-box models, and whether a study was published in a peer-reviewed journal. The scientific community can aid in the development of such guidance; for example, more research is needed on the relationship between data availability and replicability (Chang and Li 2015). With these weights in hand, the agency would be able to construct more accurate estimates of the costs and benefits of its proposed regulations. Such agency guidance would also help researchers design high-quality studies in the future while the agency would continue to have access to all relevant, available information. Moreover, this guidance would facilitate consistency within and across agency rulemaking, thus avoiding the risk that evidence is (or is perceived as) being used for political purposes rather than as the basis for making rational policy choices.

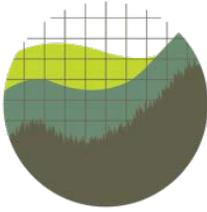
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Abstract

The U.S. Environmental Protection Agency (EPA) is considering a new policy that would prohibit the agency from issuing regulations that rely on studies whose underlying data are not publicly available. While the EPA claims it is pursuing this policy in the interest of transparency, we argue that such a prohibition would greatly hinder, rather than help, the rulemaking process and would likely result in undesirable regulatory outcomes that fail to maximize economic welfare. This policy brief argues that a good faith effort to encourage data availability should focus on forward-looking incentives for transparency rather than the exclusion of a whole class of studies, and that weighting older studies based on their evidentiary value is preferable to removing valuable information from agency consideration. (*JEL*: Q58, D04, K32)



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Oral Comments to EPA’s Science Advisory Board on Planned Actions and Their Supporting Science

Madison Condon, Legal Fellow, Institute for Policy Integrity

June 5, 2019

I am here on behalf of the Institute for Policy Integrity, a non-partisan think tank based at New York University. Policy Integrity has participated in a number of rulemakings that are on SAB’s discussion agenda, and we have submitted written comments on three different issues to which I direct your attention.

First, in the proposed Waters of the United States Rule, the agencies’ analysis of forgone wetland benefits is inconsistent with best economic practices and best scientific evidence. The SAB should look into this analysis.

Second, EPA’s proposal to flatline vehicle emissions’ standards relies on new deeply flawed economic modeling conducted by the National Highway Traffic Safety Administration—modeling that is not supported by economic theory and that has been sharply criticized by economic experts and EPA staff. The SAB should recommend that EPA not rely on such flawed models in any final rule.

Third, in EPA’s proposed withdrawal of its 2016 finding that regulating power plants’ emissions of mercury is “appropriate and necessary,” the agency unreasonably ignores co-benefits from particulate matter reductions that occur as a consequence of the plants reducing their mercury emissions. The SAB should not support this approach.

My colleagues at Policy Integrity have submitted lengthy written comments on each of these topics and I direct the Board’s attention to those comments.

Finally, I'd like to turn to EPA's Proposed Science and Transparency Rule. The proposed rule would bar regulators from relying on scientific studies that fail to meet proposed data availability standards.¹ Purporting to comply with executive orders that require economic impact analysis, EPA claims that "the benefits of this proposed rule justify the costs."² In reaching this conclusion, however, the agency both drastically underestimates the costs of compliance with the rule, and more importantly, neglects to consider how the "[e]xclusion of relevant studies... will adversely affect decision-making processes."³

For support of its conclusion, EPA cites to a single working paper issued by the Mercatus Center at George Mason University.⁴ But this paper estimated the economic impacts of a policy with a very different scope: it assumes that while 80 percent of studies will fail to meet transparency criteria, these studies will nevertheless continue to be relied upon in agency rulemaking. Under the proposed rule, however, such studies would be excluded entirely from agency consideration. The Mercatus paper, therefore, fails to capture the Proposed Rule's far-reaching costs.

These costs stem from the fact that ignoring this category of studies will lead to a worse regulatory outcome than including the studies and accounting for concerns about verifiability. If the agency's genuine aim is the scientific integrity of its rulemaking

¹ Strengthening Transparency in Regulatory Science, 83 Fed. Reg. 18768 (Apr. 30, 2018); These comments draw from Madison Condon, Michael Livermore & Jeffrey Shrader, *The Costs and Benefits of "Strengthening Transparency in Regulatory Science"* (forthcoming REV. ENV. ECON. & POLICY 2020).

² 83 Fed. Reg. at 18,772; see Exec. Order No. 12,866, 58 Fed. Reg. 51,735 (Oct. 4, 1993); Memorandum: Implementing Executive Order 13,771, Titled "Reducing Regulation and Controlling Regulatory Costs" (Apr. 5, 2017), available at <https://www.whitehouse.gov/the-press-office/2017/04/05/memorandum-implementing-executive-order-13771-titled-reducing-regulation> (referring to Executive Order 12,866 as "the primary governing [Executive Order] regarding regulatory planning and review").

³ Jeremy Berg, Philip Campbell, Veronique Kiermer, Natasha Raikhel, & Deborah Sweet, *Joint statement on EPA proposed rule and public availability of data*, 360 SCIENCE 6388 (2018) (an open response to the proposed rule by the editors-in-chief of five leading scientific journals).

⁴ 83 Fed. Reg. at 18,771, citing Randall Lutter & David Zorn, *On the Benefits and Costs of Public Access to Data Used to Support Federal Policy Making*, Mercatus Working Paper, Mercatus Center at George Mason University (2016).

processes, there are good-faith alternatives to the wholesale exclusion of studies with unavailable data. The agency could, for example, differentially weight those studies in meta-analysis. EPA's own review of meta-analysis techniques encourages accounting for the evidentiary value of different estimates, and federal agencies have successfully applied evidentiary weighting techniques in past rulemakings.⁵

The downsides of blanket information-exclusion policies can be seen in the recent proposals to repeal and replace the 2015 Clean Water Rule. The agency excluded studies for reasons such as study age, wetland type, sample size, and lack of summary statistics.⁶ But each of those issues could have been addressed by weighting the studies appropriately as part of a meta-analysis. Excluding the studies severely reduces the agencies' total sample size and increases the risk of econometric errors.

Additionally, removing these studies leads to large changes in estimated net benefits, opening the agency to charges of manipulating the data to reach a predetermined outcome.⁷ The transparency rule itself enables such manipulation, as it provides that exemptions from compliance may be granted "on a case-by-case basis."⁸

Lastly, the agency does not adequately explain the expected benefits of the proposed rule. Applying this rule retroactively does not alter the incentive for papers that have

⁵ EPA, Report of the EPA Working Group on VSL Meta-analysis, Report EE-0494, National Center for Environmental Economics (2006) (recommending the use of weighting by sample size or level of significance which would "account for differences in the uncertainty surrounding each primary estimate both within and across studies"); U.S. Food and Drug Administration, Food Labeling: Health Claims and Label Statements; Antioxidant Vitamins and Cancer (1992) (placing more weight on studies that met certain criteria such as the use of appropriate statistical controls, or proper storage conditions for test samples); EPA, Economic Analysis of the EPA-Army Clean Water Rule 2015 (weighting studies by sample size).

⁶ See An Evaluation of the Revised Definition of "Waters of the United States," by Peter Howard, PhD, Institute for Policy Integrity at NYU School of Law and Jeffrey Shrader, PhD, School of International and Public Affairs (SIPA) at Columbia at 2-7 (April 11, 2019), https://policyintegrity.org/documents/Shrader_Howard_Expert_Report_FINAL.pdf.

⁷ See Jason Schwartz & Jeffrey Shrader, *Muddying the Waters: How the Trump Administration is Obscuring the Value of Wetlands Protection from the Clean Water Rule*, Institute for Policy Integrity at New York University School of Law, (2017).

⁸ 83 Fed. Reg. at 18,772.

already been published, while penalizing the agency and public by excluding potentially valuable information from the regulatory process.⁹ EPA also does not assess the rule's redundancy given that many peer-reviewed journals have already updated their data transparency policies to encourage data availability.¹⁰

Transparency in research is desirable, and efforts to promote the release of data to the public are laudable. But ignoring valid and potentially valuable information in rulemaking with profound public health and economic consequences is a steep cost to pay—and at odds with the agency's mandate to use the “best available” science.¹¹ I encourage the Science Advisory Board to consider these costs, and better alternatives, in today's discussion of the rule.

⁹ Timothy Vines *et al.*, *The Availability of Research Data Declines Rapidly with Article Age*, 24 CURRENT BIOLOGY, 94 (2014).

¹⁰ Over 1000 journals have implemented policies in line with the Transparency and Openness Promotion Guidelines developed by the Center for Open Science. These guidelines promote the sharing of data while also providing for the protection of confidential or proprietary information. *See* Center for Open Science, <https://cos.io/top/>.

¹¹ Exec. Order No. 13563, 76 Fed. Reg. 3821 (Jan. 21, 2011).