"Science in the Administrative Process": Take 2
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General Description and Focus of the Study

Reform proposals offered over the last decade to redress perceived problems in regulatory science generally target one of two points in the agencies' decision-making process. One set of reforms seeks to shore up internal oversight of science within the agencies, including strengthening how agency staff and political officials assemble, weigh, and communicate the scientific information used in their regulatory decisions. A second set of reforms attempts to reinvigorate external checks on agency decisions that involve scientific information (e.g., greater White House review, less deferential judicial review, more points for interest group input, and greater congressional oversight).

This study focuses on a specific topic within the first set of reforms -- strengthening internal agency processes for communicating how it uses science for regulation -- rather than on bolstering external checks on regulatory science. Improvements in the agencies' internal procedures for explicating how it uses science will not only facilitate better use of science from within the agency, but will spill over to enhance external oversight mechanisms as well. If the agency does a better job of explaining its work, for example, it will be easier for outside parties to ensure that the agencies' use of science comports with the authorizing law, the larger scientific record, and political preferences. Considerable attention has also been focused within the Obama Administration on improving the transparency of the agencies' use of science for regulation.

I. Science in the Regulatory Process: The Larger Landscape

The vastness of the topic of "science in the administrative process," plus the tremendous variation between agencies, make it practically impossible to understand how agencies use science in anything close to a comprehensive way. The best that can be done is to explore parts of the administrative state with the obvious risk that the problems most in need of attention have been missed.

This introductory section endeavors to identify the general issues that emerged from agency interviews, documents, and the literature in the course of the study regarding problems involved in the agencies' use of science. This preliminary map of the larger set of issues should be helpful not only to situate the study within the larger terrain, but also to spotlight a host of other issues that deserve attention in the future.

A. There is very little cross-fertilization and coordination between agencies on overlapping science-based projects (e.g., the use of computational models; risk assessments).
B. There are continuing challenges in protecting the scientific independence of government scientists and protecting against the politicization of science (both intentional and inadvertent).
C. There is under-utilization of science-advisors as independent resources for science advice.

D. There is considerable variation (not all for the good) in the scientific review processes used by different agencies (e.g., FACA advisory boards; peer review processes).
E. There are concerns with respect to how the agencies use science in various settings (e.g., transparency, competency).
F. There are challenges in hiring and retaining qualified scientists, particularly those well-versed in emerging technologies, to serve in government.

II. Focus of this Study

Regulatory science is often under fire, particularly when agency decisions are hotly contested. Perhaps for that reason, the agencies have sometimes been opaque about how they use science in their regulatory projects. It can be difficult to identify how the agency actually did its literature search, ascertain what choices it made in relying more heavily on some studies and not others, and isolate other assumptions adopted by the agency. As a result, those outside (and even inside) the agency must expend considerable time and effort reconstructing the agencies' analysis by working backwards from the regulatory result.

Over the last few decades, federal agencies have been criticized repeatedly for not being clear about the role that science played in their decision-making process. A number of efforts have been made by the Executive Branch to redress this perceived problem.[1] Specifically, President Obama issued a letter 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] This directive was further elaborated by the Director of OSTP by directing 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 . . . ".[3]

This study explores how well the agencies have done and are doing in terms of explicating the role that science plays in their regulatory decisions. Are there significant lapses in the agencies' explanation of how they use science? Are agencies changing their practices in light of the recent White House directives to increase the transparency of the role science plays in the regulatory process?

A. Central Justification

There are a number of reasons that this particular issue is worthy of study as the first in a series of ACUS studies on regulatory science.

1. *Evidence of a problem.* This problem has been identified as one in need of reform by bipartisan, respected organizations like the National Academy of Sciences[4] and the

[1] *See* Section II.A.1., *infra*.
[2] Obama letter March 2009.
[3] OSTP Memo (2009).
[4] *See, e.g.*, National Research Council, Review of the Environmental Protection Agency's Draft IRIS Assessment of Formaldehyde (2011); 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)

Bipartisan Policy Center.[5] Recognition of the problem has also been a recurring theme in some of the judicial reversals of agency science-based regulation.[6] Both the Obama and Holdren memoranda on scientific integrity, as mentioned, also identify the need for greater transparency in the agency's use of science. Yet, there is not much specific evidence of the extent of this problem within government.

2. *Central Role in Accountable Regulation.* A clear explication by the agencies of how science is used improves the quality of scientific oversight, the quality of policy deliberations, and increases the accountability of regulatory agencies. None of the other potential topics discussed in part I is as fundamental with respect to ensuring the integrity of regulatory science.
3. *Limited incentives for transparency.* Despite the centrality of the principle that agencies should "show their work" when it comes to science, there are a number of institutional incentives that might reward agencies for actually being quite opaque about the role science plays in decision-making, at least in some program areas. Yet other than judicial remands for failing to explain a decision, the agencies face few penalties for failing to provide a succinct and clear statement of how scientific information informs their work.
4. *Expected prevalence of the problem across agencies.* While the bulk of the reported problems in the agency's explication of science occur within EPA and to some extent DOI, there are reasons to believe that these same problems sometimes occur in other agencies. Examination of this problem in other agencies will advance understanding of regulatory science and likely spotlight other, related problems that deserve attention in the future.
5. *Amenable to Reform.* Unlike some other systemic problems – e.g., lack of interagency coordination – providing stronger incentives for agencies to provide a clearer explication of the role science plays in their decision is a process-based reform that seems, at least in the abstract, to be capable of implementation. Moreover, the considerable interagency variation in the use of science provides reason for optimism that a "better way" may already be instituted in some regulatory programs that can serve as models.

B. Additional Benefits

Understanding and, if needed, redressing the agencies' explication of the role of science in their decisions, is so central to administrative process that it also lays the foundation for reform of other, related problems:

1. Clearer statements of how the agency used science will provide the courts with a record for reviewing what the agency has done and reduce the risk of judicial challenge. The agencies' failure to explain their work is one of the most common bases for remands.[7]

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[5] 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).

[6] For an early example, *see Ethyl Corp. v. EPA*, 541 F.2d 1, 68 (D.C. Cir. 1976) (Bazelon, concurring) ("It is not enough for an agency to prepare a record compiling all the evidence it relied upon for its action; it must also organize and digest it, so that a reviewing court is not forced to scour the four corners of the record to find that evidence for itself. . . . . In informal rule-making, the record should clearly disclose when each piece of new information is received and when and how it was made available for comment.")

[7] Nearly forty percent of the vacaturs of agency regulations apparently occur because the agency failed to adequately explain or document its reasoning. *See, e.g.*, Patricia M. Wald, *Judicial Review in the Time of Cholera*, 49 ADMIN. L. REV. 659, 665 (1997); *see also* Christopher H. Schroeder & Robert L. Glicksman, *Chevron, State Farm and*

2. Clearer statements of how the agency used science in advance of OMB review could provide a bulwark against allegations that OMB changed (or will change) the substance of the agency's technical analysis.
3. There are concerns that the agency does not always use cutting edge methods and techniques, including more sophisticated use of social science, or that it does not use several alternative models/techniques to illuminate the scientific uncertainties. If the agency clearly states its methods for searching the literature and the studies it relied on, future research discoveries and alternate approaches could be integrated into the regulatory project more effectively.
4. Clearer statements of the agency's use of the available science could facilitate better inter-agency coordination since agencies could isolate points of disagreement more expeditiously.
5. Clearer statements of the agency's use of the available science will provide a more accessible view of what research has been done and what hasn't, and the quality of the research that is available. Such a clear statement thus identifies the most promising areas for future research, invites a broader range of stakeholders into the process, and highlights when the agency may have very little research available for carrying out its mandate, which in some settings will justify precautionary action.
6. Requiring agencies to explain the role science played in their regulatory decisions helps deter politicization of science and impedes the ability of stakeholders to drag agencies down into distractions or debates over the almost infinite ways that the scientific literature could have been weighted differently. Explication thus serves to focus and narrow the issues in dispute.
7. When a researcher publishes a review article that summarizes the research, he or she must include a methods statement of how he or she used the literature: At the very least, when an agency is using science, it should follow these same, well-established scientific practices.

C. Methods and Design

This study will focus on four agencies that use science extensively in their regulatory decision-making: EPA, FDA, NRC, and DOI. EPA and FDA are high profile and often controversial users of science. DOI is also a high profile agency, but its issue areas are environmental and natural resource protection rather than public health protection. NRC is an independent agency and thus provides a point of departure with respect to Executive Branch oversight. The study is limited to four agencies because of limited time and resources.

Each of these agencies will be studied by seeking relevant documents from within the agencies that pertain to their methods for explicating the use of science; through interviews with agency staff (past and present) and knowledgeable stakeholders; and reliance, where appropriate, on other government-related studies by NAS, OTA, GAO, and the general literature.

The following general questions will be explored in this research: Do agencies currently "show their work" in explaining how they searched the literature and how they used the available studies/literature? For example, do the agencies explain:

a. The question(s) in need of scientific guidance?
b. How they searched the scientific literature?

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the EPA in the Courts of Appeals in the 1990s, 31 ENVTL. L. REP. (ELI) 10371, 10405 (April 2001) (describing a decade of cases in which EPA rules were remanded for failure to support the agency's reasoning).

c. Whether all the relevant literature was included and made available to the public to the extent possible, including internal information and confidential information?
d. How the agency then used the relevant studies and weighted them?
e. How the agency incorporated (or at least discussed) applicable, cutting edge methods and technologies or other bodies of evidence that interface with regulatory decisions?
f. The timing of the agency's assessment of the science in light of the policymaking features of the decision?
g. The agency's ability to revisit the decision at regular intervals as the science changes?

III. Findings

A. Agency Successes in Explicating and Using Science for Regulation
[tbd]

B. Evidence of Problems
[tbd]

C. If/when the agencies don't do a good job showing their work, why not? Are there barriers/requirements/other impediments to communicating how they used the relevant science?
[tbd]

IV. Reform Recommendations [a *very* preliminary sketch, which is a placeholder for tbd]

Reforms will hopefully draw on advances already made by some agencies. Some recommendations could include:

1. Explanation of the Scientific Evidence Considered (including Literature Search Methods, etc.)

In cases where internal agency staff provides some of the basic scientific evidence that informs decisions, this research must be included in the decision and made publicly available.

2. Explication of the Agency's Assessment of Studies, its Assumptions, and its Methods of Analysis

The agencies should be encouraged to follow the NAS Formaldehyde Report (chpt. 7) and provide a clear, concise statement of how they reviewed the relevant scientific literature; identify the studies they included/excluded and why; and explain how they weighted and critiqued the studies. Ideally, these "methods for integrating science in a regulatory decision" would be captured in government-wide or at least agency-wide general guidances that provide a general set of rules. Then, in individual regulatory projects, the agency would apply the guidance and be explicit in its use of science in case-specific settings.

a) Authorship of the Scientific Assessment

An assessment that explicates the role that science plays in a regulatory decision should be developed by the agency's experts.

b) Timing/Process of the Assessment

A statement that explicates the role that science plays in a decision should be prepared before a proposed rule is published since it informs the agency's view of the literature, much like EPA's integrated science assessment for NAAQS.

c) Form of the statement

The scientific assessment should be succinct and clear, following the recommendations in the NAS Formaldehyde report. The basic assessment should be published, in full or part, in the preamble of the proposed rule, although it would not be subjected to notice and comment separately from the proposed rule.

3. Incentives for Doing a Good Job Explicating the Role of Science

Recommendations for a clearer explication of the role of science operates in a realm where agencies are already suffering from multiple, demanding analytical requirements and operating on thin budgets. A critical feature of these recommendations is to identify ways that a clear explication of the role of science can replace other, largely duplicative analytical requirements so that the recommendation ultimately lightens, rather than burdens the agencies' workloads.

Interview Protocol (tailored depending on interviewee)

Explicating How Science is Used in Regulatory Decisions

1. If you are familiar with the NAS's recent Formaldehyde report (2011), do you have a sense that _____ struggles with some of these same difficulties in explicating the role that science plays in a regulatory decision?
   For example, does ____ have general or program-specific guidelines that direct staff to provide an accessible and succinct explanation of how it used science in its decision (e.g., how the agency conducted the evidence/literature search; the inclusion/exclusion criteria for studies; how the various studies were weighted; explication of assumptions (particularly policy-based) and uncertainties; a candid discussion of challenges in incorporating certain cutting-edge evidence or methods into the analysis)?
2. If there is a formal or informal protocol at _____ for this clear explication of science, does this type of integrated science assessment occur early in the decision-making process, largely prior to the policy-making stages? If so, is this science assessment publicly available? And is the assessment reviewed at regulator intervals (e.g., every five years) or when the science advances significantly?
3. If _____ doesn't have general guidance or policies directing _____ staff to explain their use of science, would such guidance be helpful (e.g., guidelines that direct staff to explain succinctly and in ways that can be replicated how they did the literature search, weighted studies, reached assumptions, and even instructions regarding the timing of preparing and publishing of such an assessment)?

Scientific Freedom of Staff

4. Are there assurances of scientific freedom to ___'s staff. What has ____ done to comply with the recent Holdren memorandum on this issue?

Inter-agency Communications and Collaborations

5. Does OMB play a role in _____'s evaluation of the scientific literature and its description of how that literature affects its resulting regulatory decisions?
6. Is there much inter-agency coordination between _____ and other regulatory agencies? For example does your office meet w/ the Department's Science Advisor periodically?
7. What effort has _____ expended to ensure that it is making good use of emerging technical and scientific discoveries? Are there approaches/methods that _____has pioneered that can be easily grafted over to other agencies struggling with the same challenges?