



## Science in the Administrative Process

### Committee on Regulation

Proposed Recommendation | June 13–14, 2013

#### Proposed Amendments

***This document displays manager's amendments (with no marginal notes) and additional amendments from Conference members (with the source shown in the margin)***

1 | ~~For Over~~ the last three decades, several authorities ~~have~~ made recommendations for  
2 | improving transparency in the use of science<sup>1</sup> in the administrative process.<sup>2</sup> Partially in  
3 | response to these recommendations, the Executive Branch and Congress have made a number  
4 | of reforms to the scientific process undergirding agency decisionmaking. In 2009, President  
5 | Obama issued a memorandum directing that, “[t]o the extent permitted by law, there should  
6 | be transparency in the preparation, identification, and use of scientific and technological  
7 | information in policymaking.”<sup>3</sup> “Each agency should [also] have appropriate rules and  
8 | procedures to ensure the integrity of the scientific process within the agency.”<sup>4</sup> The Office of  
9 | Science and Technology Policy (OSTP) elaborated upon this memorandum in 2010, instructing  
10 | agencies to “communicate scientific and technological findings by including a clear explication

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<sup>1</sup> For purposes of this recommendation, the term “science” refers only to “natural sciences” (e.g., chemistry, physics, medical science, geology, etc.), mathematics, statistics, computer science, and other allied fields rather than “social sciences” (e.g., economics, psychology, sociology, etc.).

<sup>2</sup> 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, RISK 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 111<sup>TH</sup> CONGRESS 26, 34, 47 (2008).

<sup>3</sup> Memorandum from the Admin. of Barack H. Obama for the Heads of Executive Departments & Agencies on Scientific Integrity, DAILY COMP. PRES. DOCS., 2009 DCPD No. 00137 (Mar. 9, 2009) [hereinafter “Obama Scientific Integrity Memo”], available at <http://www.gpo.gov/fdsys/pkg/DCPD-200900137/pdf/DCPD-200900137.pdf>.

<sup>4</sup> *Id.*



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11 of underlying assumptions; accurate contextualization of uncertainties; and a description of the  
12 probabilities associated with both optimistic and pessimistic case projections.”<sup>5</sup>

13 At base, these initiatives demand heightened transparency of agencies’ use of science as  
14 a central means of ensuring the basic accountability of agency regulation. If an agency  
15 identifies the role that scientific information plays in its ultimate decision and explains how it  
16 ensured that its scientific analysis was rigorous, then the public has a basis against which it can  
17 evaluate both the scientific and policy judgments underlying the agency’s decision. This  
18 transparency allows those outside the agency to assess whether the agency’s policy decision  
19 comports with the authorizing law and the ~~larger~~ scientific record. A transparent  
20 decisionmaking process also advances other institutional and scientific goals, such as identifying  
21 promising areas for future research and serving as a bulwark against misuse of science for  
22 political ends.<sup>6</sup>

23 Despite these important initiatives, a study commissioned by the Administrative  
24 Conference<sup>7</sup> (and public meetings that considered questions it raised) ~~has~~ revealed that agency  
25 decisionmaking processes would benefit from further improvements. Drawing on this learning,  
26 the recommendation offers several proposals for enhancing the transparency of agencies’ use  
27 of science. At the same time, the Conference recognizes that agencies’ abilities to implement  
28 this recommendation may be affected by resource limitations.

29 First, the recommendation highlights a number of innovative practices undertaken by  
30 different federal agencies to enhance the transparency of their scientific decisionmaking

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<sup>5</sup> Memorandum from John P. Holdren, Director of the Office of Science and Technology Policy, to the Heads of Executive Departments and 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.

<sup>6</sup> BPC REPORT, *supra* note 2, at 3.

<sup>7</sup> WENDY WAGNER, SCIENCE IN REGULATION: A STUDY OF AGENCY DECISIONMAKING APPROACHES (Feb. 18, 2013), *available at* [http://www.acus.gov/sites/default/files/documents/Science%20in%20Regulation\\_Final%20Report\\_2\\_18\\_13\\_0.pdf](http://www.acus.gov/sites/default/files/documents/Science%20in%20Regulation_Final%20Report_2_18_13_0.pdf).



31 processes. As a general matter, agencies should articulate the specific questions to be  
32 informed by scientific information, specify study designs for new research, and establish criteria  
33 for weighing existing studies.<sup>8</sup> Agencies should identify scientific reports or data upon which  
34 they relied, and material literature that they considered but **rejected upon which they did not**  
35 **rely**, to the extent practicable and permitted by law.<sup>9</sup> Agencies should establish checkpoints  
36 (i.e., times for closing off consideration of additional research or debate prior to making a final  
37 regulatory decision) and policies for reopening that consideration. Agencies should also  
38 consider extending attribution to individual staff who participate in the preparation of scientific  
39 reports and taking other steps to promote robust debate among agency scientists.<sup>10</sup> Finally,

<sup>8</sup> In so doing, agencies should endeavor to explain the relationship between scientific research and the policy decisions the research is intended to inform. 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).

<sup>9</sup> 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 on Increasing Access to the Results of Federally Funded Research (Feb. 22, 2013) (requiring agencies to permit public access to research papers, funded in whole or in part with federal monies, beginning one year after publication). As a general matter, the agency should make publicly available any scientific **literature references** it considered, including **literature those** it reviewed but upon which it ultimately did not rely. For purposes of the recommendation, **literature references** that an agency "considered" include: not only any study an agency official relied upon but also any study an agency official reviewed but ultimately determined not to rely upon (because it was deemed to be outside the scope of the scientific study at hand, was not considered sufficiently reliable, or was otherwise rejected by the agency official). Cf. Administrative Conference of the United States, Recommendation 2013-\_, *The Administrative Record in Informal Rulemaking*, \_\_ Fed. Reg. \_\_ (providing a similar definition of "consider" in the context of the administrative record in informal rulemaking). If an agency official merely had access to a study but did not specifically analyze it to determine its relevance, that study has not been "considered" within the meaning of the recommendation for purposes of making such **literature references** publicly available.

<sup>10</sup> 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 3, a number of agencies have promulgated integrity policies to promote open debate among agency scientists. See, e.g., **ENVTL. PROT. AGENCY, SCIENTIFIC INTEGRITY POLICY (Feb. 2012), available at [http://epa.gov/osa/pdfs/epa\\_scientific\\_integrity\\_policy\\_20120115.pdf](http://epa.gov/osa/pdfs/epa_scientific_integrity_policy_20120115.pdf)**; 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](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.

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40 agencies should share best practices with other agencies and should recommend the removal  
41 of any legal impediments to promoting transparency in decisions in which science is an  
42 important element.<sup>11</sup>

43 Second, the recommendation offers a series of proposals to bring greater congruity to  
44 the treatment of publicly and privately funded scientific research. Specifically, it **recommends**  
45 **extending data disclosure requirements applicable to agency funded research to privately**  
46 **funded research upon which an agency relies encourages the disclosure of data underlying**  
47 **scientific research, including both privately funded and federally funded research, that an**  
48 **agency is considering** (to the extent practicable and permitted by law).<sup>12</sup> Similarly, it  
49 recommends extending **financial conflict of interest** disclosure norms to private parties who  
50 submit studies used by an agency.

## Recommendation

### 51 Suggested Agency Practices Regarding the Use of Science in the Administrative Process

52 1. *Explaining Agency Scientific Decisionmaking:* Agencies should explain in  
53 proposed **orand** final decision documents how they ensured rigorous review of the scientific  
54 information underlying each science-intensive regulatory project. This includes a statement of  
55 how the agencies evaluated the scientific information used in their analysis; how the agencies  
56 made that information available to reviewers and the public; how the analysis was reviewed by  
57 experts and interested parties; and how the agencies ensured that the final decision was  
58 supported by the scientific record.

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Grifo, Federal Agency Scientific Integrity Policies: A Comparative Analysis (Mar. 2013), [http://www.ucsusa.org/assets/documents/scientific\\_integrity/SI-policies-comparative-analysis.pdf](http://www.ucsusa.org/assets/documents/scientific_integrity/SI-policies-comparative-analysis.pdf).

<sup>11</sup> See Wagner, *supra* note 7, at 135–38 (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).

<sup>12</sup> Legal restrictions that may limit agencies' ability to provide such disclosures include, among other things, protections for personal privacy, trade secrets, and confidential business information.



59 | 2. *Assuring Transparent Assessments:* At an early stage in their **regulatory**  
60 | **development decisionmaking** processes, agencies should identify the specific policy questions  
61 | that may be informed by science; describe the design of the assessments needed to  
62 | characterize risks and inform policy decisions; and describe the criteria to be used in reviewing  
63 | and weighing existing studies. When completed, assessments should: identify other  
64 | appropriate analytical choices **and explain why they were not chosen**; provide a synthesis of the  
65 | available evidence and relevant literature guided by the assessment design or criteria; identify  
66 | significant assumptions and choices of analytical techniques; provide a statement of remaining  
67 | uncertainties; and discuss how different plausible choices might change the results of the  
68 | assessment. Where possible, agencies should also explain the relationship between their  
69 | scientific findings and **policy choices the final policy choice**.

70 | 3. *Disclosing Underlying Studies and Data:* **To the extent practicable and**  
71 | **permitted by law and applicable policies, each agency should identify and make publicly**  
72 | **available (on the agency website or some other widely available forum) references to the**  
73 | **scientific literature, underlying data, models, and research results that it considered. In so**  
74 | **doing, the agency should list all information upon which it relied in reaching its conclusion, as**  
75 | **well as any information material to the scientific analysis that it considered but upon which it**  
76 | **ultimately did not rely.** Consistent with the limitations in the Information Quality Act (IQA)  
77 | guidelines issued by the Office of Management and Budget and its own IQA guidelines, each  
78 | agency should ensure that members of the public have access to the information necessary to  
79 | **reproduce or verify confirm** the agency's **analytical technical or scientific** results. **To the extent**  
80 | **practicable and permitted by law and applicable policies, each agency should identify and make**  
81 | **publicly available (on the agency website or some other widely available forum) references to**  
82 | **the scientific literature, underlying data, models, and research results that it considered. In so**  
83 | **doing, the agency should list all information upon which it relied in reaching its conclusion, as**  
84 | **well as any information material to the scientific analysis that it considered but upon which it**  
85 | **ultimately did not rely.**

**Comment [CMA1]:** Siciliano Amendment: I believe that the term "confirm" captures the intent of this paragraph without implying a level of mathematical precision suggested by the terms "reproduce or verify."



86           4.     *Checkpoints and Explanations:* Agencies should consider establishing explicit  
87 checkpoints for regulatory projects, defining both the conditions under which they intend to  
88 close their consideration of research or debate in order to reach a decision and when they  
89 might reopen that consideration, particularly in cases when they are not bound by judicially  
90 enforceable deadlines. In any case, agencies should explain their decisions to initiate, stop, or  
91 reopen consideration of research or debate. Such explanations should reference significant  
92 relevant ongoing research or other relevant factors.

93           5.     *Identifying Future Research Projects:* For science-intensive **regulatory research**  
94 projects, agencies should identify specific types of future research **that may be** needed to  
95 reduce significant uncertainties in order to advance understanding of the **regulatory research**  
96 issues.

97           6.     *Attribution for Agency Personnel:* Agency personnel play an important role in  
98 producing their respective agencies' scientific analyses. Agencies should consider providing  
99 their personnel with some form of consensual attribution for reports or analyses to which they  
100 contribute in a significant way. If appropriate, such attributions should be made for personnel  
101 who contributed in a significant way to a technical or scientific report, including not only  
102 scientists but also economists, lawyers, and other contributors. Reviewers and other  
103 contributors could be identified by name and general contribution.

104           7.     *Encouraging Debate:* Agencies should encourage vigorous debate among  
105 scientists and should explore ways of incorporating the diversity of that debate in any resulting  
106 work product. Employees should be encouraged to publish their scientific work in the peer  
107 reviewed literature, provided that they follow applicable agency procedures and that  
108 confidential governmental deliberations are not compromised. Dissenting staff members  
109 should be protected from reprisals.

110           8.     *Sharing of Agency Best Practices:* Agencies should identify and publicize the  
111 innovations they have developed for transparently incorporating science into their regulatory



112 decisions. OSTP, an interagency group headed by OSTP, or another body should consider  
113 occasionally convening agency representatives to discuss and share best practices.

114 9. *Addressing Legal Obstacles to Transparent Decisionmaking:* Agencies should  
115 identify legal obstacles that may impede otherwise appropriate public access to the scientific  
116 information underlying agency analyses or that may prevent the agencies' development of  
117 scientifically robust decisionmaking processes. Agencies should recommend appropriate  
118 actions to eliminate such impediments, including revisions in existing law, to the Executive  
119 Office of the President.

#### 120 **Agency Disclosures to Enhance the Transparency of Research**

121 10. *Data Disclosure:* To the extent practicable and in compliance with applicable  
122 legal restrictions, privileges, protections, and authorities, agencies should seek to provide  
123 disclosure of data underlying scientific research, including both privately and federally funded  
124 research being considered by the agencies. Where such data are not subject to legal or other  
125 protections, and the data's owners nonetheless will not provide such access, agencies should  
126 note that fact, ~~and explain why they used the results if they chose to do so, and assign less~~  
127 ~~weight to such research, when appropriate.~~ Agencies should review their ~~CB~~confidential  
128 ~~business information~~ policies to ensure that they include appropriate mechanisms to prevent  
129 over-claiming.

130 11. *Conflict of Interest Disclosure:* Agencies should require conflict of interest  
131 disclosures on all scientific research submitted to inform an agency's licensing, regulatory, or  
132 other decisionmaking process. This disclosure should be similar to the conflict of interest  
133 disclosure required by some scientific journals, such as that used by the International  
134 Committee of Medical Journal Editors. The regulatory conflict of interest disclosure should  
135 also, where permitted by law, identify whether the experimenter or author had the legal right  
136 ~~[without approval of the sponsor of the research]~~ to: design the research; collect the data;  
137 interpret the data; and author, publish or otherwise disseminate the resulting report or full  
138 dataset ~~without approval of the sponsor of the research.~~ To the extent that a party other than

**Comment [CMA2]:** Siciliano Amendment: I have two concerns with the phrase "assign less weight." First, agencies balance a number of factors in determining the weight to assign to particular research, and data access is only one factor. Second, the recommendation also encourages agencies to explain why they are using the data notwithstanding limitations on data access. I believe that portion of the recommendation will achieve the desired transparency without triggering the first concern.



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139 the principal investigator (e.g., the study sponsor or funder) had control over the design or  
140 publication of the study, agencies should disclose this fact and specify the nature of the control  
141 such an entity exercised.