



Science in the Administrative Process

DRAFT March 18, 2013

For the last three decades, many have criticized federal agencies for being insufficiently transparent in their use of science¹ in agency decisionmaking.² Partially in response to these criticisms, the Executive Branch and Congress have issued a number of reforms of the scientific process undergirding agency decisionmaking. Most recently, in 2009 President Obama issued a memorandum to the agencies directing that, “[t]o the extent permitted by law, there should be transparency in the preparation, identification, and use of scientific and technological information in policymaking.”³ “Each agency should [also] have appropriate rules and procedures to ensure the integrity of the scientific process within the agency.”⁴ John Holdren, the Director of the Office of Science and Technology Policy (OSTP), elaborated upon this memorandum in 2010, instructing agencies to “communicate scientific and technological findings by including a clear explication of underlying assumptions; accurate contextualization of uncertainties; and a description of the probabilities associated with both optimistic and pessimistic case projections.”⁵

At base, these initiatives demand heightened transparency of agencies’ use of science as a central means of ensuring the basic accountability of agency regulation. If an agency isolates the role that scientific information plays in its ultimate decision and explains how it ensured that its scientific analysis was rigorous, then the public has a basis against which it can evaluate both the scientific and policy judgments underlying the agency’s decision. This transparency allows those outside the agency to assess whether the agency’s use of science comports with the authorizing law, the larger scientific record, and political preferences. This transparent decision

¹ For purposes of this recommendation, the term “science” refers only to “natural sciences” (e.g., chemistry, physics, medical science, geology, etc.) rather than “social sciences” (e.g., economics, psychology, sociology, etc.).

² See e.g. NAT’L RESEARCH COUNCIL, REVIEW OF THE ENVIRONMENTAL PROTECTION AGENCY’S DRAFT IRIS ASSESSMENT OF FORMALDEHYDE (2011); COMM. ON RISK ASSESSMENT OF HAZARDOUS AIR POLLUTANTS, NAT’L RESEARCH COUNCIL, SCIENCE AND JUDGMENT IN RISK ASSESSMENT (1994); NAT’L RESEARCH COUNCIL, ASSESSMENT IN THE FEDERAL GOVERNMENT: MANAGING THE PROCESS (1983); BIPARTISAN POLICY CTR., IMPROVING THE USE OF SCIENCE IN REGULATORY POLICY 16, 41-42 (2009) [hereinafter “BPC REPORT”]; see also CTR. FOR EFFECTIVE GOV’T, ADVANCING THE PUBLIC INTEREST THROUGH REGULATORY REFORM: RECOMMENDATIONS FOR PRESIDENT-ELECT OBAMA AND THE 111TH CONGRESS 26, 34, 47 (2008).

³ Memorandum from the Admin. of Barack H. Obama for the Heads of Executive Departments & Agencies on Scientific Integrity (Mar. 9, 2009) [hereinafter “Obama Scientific Integrity Memo”], available at <http://www.gpo.gov/fdsys/pkg/DCPD-200900137/pdf/DCPD-200900137.pdf>.

⁴ *Id.*

⁵ Memorandum from John P. Holdren for the Heads of Executive Departments & Agencies on Scientific Integrity (Dec. 17, 2010), available at <http://www.whitehouse.gov/sites/default/files/microsites/ostp/scientific-integrity-memo-12172010.pdf>. To effectuate this and a number of other responsibilities, agencies were asked to report back to OSTP on the actions taken to develop and implement their scientific integrity policies by April 2011.



process also advances other institutional and scientific goals, such as identifying promising areas for future research and serving as a bulwark against the politicization of science.⁶

Despite these important innovations, agency decision-making processes would benefit from further improvements, and this recommendation offers several recommendations for enhancing the transparency of agencies' use of science. First, the recommendation highlights a number of innovative practices undertaken by different federal agencies ~~to~~ enhancing the transparency of their scientific decisionmaking processes. As a general matter, agencies should articulate the specific questions to be informed by scientific information and specify study designs for new research and criteria for reviewing and weighing existing set forth a systematic approach both for identifying relevant literature and devising new studies. Agencies should identify scientific research upon which they relied (as well as the underlying data), and material literature that they rejected, to the extent practicable and permitted by law. Agencies should establish checkpoints for closing off consideration of additional research or debate prior to effectuating a regulatory decision and policies for reopening that consideration identifying future studies. Agencies should also consider extending authorship rights to staff that participate in the preparation of scientific reports and taking other steps in order to promote robust debate amongst agency scientists.⁷ Finally, agencies should share "best practices with other agencies and should recommend the removal of any legal impediments to promoting transparency in scientific decisionmaking."⁸

Comment [JC1]: These edits are intended to make this paragraph track more slavishly the recommendations it summarizes.

Second, the recommendation offers a series of proposals to bring greater congruity to the treatment of publicly and privately funded scientific research. Specifically, it recommends extending data disclosure requirements applicable to agency-funded research to privately funded research upon which an agency relies (to the extent practicable and permitted by law). Similarly,

⁶ BPC REPORT, *supra* note 2, at 3.

⁷ In response to President Obama's call for agencies to develop "appropriate rules and procedures to ensure the integrity of the scientific process," Obama Scientific Integrity Memo, *supra* note 333, a number of agencies have promulgated integrity policies to promote open debate amongst agency scientists. *See, e.g.*, FOOD AND DRUG ADMIN., SCIENTIFIC INTEGRITY AT FDA, FDA STAFF MANUAL GUIDES, VOLUME IV-AGENCY PROGRAM DIRECTIVES 2 (2012) available at <http://www.fda.gov/ScienceResearch/AboutScienceResearchatFDA/ucm306446.htm>; NAT'L OCEANIC AND ATMOSPHERIC ADMIN., SCIENTIFIC INTEGRITY (Dec. 7, 2011), available at http://www.corporateservices.noaa.gov/ames/administrative_orders/chapter_202/202-735-D.pdf; NUCLEAR REGULATORY COMM'N, COLLABORATIVE WORK ENVIRONMENT PROGRAM, <http://www.nrc.gov/about-nrc/values.html#open> (last updated May 4, 2012); *see also* Francesca T. Grifo, Federal Agency Scientific Integrity Policies: A Comparative Analysis (Mar. 2013), http://www.ucsusa.org/assets/documents/scientific_integrity/SI-policies-comparative-analysis.pdf.

⁸ *See* Wendy Wagner, Science in Regulation: A Study of Agency Decisionmaking Approaches 135–38 (Feb. 18, 2013), available at http://www.acus.gov/sites/default/files/documents/Science%20in%20Regulation_Final%20Report_2_18_13_0.pdf (identifying a number of external legal impediments to promoting transparency, including short statutory deadlines, limits on dissemination of scientific studies, resource limitations, and caps on the number of discretionary advisory committees agencies can constitute).

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it recommends extending financial disclosure requirements to private parties who furnish studies used by an agency.

Practices Worth Considering

1. *Explaining Agency Scientific Decisionmaking:* Agencies should explain in the final decision document ~~rule~~ how they ensured rigorous review of the scientific research underlying each science-intensive regulatory project. This includes a statement of how the agencies evaluate the scientific information used in their analysis; how the agencies make that information available to reviewers and the public; how the analysis is reviewed by experts and interested parties; and how the agencies ensure that the final decision can be compared against the scientific record.

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Comment [JC2]: Not every agency decision to which this recommendation applies will be a rule.

2. *Designing Transparent ~~Risk~~ Assessments:* At an early stage in their regulatory processes, agencies should articulate the specific policy questions that may be informed by science; describe the study design, in the case of new research, or the criteria to be used in reviewing and weighing existing studies; identify other analytical choices; provide a synthesis of the available evidence and relevant literature guided by the study design or criteria; identify significant assumptions and choices of analytical techniques; provide a statement of remaining uncertainties; and discuss how different plausible choices might change the resulting policy decision. If possible, agencies should also explain the relationship between its science and policy choices.⁹

Comment [JC3]: My notes are that we deleted "risk" both places it occurred in this recommendation, so that it's talking more generally about "assessments." For example, some assessments may only be dose/response assessments that do not take account of exposure (and so technically are hazard, rather than risk, assessments).
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3. *Disclosing Underlying Studies and Data:* In light of the Information Quality Act (IQA) guidelines issued by the Office of Management and Budget and its own IQA guidelines, each agency should ensure that qualified members of the public can, within the time limits provided for public comment, verify the agency's analytical results. This generally requires that the agency identify and make publicly available the scientific literature, underlying data, and models that it reviewed as well as its research results, including the results it obtained but on which it did not rely. To the extent practicable and permitted by law, the agency should identify and make publicly available (on the agency website or some other widely available forum) a list of the scientific literature it considered (including the literature it rejected when it is material to the scientific analysis, as well as the literature upon which it relied).¹⁰

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⁹ NAT'L RESEARCH COUNCIL, COMM. ON THE INSTITUTIONAL MEANS FOR ASSESSMENT OF RISKS TO PUBLIC HEALTH, RISK ASSESSMENT IN THE FEDERAL GOVERNMENT: MANAGING THE PROCESS 7 (1983).

¹⁰ See Administrative Conference of the United States, Recommendation 2011-1, *Legal Considerations in E-Rulemaking*, ¶ 4, 76 Fed. Reg. 48789, 48789 (Aug. 9, 2011); see also Memorandum from John P. Holdren, Director of the Office of Science and Technology Policy, to the Heads of Executive Departments and Agencies re Increasing Access to the Results of Federally Funded Research (Feb. 22, 2013) (requiring agencies to permit public access to fully or partially federally funded research papers twelve months after publication).



4. *Checkpoints and Explanations:* To the extent permitted by statute, agencies should consider establishing explicit checkpoints for regulatory projects, particularly in cases when they are not bound by judicially enforceable deadlines. These checkpoints should address both the conditions under which agencies will close their consideration of research or debate in order to reach a decision and when they might reopen that consideration. In any case, agencies should explain their decisions to initiate, stop, or reopen consideration of research or debate. Such explanations should reference significant relevant ongoing research or other relevant factors.

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5. *Identifying Future Research Projects:* For science-intensive rules, agencies should use the results of uncertainty analysis to identify specific types of future research projects that will best advance understanding of the regulatory options. This identification of research questions and assignment of priorities should influence the agencies' research agendas as well as provide a basis for establishing future checkpoints.

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6. *Agency Staff Authorship Rights:* Agency staff members play an important role in producing their respective agencies' scientific analyses. Agency managers should consider providing staff with some form of consensual authorship right or attribution for reports or analyses to which they contribute in a significant way. Such rights should be acknowledged for all staff authors who contributed in a significant way to a technical or scientific report, including economists, lawyers, and other nonscientists. In a similar vein, reviewers and other contributors should also be identified by name and general contribution.

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7. *Encouraging Debate:* Agencies should encourage vigorous debate among scientists and should explore ways of incorporating the diversity of that debate in any resulting work product. Employees should be allowed and encouraged to publish their scientific work in the peer reviewed literature, provided that confidential governmental deliberations are not compromised. In all cases and regardless of the public availability of these discussions, dissenting staff members should be protected from reprisals.

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8. *Sharing of Agency Best Practices through Central Executive Branch Coordinator:* OSTP, an interagency group headed by OSTP, or another body should be responsible for identifying and publicizing the innovations developed by agencies for transparently incorporating science into their regulatory decisions.

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9. *Eliminating Legal Barriers to Transparent Decisionmaking:* Agencies should identify legal barriers that impede public access to the scientific information underlying agency analyses or otherwise block the agencies' development of scientifically robust decision-making processes. Agencies should recommend appropriate revisions in existing law to eliminate such impediments to the Executive Office of the President. OSTP or another centralized entity should serve as a forum for identifying concerns affecting multiple agencies and urging appropriate changes in law.

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Agency Disclosures to Enhance the Transparency of Research

10. *Data Disclosure:* To the maximum extent practicable and in compliance with appropriate legal restrictions (e.g., protections for personal privacy, trade secrets, and confidential business information (CBI)), agencies should voluntarily comply with the Shelby Amendment¹¹ and OMB Circular A-110¹² in circumstances to which they do not literally apply. ~~In addition, agencies should seek to provide disclosure of data underlying federally funded or non-federally funded research, including from government contracts. Agencies should review their CBI policies to ensure that they include appropriate mechanisms to prevent over-claiming.~~ Where the owners of such data will not provide such access, agencies should note that fact, explain why they used the results if they choose to do so, and may assign less weight to such research.

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Comment [JC4]: This sentence simply restates the effect of the preceding sentence. It doesn't describe anything additional.

Comment [JC5]: I thought we agreed to STET the following recommendation and put this sentence at the end, so that's what I've done here.

11. *Legal Restrictions on Disclosure: Public transparency of scientific information should be the rule. However, it may not be possible because of legal restrictions. These may be based on personal privacy¹³ or because the owner of information claims it to be protected from disclosure as trade secret or other confidential business information.¹⁴ Agencies should explain these restrictions in the agency's individual analyses and indicate whether any such restricted information was relied upon and, if so, for what conclusions. Agencies should publish nonrestricted summaries of such information and consider procedures to provide for the sharing of CBI with outside parties in ways that do not compromise confidentiality (e.g., user agreements). Agencies should review their CBI policies to ensure that they include appropriate mechanisms to prevent over-claiming.*

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Comment [JC6]: See previous comment.

11.12. *Financial Interests Disclosure:* Agencies should require financial interest disclosures on all research submitted to inform an agency's licensing, regulatory, or other decision-making process. This disclosure should be similar to the financial interest disclosure

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¹¹ Omnibus Consolidated and Emergency Supplemental Appropriations Act, Pub. L. No. 105-277, 112 Stat. 2681, 2681-495 (1998) (tasking the director of the Office of Management and Budget with amending Circular A-110 "to require Federal awarding agencies to ensure that all data produced under an award will be made available to the public through the procedures established under the Freedom of Information Act").

¹² Uniform Administrative Requirements for Grants and Agreements with Institutions of Higher Education, Hospitals, and Other Non-Profit Organizations (OMB Circular A-110), 2 C.F.R. § 215 (2004). ("[I]n response to a Freedom of Information Act (FOIA) request for research data relating to published research findings produced under an award that was used by the Federal Government in developing an agency action that has the force and effect of law, the Federal awarding agency shall request, and the recipient shall provide, within a reasonable time, the research data so that they can be made available to the public through the procedures established under the FOIA.")

¹³ The Privacy Act of 1974, 5 U.S.C. § 552a (1974).

¹⁴ Trade Secrets Act, 18 U.S.C. § 1905 (2012); Freedom of Information Act, 5 U.S.C. § 552(b)(4) (2012).



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required by scientific journals.¹⁵ The regulatory financial interest disclosure should also, where possible, identify whether the experimenter or author had the legal right to design the research; collect the data; interpret the data; and author, publish or otherwise disseminate the resulting report without approval of the sponsor of the research. Finally, agencies and scientific advisory committees should be skeptical of those studies wherein a party other than the principal investigator (e.g., the study sponsor or funder) had control over the design or publication of the study.

¹⁵ *Uniform Requirements for Manuscripts Submitted to Biomedical Journals: Manuscript Preparation and Submission: Preparing a Manuscript for Submission to a Biomedical Journal*, INTERNATIONAL COMMITTEE OF MEDICAL JOURNAL EDITORS, http://www.icjme.org/manuscript_1prepare.html.