***** *JWC edits to Draft 2/27/2012 based on 3/7/12 meeting of the Committee on Regulation* *****

As promised, I have tried to assist the "Style Committee" by editing the draft 2/27 document that Jeff handed out on March 7 to reflect the changes that the Committee agreed on that afternoon.

I started out by accepting all the changes shown in that document. Then, because the Committee focused only on the text of the recommendations, I deleted all the introductory text and the various subject headings. Obviously, these or something like them would need to be reinstated in a final document. Then I tried to implement the edits that were reflected in my notes.

I tried not to add any ideas of my own, except in one place that I have highlighted with comment balloons. (I changed "literature and data" to "literature, raw data and models" because I assume someone will inevitably urge an edit along those lines, based on the phraseology of the IQA guidelines, the BPC report, etc.)

I couldn't fix two weird formatting features (a premature page break on the first page and the footnote numbering).

I realize that this may all change based on the consultation with the CSTL, but I hope this will help the Committee at least nail down where it left things on the 7th.

Best,

-- Jamie

Recommendations on the Use of Science in the Administrative Process

~~1.For the last three decades, federal agencies have been criticized for not being clear about the role that science played in their decision-making processes.[1] In response to these~~

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[1] *See, e.g.*, NATIONAL RESEARCH COUNCIL, REVIEW OF THE ENVIRONMENTAL PROTECTION AGENCY'S DRAFT IRIS ASSESSMENT OF FORMALDEHYDE (2011) [hereinafter NAS, FORMALDEHYDE REPORT];

criticisms, a number of efforts have been made by the Executive Branch and Congress to provide mechanisms that attempt to shore up the quality of the scientific process undergirding agency decision-making. Most recently, in 2009 President Obama issued a memorandum to the agencies directing that "To the extent permitted by law, there should be transparency in the preparation, identification, and use of scientific and technological information in policymaking."[2] "Each agency should [also] have appropriate rules and procedures to ensure the integrity of the scientific process within the agency."[3] This memorandum was further elaborated in 2010 by the Director of Office and Science Technology Policy (OSTP), John Holdren, who instructed agencies, among other things, 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 . . ."[4] To effectuate this and a number of other responsibilities, agencies were asked to report back to OSTP with a report on the actions taken to develop and implement their scientific integrity policies by April, 2011.

2. At base, these initiatives demand heightened transparency of the agencies' use of science, a demand that is central to 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 embedded in the agency's decision. This transparency thus 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 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.

3. Some agencies are developing innovative ways to communicate how science informs their policies in sophisticated, yet accessible ways.[5] Agencies are also establishing processes

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COMMITTEE ON RISK ASSESSMENT OF HAZARDOUS AIR POLLUTANTS, NATIONAL RESEARCH COUNCIL, SCIENCE AND JUDGMENT IN RISK ASSESSMENT (1994); NATIONAL RESEARCH COUNCIL, RISK ASSESSMENT IN THE FEDERAL GOVERNMENT: MANAGING THE PROCESS (1983) [hereinafter NAS, RISK ASSESSMENT]; BiPartisan Policy Center, Improving the Use of Science in Regulatory Policy 15-16, 41-42 (Aug. 2009); *see also* Advancing the Public Interest through Regulatory Reform: Recommendations for President-Elect Obama and the 111th Congress, c/o OMB Watch 26, 34, 47 (Nov. 2008).

[2] Memorandum on Scientific Integrity from the Administration of Barack H. Obama for the Heads of Executive Departments and Agencies (Mar. 9, 2009), http://www.gpo.gov/fdsys/pkg/DCPD-200900137/pdf/DCPD-200900137.pdf.

[3] *Id.*

[4] Memorandum on Scientific Integrity from John P. Holdren for the Heads of Executive Departments and Agencies (Dec. 17, 2010), at pt. V [hereinafter John Holdren Scientific Integrity Memo] available at http://www.whitehouse.gov/sites/default/files/microsites/ostp/scientific-integrity-memo-12172010.pdf .

[5] *See, e.g.*, Environmental Protection Agency (EPA), Policy Assessment for the Review of the Particulate Matter National Ambient Air Quality Standards, April 2011, *available at*

~~that solicit both the expert and internal review of their work and that document the changes made in response to this input.[6] Integrity policies established by at least one agency allow staff to raise scientific differences with supervisors through various informal and formal mechanisms.[7] Finally, agencies increasingly have used the Internet to list the literature and other scientific evidence they relied on when making decisions.[8]~~

~~4.Despite these important innovations, agency decision-making processes would benefit from further improvements, and two sets of recommendations are proposed here. First, a number of external constraints on agency decision-making processes limit the ability of the agencies to improve their decision processes in keeping with the President's directive. An executive order caps the number of discretionary advisory committees that agencies can establish;[9] statutory barriers impede the public's access to studies informing agencies' scientific analysis;[10] presidential review processes can alter the science underlying a rule, but are protected as deliberative process;[11] and abbreviated statutory deadlines for rulemakings and the completion of agencies' scientific analyses[12] impede the ability of the agencies to develop rigorous and transparent processes for integrating science into regulation. One set of recommendations addresses these external constraints.~~

~~5.Second, while some agencies are innovative in their use of science, little of this innovation is recorded or shared across the government. A second set of recommendations attempts to catalog some of these innovations as best practices. While scientific and policy circumstances vary from program to program, thereby limiting the ability to apply one agency's innovations to others, certain presumptive "best practices" can and should be adopted by all agencies that engage in scientific decision-making.~~

~~6.External Barriers to the Integrity and Transparency of Science-Based Regulation~~

~~7.~~

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http://www.epa.gov/ttnnaaqs/standards/pm/data/20110419pmpafinal.pdf. (a report that bridges science and law in the development of air standards for particulates).

[6] Under IRIS, EPA solicits written comments from external expert peer reviewers, the general public, and from other federal agencies. Its response to these written comments from external reviewers and the public is detailed in Appendix A of its risk assessment reports. For an example, see EPA, Toxicological Assessment of Acrylamide, March 2010, at Appendix A, *available at* http://www.epa.gov/iris/toxreviews/0286tr.pdf.

[7] *See* Nuclear Regulatory Commission, Collaborative Work Environment Program, available at http://www.nrc.gov/about-nrc/values/open-work-environment.html.

[8] See the Health and Environmental Research Online (HERO) Database, last updated on February 8, 2012, available at http://hero.epa.gov/.

[9] Exec. Order No. 12,838, 58 Fed. Reg. 8207 (Feb. 10, 1993)

[10] *See, e.g.*, 7 U.S.C. § 136h(g)(1) (barring public access to most manufacturer-supplied research unless various conditions are satisfied).

[11] *See, e.g.*, Nina A. Mendelson, Disclosing "Political" Oversight of Agency Decision Making, 108 Mich. L. Rev. 1127, 1146-59 (2010) (discussing the lack of transparency of OMB review).

[12] 16 U.S.C. § 1533(b)(5)(A)(i).

~~8.Presidential Review~~

~~9.~~

~~10.~~The Office of Science and Technology Policy (~~The Office of Management and Budget (OMB) should establish scientific integrity policies for its own personnel that at least meet OSTP's minimum standards.~~[13]

~~11.OSTP should develop a government-wide dissent policy, modeled after the Nuclear Regulatory Commission's (NRC's) Collaborative Workplace Program,~~[14] ~~which provides agency scientists and engineers with the right to dissent or withdraw their concurrence on scientific analyses to which they contributed if they feel the scientific information has been mischaracterized. The dissent policy should also include a process for the adjudication and resolution of these scientific differences, like the NRC's Differing Professionals Opinion Program.~~

~~12.~~1. OSTP) and appropriate other entities should consider ways to identify and make publicly available~~ize~~ the best practices developed by agencies for transparently incorporating science into their regulatory decisions. In doing this, OSTP and these other entities could establish a forum – e.g., a website or workshops – through which agencies can share innovations in their integration of science into policy.

~~13.Other External Impediments~~

~~14.~~

~~15.~~2. A~~OSTP and the a~~gencies should identify legal and other barriers that impede public access to the scientific information underlying agency analyses or otherwise block the agencies' development of scientifically robust decision-making processes. Once information has ~~b~~been collected on the nature and extent of these external barriers, OSTP should convene workshops and otherwise develop mechanisms for eliminating or at least minimizing these impediments. A critical complement ~~t~~of OSTP's request for agency scientific integrity policies is OSTP's leadership in identifying and redressing significant external (statutory and government-wide) impediments to the agencies' ability to use science transparently and rigorously in their regulatory products.

~~16.~~Consistent with the Information Quality Act (IQA) guidelines issued by the Office of Management and Budget (OMB) and its own IQA guidelines, each ~~Best Practices for Agency Decision-Making Processes~~

~~17.~~

~~18.Ensuring the Scientific Evidence used by the Agency is Publicly Accessible~~

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[13] *See* Holdren Memorandum, *supra* note 4.

[14] *See* Nuclear Regulatory Commission, Collaborative Work Environment Program, *available at* http://www.nrc.gov/about-nrc/values/open-work-environment.html.

~~20.In supporting its science-based regulatory decision, an~~ agency should identify and make publicly available ~~a list of~~ the scientific literature, ~~-~~ raw data and models that it consider~~ult~~ed, ~~which ideally~~ includ~~es~~ing the literature it rejected as well as the literature it relied upon. This material~~reference list~~ should be posted online, prior to any notice of opportunity for public comment, consistent with Recommendation 2011-1[15] ~~-~~ and subject to any legal restrictions~~whenever possible~~.

~~21.~~3. ~~When an agency relies on studies that are not published, it should post the studies on its website as soon as is practicable.~~ If public transparency is not possible because of trade secret or other legal restrictions, these restrictions should be explained in the agency's individual analyses.

~~22.Agency Mechanisms to Enhance Scientific Integrity~~

~~23.~~

4. Agenci~~ey s~~ should consider whether affording ~~staff plays an important role in producing the agency's analyses. When possible,~~ agency staff ~~should be afforded~~ some form of consensual authorship right for reports or analyses to which they contribute in a significant way would improve the quality of the agency's scientific work products. If authorship rights are not possible, attribution should be provided to individual agency staff for their contributions.

5. OSTP should develop guidance for a~~A~~gencies to consider in developing ~~should have widely publicized,~~ written policies that allow agency staff to dissent or express their non-concurrence on a technical analysis to which they contributed. In developing the guidance, OSTP should consider the policies of the Food and Drug Administration's Center for Drug Evaluation and Research (CDER)[16] and the Nuclear Regulatory Commission (NRC).[17] S~~Such~~ uch policies should:
    a. Be widely publicized within the agency;
    b. Provide that dissenting staff members should be protected from reprisals;
    c. Provide that a~~. A~~ny staff member's dissent or non-concurrence should ~~should~~ be made part of the public record at the agency staff member's request; and~~.~~

Comment [JC1]: JWC suggestion; not discussed on 3/7

Comment [JC2]: Ditto

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[15] Administrative Conference of the United States, Recommendation 2011-1, "Legal Considerations in E-Rulemaking" (June 16, 2011).

[16] http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ManualofPoliciesProcedures/ucm073557.pdf

[17] *See* Nuclear Regulatory Commission, Collaborative Work Environment Program, *available at* http://www.nrc.gov/about-nrc/values/open-work-environment.html.

d. In-clude a process for the adjudication and resolution of these scientific differences, like the CDER's and NRC's Differing Professional Opinions procedures.[18]

~~24.~~

~~25.~~6. An agency's scientific analysis should be ~~reviewed by other experts or~~ subject to appropriate peer review~~some mechanism of quality control, even if this oversight occurs wholly inside the agency~~.[19] ~~Agencies should not be impeded in their utilization of this expert peer review. Additionally and when possible, agencies should endeavor to explain how they ensured the rigorous review of their scientific products for each regulatory project.~~

7. Draft scientific analyses can be made public with the disclaimer that they do not necessarily represent the policy or scientific position of the agency.

~~26.Agency Mechanisms to Enhance Scientific Transparency~~

~~27.~~

~~28.~~

8. An agency's decision should be capable of being compared against the scientific record in a way that identifies the agency's most significant policy-based choices among the alternatives and that also identifies the agency's scientific judgments that were subject to rigorous expert review. At an early stage in their regulatory processes, agencies should:

a. -Articulate the specific policy questions arising in a regulatory project that might be informed by science;

b. Assess the available evidence bearing on these policy-relevant questions;

c. Apply the evidence to the policy questions at issue, with robust statements of all material uncertainties and assumptions; and

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[18] http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ManualofPoliciesProcedures/ucm073558.pdf

[19] *See* OMB Final Information Quality Bulletin for Peer Review, 70 Fed. Reg. 2664 (Jan. 14, 2005). *See also* ~~Obama~~ Memorandum from the President for the Heads of Executive Departments and Agencies regarding Scientific Integrity (Mar. 9, 2009), available at http://www.whitehouse.gov/the-press-office/memorandum-heads-executive-departments-and-agencies-3-9-09, ~~*supra* note 2,~~ at 1 (directing that "[w]hen scientific or technological information is considered in policy decisions, the information should be subject to well-established scientific processes, including peer review where appropriate, and each agency should appropriately and accurately reflect that information in complying with and applying relevant statutory standards"); Memorandum from the John Holdren for the Heads of Executive Departments and Agencies regarding Scientific Integrity (Dec. 17, 2010), available at http://www.whitehouse.gov/sites/default/files/microsites/ostp/scientific-integrity-memo-12172010.pdf, ~~Holdren Memorandum, *supra* note 4,~~ at 1-2 (agencies should develop policies that ensure "that data and research used to support policy decisions undergo independent peer review by qualified experts, where feasible and appropriate, and consistent with law"); ~~*see also*~~ Administrative Conference of the United States, Recommendation 2011-7 (recommending rescission of a cap on the number of discretionary advisory committees an agency may form).

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d. Identify the various plausible policy alternatives, based on the scientific record, in way that is accessible to policymakers.

~~identify the policy-relevant questions that can be informed by science, and when possible, provide a review of the available scientific evidence with respect to these policy-relevant questions.~~ In applying scientific~~this~~ evidence to the policy questions at issue, the agency should also identify ~~what~~ their significant assumptions, choices of analytical techniques, and remaining uncertainties, ~~were~~ and discuss how different plausible choices would change the resulting policy decision. In explaining the various plausible policy options, t~~T~~he agency should ~~also~~ endeavor to ~~follow the model of the NAAQS policy assessment in~~ bridg~~eing~~ science and policy in ways that enable nonscientists to understand how the agency's scientific analysis informs the core policy questions. T~~, although t~~his step will likely involve more effort and experimentation.

9. A~~OSTP should require a~~gencies should~~to~~ make publicly available ~~provide~~ a flow chart or other ~~detailed and~~ accessible description of how they integrate science into their decisions for each of their science-intensive programs. This should include~~s~~ a statement of how an agency evaluates the scientific information used in its analysis; how the agency makes that information available to reviewers and the public; how the analysis is reviewed by experts and interested parties; and how the agency ensures that the final decision can be compared against the scientific record. The agencies' description should be circulated as a publicly available memorandum to agency staff and ideally should be posted on the agency's website.

10. In regulatory settings, particularly in cases when they~~agencies~~ are not bound by judicially enforceable deadlines, ~~the~~ agencies should explain the basis for their choices in ~~establish explicit "~~stopping or reopening ~~rules" (i.e., the point at which the agency will close its~~ consideration of ~~emerging~~ research and ~~when it chooses to close~~ scientific debate ~~in order to reach a decision)~~.

~~External peer review bodies are particularly useful to agencies in establishing scientifically credible points at which debate should cease.~~

~~2~~9.11. OMB should, within a reasonable time, consult with OSTP to develop scientific integrity policies for its own personnel that are appropriate to OMB. [20]

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[20] *See* Holdren Memorandum, *supra* note 19 [? – should be 5]. ~~4.~~