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Science in the Administrative Process: A Study of Agency Decisionmaking Approaches

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Regulatory science is often under fire, particularly when agency decisions are hotly contested. For at least the last three decades, federal agencies have been criticized in particular for not being clear about the role that science played in their decision-making process. This problem has been identified as one in need of reform by bipartisan, respected organizations like the National Academy of Sciences[2] and the Bipartisan Policy

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

Center.[3] The agencies' failure to explain their work is one of the most common bases for remands.[4] It is also tied to more fundamental concerns about how a lack of scientific transparency in the agencies can fuel the politicization of science.[5]

It is not surprising that regulatory science presents difficult challenges for the administrative state. Evaluating the rigor of a scientific analysis requires expert training, often in the discrete area under study. It is thus difficult for agency decision processes, which depend heavily on public comment and institutional checks by nonscientific entities, to ensure that science has been used properly. The newsworthy examples within administrative practice when the scientific analyses were not conducted rigorously or, even worse, were manipulated to justify a particular result serve as a testament to the possibility that existing administrative processes are not adequate to police the quality and transparency of agency science.[6] Equally serious, when a controversial decision is made that depends heavily on science, it is difficult for nonscientific participants to tell where the science leaves off and the policy choices begin. In this setting, agency officials and even the President can dodge accountability by pretending that the "science made me do it" when nothing could be further from the truth.

In response to these dual problems of using science robustly and transparently for public decisions, a number of efforts have been made by the Executive Branch and Congress to shore up the quality of the science undergirding regulatory products. Most recently, 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."[7] This

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[3] 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).

[4] 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 the EPA in the Courts of Appeals in the 1990s*, 31 Environmental 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). For an early example of these opinions, 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.")

[5] Shortly after taking office, for example, President Barack Obama observed that "we have watched as scientific integrity has been undermined and scientific research politicized in an effort to advance predetermined ideological agendas." President Barack Obama, Remarks at the National Academy of Sciences (Apr. 27, 2009).

[6] *See generally* Holly Doremus, *Scientific and Political Integrity in Environmental Policy*, 86 TEX. L. REV. 1601 (2008) (describing these problems in the natural resource field); Union of Concerned Scientists, Federal Science and the Public Good (Dec. 2008); *see also infra* note 389.

[7] 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.

memorandum was further elaborated by the Director of the Office of Science and Technology Policy (OSTP), John Holdren, who directed the 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 . . . "[8].

Because occasional lapses in the transparency and rigor of the agencies' use of science have been spotlighted in the news and political process so regularly over the last three decades, however, there is reason to believe that the problems require more fundamental changes to agency processes. It is possible, for example, that at least some of these problems originate in decision-making structures that are deeply embedded in agency practice and are not easy to change with well-intended directives. It is also possible that in some cases the lack of transparency and rigor in the agencies' scientific analyses has more to do with forces outside the agencies' control. Hard constraints on agency decision-making imposed by Congress or interference with agency processes from the White House can also contribute to reduced transparency and rigor in the agencies' scientific analyses. If these outside sources are the primary causes of these recurring problems, then commanding the agencies to provide more robust analyses may be preaching to the wrong choir.[9]

This study looks behind agency work products to examine the agencies' actual decision-making processes themselves – the flow charts that show how the agency incorporates science into its regulatory products. These flow charts reveal the points at which agencies look to external peer reviewers, the public, and other entities for critical feedback and advice. The flow charts also reveal internal oversight processes that are intended to increase scientific and other sources of engagement in the agency's science-based regulatory projects.

A comparative investigation of the decision-making structures that the agencies use to incorporate science into regulatory projects helps provide purchase on this challenging topic of regulatory science in several ways. First and perhaps most important, there has been little to no attention to the decision-processes used by agencies to incorporate science, particularly at a level that goes beyond the study of a specific program. Understanding the basic flow charts or processes by which agencies integrate science is thus largely unexplored territory. Indeed, precisely because they are often not well described, these basic decision-making structures are particularly promising in their potential to spotlight areas of innovation and also areas that might benefit from reform.

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[8] 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 .

[9] The reforms to date seem to assume that agencies need only understand they need to do a better job "showing their work" and that if problems are occurring with the agencies' scientific integrity, they are internal problems and are not caused by external forces.

Second, and perhaps equally important, some of the most publicized problems in agency science in recent years, ranging from the prominent Department of Interior (DOI) scandal over high level manager, Julie MacDonald's, scientific misconduct[10] to the more run-of-the-mill charges by the National Academies of Sciences (NAS) that the Environmental Protection Agency's (EPA) assessments are unduly voluminous and difficult to understand,[11] all arguably originate with problems in the agency processes. DOI's Inspector General report that documents the manipulation of science at DOI traced many of the examples of that manipulation to "enormous" gaps in guidelines governing the processes that the FWS uses to integrate science into its decision processes.[12] Even more subtle problems originate from the structures that agencies use for making decisions. For example, high level EPA staff concedes that its Integrated Risk Information System (IRIS) risk assessments are lengthy and unwieldy due in part, and perhaps in large part, to the convoluted decision processes that those assessments undergo.[13] The possibility that decision-processes may be to blame for some of the continued dissatisfaction with how well agencies show their work and protect science, then, seems inescapable.

Third, a process-focus allows a legal analyst to make a useful contribution to assessing the reliability and transparency of the agencies' use of science. While legal analysts cannot identify, or at least will have a difficult time identifying agency analyses that are incomplete in their use of the scientific literature or in their explanation of alternative interpretations or assumptions, a legal analyst can trace the process by which the science enters the regulatory process.[14] This diagrammatic study not only provides a helpful basis for comparing very different types of regulatory programs, but it helps identify the role of institutional actors outside the agency, which can also influence how the agencies use science.

Finally, understanding how the science is used by the agencies is a fundamental first step in identifying ways to improve agency processes. If an agency isolates the role scientific information plays in its ultimate decision and explains how it ensured that scientific information 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 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. Distinguishing the role science plays in informing decisions from the role

[10] See, e.g., U.S. Department of Interior Office of Inspector General, Report of Investigation: The Endangered Species Act and the Conflict between Science and Policy, Dec. 15, 2008 [hereinafter OIG MacDonald Report].
[11] *See, e.g.*, NAS, FORMALDEHYDE REPORT, *supra* note 2.
[12] See OIG MacDonald Report, supra note 10, at pg. 2 of cover letter.
[13] Interview with EPA Staff, National Center for Environmental Assessment, Office of Research and Development, Feb. 3, 2012.
[14] *Cf.* Jamie Conrad, comments on draft ACUS Outline on Science in the Administrative Process project, Dec. 5, 2011 (raising this concern).

played by policy judgments is in fact central to ensuring the accountability of science-intensive regulations. In addition, clearly explicating how science informed a policy decision advances other institutional and scientific goals, such as making agency decisions accessible to a broad range of stakeholders, providing a bulwark against some of the risks of the politicization of science, and identifying promising areas for future research. A clear description of how the agency used science may even provide the courts with a record that reduces the risk of judicial challenge.

At the risk of giving away the ending, this study ultimately concludes that one of the greatest obstacles to the Executive Branch agencies' efforts to develop a more rigorous decision-making process for incorporating science (e.g., relying on more robust external peer review; providing more transparency in the analytical process; protecting authorship rights) comes from outside the agencies themselves. In several important areas of regulatory decision-making, the agencies enjoy only partial control over their decision-making processes, and their efforts to develop more robust external peer review or more transparent analyses were effectively blocked by constraints placed on their decisions by statute or Executive Branch demands. Thus, while agencies certainly can improve their processes at the margin, some of the most substantial impediments to further improvements in the rigor and transparency of the agencies' use of science must come from outside the agencies.

The study of the agencies' use of science is developed in four sections. The first section provides a brief overview of the basic challenges caused by the frequent conflation of science and policy and discusses how these challenges complicate a study of the agencies' use of science. The second section details the methods used in this study. The third, more detailed and lengthy section then presents the findings; namely the decision-making processes agencies use to integrate science in five separate regulatory settings. In the fourth and final section, these findings are analyzed and this analysis provides the basis for a series of recommendations.

I. Background: The Illusive Line between Science and Policy

Most of the clashes in the use of science for policy arise from the difficulty of determining where the science leaves off and the policymaking begins. There is no clear point of demarcation. Scientists can credibly count many of the judgments and assumptions interlaced in a computational model as "scientific judgments"; yet policymakers can also credibly argue that many of these same choices – which essentially select among plausible options – are better understood as policy judgments that fill in the many gaps that science leaves behind. The line between science and policy is so contested that the battles over it have a name in the social studies of science – "boundary

work."[15] There are multiple, historical accounts, spanning back centuries, over whether scientists on the one hand or religious leaders or politicians on the other should make the important choices needed to fill the cracks in scientific evidence, models, and predictions.[16]

The deeply intertwined roles of science and policy in the development of regulation lie at the core of many of the clashes over the agency's use of science, but this feature also complicates efforts to study science-policy. It is difficult to assess decisions and choices that defy exclusive ties to either science or policy and thus lack a disciplinary home. Before explaining how the methods of this study have been designed to take these challenges into account, this first section offers a brief tutorial on why this line between science and policy is so difficult to pin down.

In the realm of science-policy, scientific information is available to test narrow and discrete hypotheses or collect observations, but to make the evidence useful to policy, extensive extrapolation beyond the study is generally necessary. The analyst must also choose between competing models or analytical tools in making these extrapolations, must identify basic assumptions or defaults in order to make the models run, and encounters considerable uncertainty in the resulting findings. As a result of these and other judgment-laden steps, an analyst encounters a veritable landmine of choices that need to be resolved to bridge existing evidence about, for example, the toxicity of a chemical to its potential effects on an endangered species. Since these choices are not purely scientific and since they often have considerable implications with respect to their public consequences, the choices require input from scientists, policymakers, stakeholders, and the general public.

To make this abstract concept of the intermingling of science and policy more concrete, consider one of the controversies that arose in a regulatory program covered by this study.[17] Currently the U.S. Fish and Wildlife Service (FWS) and the Environmental Protection Agency (EPA) are at loggerheads on how to use the best available scientific evidence to predict the adverse impacts of individual pesticide products on endangered species. The agencies reach very different conclusions from the data about these potential adverse impacts, as illustrated in the text box below. In comparing the agencies' answers to these science-policy questions, consider their very different statutory instructions for assessing risks. The FWS is tasked with preventing the extinction of endangered species, and when a species may be adversely affected by a federal activity, the Endangered Species Act requires the FWS to use the best available

[15] See, e.g., Thomas F. Gieryn, *Boundary-Work and the Demarcation of Science from Non-Science: Strains and Interests in Professional Ideologies of Scientists*, 48 AM. SOC. REV. 781, 782 (1983).
[16] *Id.*
[17] The nature of this controversy is summarized briefly in the agencies' charge to the NAS Committee examining "Ecological risk Assessment under FIFRA and ESA." This Statement of Task is available at http://dels.nas.edu/Study-In-Progress/Ecological-Risk-Assessment-Under-FIFRA/DELS-BEST-11-01.

evidence in a way that gives the endangered species the benefit of the doubt.[18] By contrast, in its regulatory assessment of a pesticide registration, the EPA is required to balance the benefits of a pesticide against its costs to human health and environment.[19] This net balancing produces a much more open-ended framework that does not afford species the benefit of the doubt. Instead, the species' risks are compared against the benefits of the pesticide.

Text Box 1: Comparison of FWS vs. EPA judgments in assessing pesticide risks to endangered species (these differences are inferred from documents and interviews and are illustrative only).[20]

Questions arising in the scientific analysis	FWS's Answers	EPA's Answers
Should a study with methodological problems be excluded from the analysis? (e.g., what is the definition of "best available science"?)	Not if part of the study does not suffer from the methodological problems and the findings of that part of the study suggest risks to endangered species.	Yes. Standard exclusion criteria exclude studies that have methodological flaws that cause the studies to be unreliable.
What types of endpoints[21] should be measured?	Sub-lethal, indirect and cumulative effects on species must be considered.	Only endpoints that can be measured with some precision can be included in the analysis.
How should chemical mixtures be assessed?	The effects of chemical mixtures, as well as inactive ingredients, are critical to an assessment of risks to a species.	There is so much variation in mixtures that they cannot be included in a reliable model.
What types of assumptions should be included in the models?	Liberal spray drift[22] assumptions must be factored into an exposure model.	Reasonable spray drift assumptions should be factored into an exposure

[18] 16 U.S.C. § 1533(b).
[19] EPA must ensure that the pesticide does not present "unreasonable adverse effects on the environment." 7 U.S.C. § 136a(a).
[20] These differences are drawn largely from Statement of Task to the NAS Committee, *supra* note 17; from letters from EPA to NMFS regarding draft biological opinions on various pesticide decisions, see Letters at http://www.epa.gov/espp/litstatus/effects/epa-to-nmfs.pdf (page 3 and 4); http://www.epa.gov/espp/litstatus/11-18-08-nmfs-biop.pdf (page 2); and Interview with FWS Staff, Endangered Species Program, Jan. 26, 2012.
[21] An endpoint is the adverse effect that a researcher measures in a toxicity study. Mortality is one of the most straightforward endpoints. Other endpoints include various measures of neurological effects (e.g., spontaneous locomotion of a mouse in an open field), tumors (e.g., benign and malignant), reproductive and development effects (e.g., brain weights of offspring at birth), etc. The challenge in toxicology is identifying one or more endpoints for a study that can be measured reliably. Behavioral change in animals, for example, is a much more difficult endpoint to measure as compared with mortality.

		model.
How should the species' range be determined?	The species' range should be measured by assuming the most expansive range.	Population models need to adopt reasonable assumptions and require documentation for all assumptions.
How extensively should possibilities of pesticide misuse (beyond the label) be considered?	Pesticide misuse should be factored into the model in all cases.	Pesticide misuse should not be considered unless there is evidence of that misuse.

As the table of disagreements reveals, there are important judgments at each point in the process of assessing pesticide risks to endangered species. At the first step, the agency must determine which of the existing studies inform the regulatory project and which do not. While one might imagine that generic "exclusion/inclusion" criteria could be designed to sort out the available research, even decisions about how to use the literature depends on whether the agency seeks to afford every benefit of the doubt to the species or instead simply to produce a replicable, "mean" answer to a question. Choices also arise in identifying the parameters that will be used in a model. For example, what effects should be considered in predicting adverse impacts (e.g., sub-lethal effects or easily measured mortality) and what pesticides should be included (e.g., the entire chemical mix or one pesticide at a time)? Choices arise again in determining how to account for various scenarios, such as assumptions regarding spray drift, species' range, and even the misuse of pesticides during application. All of these decisions are informed by scientific and technical judgments about plausible options, yet none is resolved by them. While the text box extracts only a handful of these choices, in science-policy work ordinarily done by agencies there are dozens, and according to one classic NAS report, often as many as fifty significant choices that can punctuate any given effort to characterize the risks of a product.[23]

No wonder, given these different statutory directions, that the two agencies' approaches to the scientific literature and related analytical steps are divergent and have been the source of continued technical disagreements and interagency strife.[24] Yet drawing out some of the disagreements – that the agencies have sent to the National Academies for guidance – also illuminates the types of embedded science-policy choices that are commonplace in the agencies' use of science. This illustration also underscores that there is clearly no one size that fits all with respect to either the questions or the

[22] Spray drift refers to how far the pesticide sprays into the environment (and beyond the target) when it is applied. Spray drift is affected by a number of factors, including the contents of the pesticide product, its method of application, and wind speed.
[23] *See, e.g.*, NAS, RISK ASSESSMENT, *supra* note 2, at 29-33.
[24] *See, e.g.*, Interview with FWS Staff, Endangered Species Program, Jan. 26, 2012; Interview with EPA Staff, Office of Pesticide Programs, August 5, 2011.

answers, and thus calls for generic risk assessment guidelines may be misplaced if not mistaken.[25]

II. Methods

These intertwined science-policy choices help to highlight the methodological benefits of focusing on the process by which agencies make science-intensive decisions. Such a process orientation avoids the need to draw lines between "science" or "policy" and focuses the analysis instead on whether the agency's decision process, including the assumptions, framing, and integration of science and policy, is conducted in a way that helps ensure it will be both robust and transparent. Staff papers that identify and interpret the available scientific evidence, or that place that evidence into risk assessment models are not simply "science"; they involve choices made necessary by limits in information. The goal, then, is to develop a process that helps ensure the resulting analysis will state these core assumptions, uncertainties, and framing assumptions clearly and subject them to scientific and public review.

This section first describes in more detail why the decision-making process is a particularly good vehicle for assessing the scientific rigor and transparency of the agencies' use of science. The remainder of the section then outlines the more detailed methods used to examine these processes in this study.

A. Decision Processes as a Diagnostic Tool for Studying the Agencies' Use of Science

Adherence to a basic, well-established process is one of the cornerstones of rigorous science. For example, standard scientific practices insist, at a minimum, that research be rigorously peer reviewed and that the methods be communicated in a way that allows the research to be replicated.[26] Over time, sectors within science, particularly editors of biomedical journals, have also insisted that the underlying data be shared;[27] the

[25] *But see* Nicholas Bagley & Richard L. Revesz, *Centralized Oversight of the Regulatory State*, 106 COLUMBIA L. REV. 1260, 1320-24 (2006) (recommending the centralization of risk assessment guidelines).
[26] *See, e.g.*, HELEN E. LONGINO, SCIENCE AS SOCIAL KNOWLEDGE 80 (1990); Philip Kitcher, *Patterns of Scientific Controversies, in* PETER MACHAMER, MARCELLO PERA, & ARISTIDES BALTAS, EDS., SCIENTIFIC CONTROVERSIES: PHILOSOPHICAL AND HISTORICAL PERSPECTIVES 31-35 (2000) (on methods and theories); AAAS, SCIENCE FOR ALL AMERICANS: A PROJECT 2061 REPORT ON LITERACY GOALS IN SCIENCE, MATHEMATICS, AND TECHNOLOGY 28 (1989).
[27] *See, e.g.*, NATIONAL RESEARCH COUNCIL, NATIONAL ACADEMIES OF SCIENCES, SHARING PUBLICATION-RELATED DATA AND MATERIALS: RESPONSIBILITIES OF AUTHORSHIP IN THE LIFE SCIENCES 4 (2003) (advocating a "uniform principle for sharing integral data and materials expeditiously" or UPSIDE); NATIONAL RESEARCH COUNCIL, NATIONAL ACADEMIES OF SCIENCES, RESPONSIBLE SCIENCE 11 (1992) (noting that scientists "are generally expected to exchange research data as well as unique research materials that are essential to the replication or extension of reported findings"); ROBERT K. MERTON, THE SOCIOLOGY OF SCIENCE (1973, ed. Norman Storer).

researchers' affiliations and biases be openly disclosed;[28] and that authorship be certified to ensure that an author has the right to make all final decisions on a manuscript, which also serves as an endorsement by the scientist that the research findings and statement of methods are correct.[29]

Just as processes and decision-making structures serve as a proxy for ensuring a minimum level of quality and transparency in research science, so they would seem to provide an equally if not more valuable proxy in assessing the agencies' use of science for regulation. When scientific oversight processes within science do not include these bare minimum qualities, scientists generally draw an adverse inference about the quality of the resulting product. Again, these same measures seem to be fairly used to evaluate regulatory science.

Due to differences between research science and regulatory science, the basic design of the study – applying standard scientific conventions regarding ideal decision-processes to the regulatory arena – requires at least one significant adjustment, however. As just described, the agency's use of science involves many more judgments, assumptions, and uncertainties than most basic research, and each of these major choices is likely to affect a range of parties. The agency is thus developing policy at the same time it is attempting to use the available evidence in a robust way. As a result, the agency's decision-making process must ensure not only that the science is used rigorously but also that important choices are exposed in the analysis. Expert peers are not the only important reviewer of agency analyses, and stakeholders and the public must also review this work. As a result, iterative reviews may be needed to draw out all these intertwined, yet very different science and policy choices and decisions.

While a process-based examination of the agencies' use of science sheds light on the extent to which the process itself ensures that these basic principles are given some weight, a study of flow charts and agency processes is not the most direct way to examine the agency's use of science. The National Academies of Sciences (NAS) panels that examine all facets of an agency's scientific work – from the agency's identification and interpretation of the literature through the use of models to its ultimate explication of how it conducted the analysis – for example, will provide both more complete and more robust accounts of the actual quality of the agency's work. Yet the chief strength of these NAS studies – a deep, detailed account of the agency's use of science – is also a limitation, since by their nature the studies can typically only drill down deeply into a few

[28] *See, e.g.*, SHELDON KRIMKSY, SCIENCE IN THE PRIVATE INTEREST 125-40 (2003); C. D. DeAngelis, P. B. Fontanarosa, & A. Flanagin, *Reporting Financial Conflicts of Interest and Relationships between Investigators and Research Sponsors*, 286 JAMA 89 (2001).

[29] For example, the Journal of the American Medical Association (JAMA) requires as a condition to publication that "[f]or all reports (regardless of funding source) containing original data, at least 1 named author (eg, the principal investigator) who is independent of any commercial funder or sponsor must indicate that she or he "had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis." JAMA Instructions for Authors, Data Access and Responsibility, available at http://jama.ama-assn.org/site/misc/ifora.xhtml#DataAccessandResponsibility.

regulatory projects. These substantive studies also generally do not investigate *why* the agency might be missing opportunities for the robust utilization of science in its products; NAS reports focus primarily on ways that the agency's substantive discussions and analyses could be improved.

The tack taken in this study is thus a complement to a detailed substantive study of the agency's science since this study looks at these same regulatory projects from a process perspective. The NAS report highlights ways that the agency's report could be better, but there is little to no attention given to the actual flow chart or process by which science is incorporated by the agency. Indeed, this feature is generally bracketed. Examining the actual processes themselves, then, hopefully illuminates process or related features that may be causing repeat problems in agency work products. Until fixed, these process problems may stand as an impediment to the agencies' ability to increase the rigor and transparency of regulatory science.

In focusing exclusively on agency decision-making processes, this study necessarily ignores other, equally important factors that inevitably impact the quality, and transparency of the agency's use of science. The focus on decision-making process thus illuminates some important features of the agency's use of science at the expense of eclipsing or even obscuring other features. This is an analytical hazard that seems unavoidable, at least to the extent that the study does not provide a reconnaissance inventory of potential problems and issues.[30] Indeed, even with respect to examining only this one specific feature – agency decision-making processes – the study must bracket several process features that could ultimately alter its conclusions. Two of these features deserve mention because they are particularly critical to the analysis. First, it is assumed that when external peer review is done, it is done in a way that is both competent and fairly neutral. Potential problems with the selection and use of reviewers, for example, are not explored in this study but left for another day.[31] It is also assumed that an agency's scientific staff is much like the scientific staff one might find in academic or other research settings in terms of competence, expertise, and ethical commitments to do excellent work. In this study, these two important features of the analysis were not investigated in any detail.[32] Indeed, if the staff is not sufficient or the peer review selection is badly biased, the best response is to repair them since both are fundamental to so much of the work that the agency does.

[30] The Regulation Advisory Committee recommended a narrower study as opposed to reconnaissance research.

[31] *See infra* Section IV.C. (recommending this topic for further study).

[32] It may be helpful to note that at least with respect to the competency and strength of the agencies' scientific and technical staff, the interviewees and documentary evidence was generally favorable with regard to the quality of the agency's scientific work. Thus at least the evidence collected here did not undermine the assumption nor given an evidence that the ethics and competence of agency scientific work is relatively strong.

B. Methods

Given the vastness of the science-based regulatory universe, the study required substantial narrowing to keep it to a manageable size. This entailed several consecutive "cuts" or screening steps. These screening decisions and related methodological choices are explained below.

1. Identifying the Types of Science-based Regulatory Projects most in need of Study

The first step in the screening process was to identify which part of the universe of science-based regulation to examine. Many and perhaps the majority of agency decisions involve some type of scientific or factual information that counts as scientific, but given the breadth and variation in this universe of science-based regulatory projects, further focus is necessary.

This study examines only those agency decisions that require mastery of a large body of scientific literature (natural sciences and engineering) as applied to a particular policy question. Identifying and interpreting the diverse studies, applying them through models to reach predictions, and then explaining the limitations of these processes and what they imply for policy are all critical features of the regulatory projects selected here for in-depth study. By contrast, the study does not examine regulatory work that involves much more limited use of scientific or technical information – such as the use of medical information in entitlement hearings or the use of engineering data in transportation decisions. The study also does not examine the agencies' use of social science.

2. Which Agencies

The second screening step involved identifying which agencies and processes to examine within this still very large set of possible science-intensive regulatory programs. Because so little is known about agency decision-making structures, an examination of diverse approaches among the agencies was expected to yield more insights than an examination of a single set of regulations within one agency. To that end, three agencies were selected for study that engage in very different types of science-based decision-making projects.

The three agencies occupy different points within a larger matrix of agency science-based regulation. The first agency – the EPA – generally develops regulations that protect the public health and environment from pollution and dangerous products. A great deal of the science that informs EPA's work comes from toxicology, epidemiology, and ecological sciences. Because EPA covers a broader range of issues than other science-intensive agencies like the Food and Drug Administrative, it was selected as the best candidate for studying agency processes in the general area of environmental and

public health protection.[33] The second agency – the Fish and Wildlife Service (FWS) of the Department of the Interior – protects certain natural resources, including endangered species. The sciences the FWS utilizes for its science-intensive regulation is more heavily based in taxonomy, animal behavior, ecology, and related environmental studies. The FWS, perhaps more than other natural resource agencies, has come under political fire repeatedly over the last few decades, particularly with respect to its endangered species decisions. Because of this more intense scrutiny, the FWS was selected as the agency that would provide a particularly useful window into the decision processes used by natural resource agencies (as contrasted to health and environmental protection agencies like EPA) to incorporate science into publicly important decisions. The third agency – the Nuclear Regulatory Commission (NRC) – develops requirements for nuclear safety, including licensing nuclear reactors. Its formal and informal rulemakings rely on radiation sciences, but also often involve issues that are informed by complex engineering and operational sciences. The NRC is an independent agency, which provides a valuable point of contrast with the other two agencies, particularly with respect to Office of Management and Budget (OMB) review.

Although these three agencies engage in quite different types of science-based regulatory work, it is surely the case that they do not represent the waterfront of agency approaches to science, nor may they even offer windows into what are likely to be the worst practices or possibly even the best practices among the agencies (although the latter seems less likely as discussed below).[34] As such, then, this first foray into agency decision-making processes represents only the tip of the iceberg in terms of identifying regulatory features worthy of study and selecting the most varied and interesting processes within the agencies for investigation.

3. Which Programs

Because individual programs within a single agency can sometimes vary dramatically, the third step involved choosing specific programs within each agency to examine in greater detail. In the case of EPA, in particular, the agency's decision-making processes vary considerably from one regulatory program to another, although there are some common themes that run through the programs. Regulatory programs were selected within EPA that represent some of this variation. The first program selected for study is EPA's regular review of the six national air quality criteria pollutant standards

[33] The Food and Drug Administration (FDA) was actually one of the agencies originally slated for investigation in this Study. In part because the nature of FDA's regulatory work parallels that of the EPA and in part because the scope of this Study was already substantial, FDA was ultimately dropped from the Study. At the point that FDA was dropped, Wagner had already conducted one set of interviews and collected a small stack of documents on the agency's decision-making. Thus if the FDA becomes a focus in further research, there is an initial set of research materials available on the agency.

[34] In the analysis section, the larger literature that bears on agency science and decision-making processes is integrated with this more grounded research to provide additional perspective on the extent to which the regulatory programs under study are wholly unique or relatively typical of other regulatory areas.

(NAAQS), which are conducted through large, informal rulemakings. This NAAQS program is renowned for its scientific quality and also for the extraordinary size of the literature that informs EPA's review. A second EPA program – the review of registrations for conventional pesticides – involves a much higher regulatory throughput (1000 chemicals as opposed to standards for six pollutants) and is conducted as a licensing decision. The nature of the scientific analyses is more uncertain and the data is much thinner as compared with the NAAQS reviews. The third EPA program selected for study – the EPA's integrated risk assessment system (IRIS) – produces "safe" values for exposure to toxic substances, but the assessments are informational only; these assessments are not required by statute and are not judicially reviewable. As a scientific matter, the analyses are simpler than pesticide registration reviews, since they do not involve exposure estimates, but the available literature is generally even more incomplete than is the case even for pesticide registration reviews; thus scenarios and uncertainties are many and complicated and permeate these risk assessments. These EPA programs also offer an in-depth view of science-based decisions at three different points in the administrative process spectrum (i.e., informal rules; licensing decisions; and nonbinding risk assessments) and vary with respect to the nature of the available evidence and the type of analytical models needed to reach a decision.

FWS conducts a wide range of science-based regulatory projects, but because it uses a relatively truncated approach for incorporating science into policy, it does not appear that, as compared with EPA, there is nearly as much variation from program to program in the decision-making steps that the FWS follows. In any event, due to an effort to keep the study to a manageable size, only one program was examined in the Fish and Wildlife Service that appears relatively representative – the listing of endangered species and the designation of critical habitat. These particular decisions are heavily informed by scientific analyses of the species and their need for survival, but the latter decisions on critical habitat must also be informed by economic and related considerations. FWS's decisions on listing and habitat designations are also published as informal rulemakings, and this more standard type of regulatory output should allow for easier comparisons to other agency informal rules.

Finally, the NRC, an independent agency, conducts a wide range of informal rulemakings (e.g., to establish requirements governing nuclear waste and nuclear safety) and licensing decisions. Like the FWS and perhaps even more so, NRC does not appear to have sharp differences in its approach to the incorporation of science from one type of program or regulatory decision to the next, as is the case with EPA. Thus the decision-making processes at NRC seem largely generalizable on an agency-wide level. It is assumed that NRC's informal rulemakings may be the most useful feature to study to allow for a comparison with other agencies' work, but given the importance of licensing decisions at NRC, some attention is also given to these decisions.

4. What Factors

To ensure the various regulatory programs were consistently evaluated, several key principles were identified to frame the analysis. The principles emerged by melding the practical realities of regulatory science with established scientific norms and goals, such as skepticism and disinterestedness. A discussion of each of these principles follows:

1. Transparency: In using science, agencies should explain their use of the existing evidence in as robust a way as practicable. This includes detailing the literature consulted; explaining how or why they weighted or excluded a study bearing on a policy question; how the use of different assumptions and models might alter conclusions; areas of uncertainty that limit the evidence; and what the policy questions were and how the framing of the questions themselves affected the integration of scientific evidence for the issue at hand.[35] This transparency makes it possible for others to evaluate and replicate the analysis and is thus critical to the rigorous use of science.

2. Disinterestedness: Agencies should, where-ever possible, attempt to conduct their initial analysis of the scientific literature and evidence bearing on a policy question without being influenced by a preferred policy outcome.[36] While the complete separation of science from policy is not possible, a rigorous and candid explication of how the existing evidence intersects with the policy question(s) will help separate the analysis from the decision-making.[37] Ideally, this is accomplished by a first step that provides a statement of the general policy questions and an analysis of the evidence and alternative applications of that evidence to a decision, including a robust statement of uncertainties, in relation to those questions. A second step then selects the best policy choice from the resulting options. While this approach does not exactly map against the "findings of facts" and "conclusions of law" bifurcation used in trial courts, the basic idea is that a vigorous and robust airing of the facts, including uncertainties and their implications, provides a clearer record against which subsequent policy considerations can then be judged.[38]

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[35] *See supra* note 26 (citing sources); *see also infra* note 435 and accompanying text (identifying these same principles in President Obama's Memorandum on Scientific Integrity).
[36] *See, e.g.*, SHELDON KRIMKSY, SCIENCE IN THE PRIVATE INTEREST 125-40 (2003).
[37] *See, e.g.*, Bipartisan Policy Center, *supra* note 3, at 15 (2009) (recommending that "[t]he Administration needs to devise regulatory processes that, in as many siutations as possible, could help clarify for both officials and the general public which aspects fo disputes are truly about scientific results and which concern policy").
[38] *Id*. (recommending that "the Administration should require that a section of the Federal Register notie for any proposed guidance or rule that is informed by scientific studies describe the primary scientific questions and the primary policy questions that needed to be answered in drafting the rule").

3. Skepticism: Skepticism from a diverse set of experts is vital to robust science and also improves the transparency of the analysis.[39] There are at least two features necessary to develop this vigorous skepticism

a. Peer (expert) review or related oversight. Agencies conducting science-based decisions should insist on a rigorous expert review of their scientific analyses.[40] This expert skepticism should be applied first and foremost to the judgments embedded in the agency's scientific analysis and in the agency's explication of its assumptions. This can be done through a range of techniques that include periodic audits of technical analyses; routine intra-agency review processes; or the solicitation of expert peer reviewers that can provide input individually or through a Federal Advisory Committee Act (FACA) panel.

b. Internal debate and dissent. There should also be constant vigilance against the tendency to devolve into a "group think" mentality, which can stem from a number of diverse, but reinforcing forces within the agency including: 1) career staff scientists who work together over years or decades and seek to maintain a united front against outside criticism; 2) a perception that a management-held position should prevail when at all possible; and 3) direct intervention from supervisors or strong-willed colleagues. To protect against these risks, individual scientists should have a right to dissent, which can range from removing their name from authored reports to lodging formal dissents on decisions within the agencies.

4. Use of Stopping Rules: Science-based dialog, if done in keeping with the norms of science, has no clear stopping point. Science is continually evolving and, in theory, policy should be constantly evolving with it. This creates the need for artificial and explicit deadlines, usually based on policy, for completing the analysis associated with any given decision (referred to as "stopping rules" throughout the paper). Stopping rules thus identify the point at which the scientific record will be closed and disagreements and debates bracketed and reserved for a later day for purposes of a decision, since these scientific questions will never be resolved completely.[41] While stopping rules can be amended, decision theory suggests that it is best that they be established in advance of a process, with an opportunity to make exceptions later.[42]

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[39] Longino, *Science as Social Knowledge, supra* note 26, at 80.
[40] *See supra* note 26.
[41] *See generally* Sheila Jasanoff, *Transparency in Public Science: Purposes, Reasons, Limits*, 69 LAW AND CONTEMPORARY PROBLEMS, Summer 2006, at 22, 37-39 (introducing the concept of stopping rules to the science and law literature).
[42] For a discussion of setting stopping rules ex ante in decision theory, see WARD EDWARDS, ET AL., DECISION SCIENCE AND TECHNOLOGY: REFLECTIONS ON THE CONTRIBUTIONS OF WARD EDWARDS 86 (James Shanteau, Barbara Mellers & David Schum eds. 1999) (describing "simple stopping rules" in decision theory that specify computationally simple conditions for halting the gathering of more information). For a discussion about their ex ante use in regulatory science with regard to identifying a point at when clinical trials can be stopped because adequate information has been collected, see Nigel Stallard, et al., *Stopping rules for phase II studies*, 51 BRITISH J. OF CLINICAL PHARMACOLOGY 523 (2001).

5. Setting the Policy Choices against the Evidence: Those making the ultimate policy decision should be challenged on their use of science, and the decision-maker should explain his/her science-policy choices against the scientific record. This provides a mechanism for "policy" transparency. Rather than simply dropping out studies or invisibly changing assumptions or the algorithms of complex computational models, the decision-maker must be forced to explicate both technical and policy decisions and explain why they were reached.

6. Utilitarian considerations: These ideals or goals for scientific transparency must be balanced against other goals and principles. Resources, time, or other features may simply not justify an agency's ability to ensure that all five principles for scientific transparency enumerated above are met in a given decision-making process.

The programs varied, sometimes considerably, in their commitment to these principles. These differences are discussed in detail in the analysis section.

5. Sources of information about the Agency Decision-making Processes

Agency documents and interviews provided the primary source of information about the agencies' decision-making processes. Agency documents ranged from publicly available emails to short summaries of decision processes posted on the internet to lengthy decision documents. Interviews were conducted primarily by phone and typically with top managers within the agency; more than thirty current and former agency officials and staff at EPA, FWS, the Department of Interior (DOI), NRC, the Office of Management and Budget (OMB), the Office of Science and Technology Policy (OSTP), and the National Academies of Science (NAS) were interviewed over a seven month period.[43] This information was supplemented by over a dozen interviews with various stakeholders;[44] a search of a few individual rules to provide samples of the agency's work; and surveying Governmental Accountability Office (GAO) reports, Inspector General reports, and congressional oversight hearings. While an attempt was made to document every important process step with written records to the extent possible, for some features of agency processes, agency interviews provided the only source of information on how science is integrated into the decision-making process. This "non-transparent" feature of the agencies' decision-making process is taken up again in the analysis and recommendations section.

[43] Several academics who have worked with or researched the agencies' use of science were also interviewed.

[44] The organizations interviewed generally, although not always, have PhD scientists on staff who are deeply involved in oversight of the agency's science-based decisions. The stakeholders interviewed from the public interest community included staff from: Beyond Nuclear; Environmental Defense; the Natural Resources Defense Council, PEER, Pesticide Research Institute, and the Union of Concerned Scientists. Stakeholders interviewed from industry included: the American Chemistry Council, and the Center for Regulatory Effectiveness, and Exponent.

As noted, the basic study design focuses on discrete programs within three agencies. This narrow focus makes it difficult to generalize beyond the specific programs under study. To work around this practical limitation, the analysis and recommendations identify general themes that run through many or most of the programs and suggest best practices that operate presumptively and can be rebutted when circumstances make them impracticable or otherwise ill-advised. When there is supporting evidence in the literature that a problem may be occurring more widely within the government, this information is also included in the analysis.

III. Findings

This section, which details the findings, is divided into two parts. The first part provides a detailed discussion of the decision-making approaches or flow charts used in the five regulatory programs under study. These descriptions identify comparable features of the processes used across agencies, as well as key differences.

The second part focuses more specifically on the agencies' scientific integrity policies used to protect the autonomy of scientific staff. These policies also attempt to encourage internal skepticism within the agency and provide mechanisms for internal dissent on science-intensive analyses and decisions. Because these scientific integrity programs are implemented agency-wide, they were investigated at the Departmental level. For example, rather than examine specific regulatory programs within EPA, the entire agency was studied holistically. Similarly, overall Department of Interior policies were studied rather than those specific to the Fish and Wildlife Service.

Together the two parts provide a relatively complete picture of how the agencies incorporate science into policy, at least for the regulatory programs selected for study.

A. The Incorporation of Science into Specific Regulatory Programs

1. The Environmental Protection Agency (EPA)

a. The Review of National Ambient Air Quality Standards (NAAQS)

The findings begin with a particularly detailed examination of the NAAQS review process because it presents the equivalent of a five-star process for incorporating science into regulatory policy. Indeed, the extraordinarily elaborate, five year NAAQS review process appears unprecedented, and it is difficult to imagine any other regulatory setting where such an extravagant science-policy process may be necessary. On the other hand, precisely because the NAAQS decision-making process is so exemplary, it offers numerous lessons for simpler, low-budget agency processes with respect to developing a rigorous analytical approach to science-policy.

The initial section on the NAAQS process concludes with a discussion of some of its most innovative features. This discussion spotlights features that then inform the analysis of other agency programs.

The Law of NAAQS

Under Section 109 of the Clean Air Act, EPA is required to revise at regular, five-year intervals the standards for six criteria or general pollutants that EPA has identified under Section 108 of the Act.[45] Section 109 of the Clean Air Act not only sets specific deadlines for EPA's staggered review of the criteria pollutant standards, but it also provides several substantive and procedural constraints on that decision-making process.[46] First, Congress required that a NAAQS standard be set at a level that is "requisite to protect the public health" with "an adequate margin of safety."[47] The Supreme Court has confirmed that this mandate allows EPA to consider only scientific and not economic factors in setting the primary health standards for these criteria pollutants.[48] Second, Congress required that EPA's analyses and recommendations for the revision of each air quality standard be reviewed by a seven-member expert panel that "includ[es] at least one member of the National Academies of Sciences, one physician, and one person representing State air pollution control agencies."[49] In response, EPA created the Clean Air Science Advisory Committee (CASAC), a standing committee chartered under the Federal Advisory Committee Act (FACA), which plays an important role in the EPA's NAAQS review process. Finally, EPA's revisions of the NAAQS must undergo a public notice and comment period.[50]

In the forty years that have followed passage of the Clean Air Act, EPA's implementation of its NAAQS reviews has evolved over time. The scientific analyses in these reviews have grown from short, relatively simple assessments to encyclopedic assessments that even experts sometimes label as impenetrable.[51]

EPA's challenges in conducting NAAQS reviews are made still more daunting because the literature that EPA must consider during a revision period is substantial. A

[45] 42 U.S.C. § 7409(d)(1). This review process of National Ambient Air Quality Standards (NAAQS) is mandatory, and EPA has been sued numerous times for missing its deadline. *See, e.g.,* Comm. for a Better Env't v. U.S. E.P.A., No. C 07-03678 JSW, 2008 WL 1994898, at *1 (N.D. Cal. May 5, 2008) (bringing suit to compel the EPA to perform its past due, mandatory review duties). Indeed, EPA's review and reform of the NAAQS process in 2006, discussed below, was triggered by a realization that EPA was growing only further and further behind in meeting its statutory deadline and was at risk of becoming in perpetual contempt of court. Interview with EPA Staff, National Center for Environmental Assessment, Office of Research and Development, Jan. 18, 2012.
[46] 42 U.S.C. § 7409(d)(1).
[47] *Id.* at § 7409(b)(1).
[48] *Id.* at § 7409(b)(1); *see* Whitman v. American Trucking Associations, Inc., 531 U.S. 457 (2001).
[49] *Id.* at § 7409(d)(2)(A)-(B).
[50] *Id.* at § 7409(b)(1), *referencing* (a)(1)(A).
[51] EPA, Review of the Process for Setting National Ambient Air Quality Standards, March 2006, Review at E-1, available *at* http://www.epa.gov/ttnnaaqs/pdfs/naaqs_process_report_march2006.pdf.

single NAAQS review can involve the analysis of thousands of studies.[52] As a result of this highly complex and involved analysis, EPA has experimented over the decades with different techniques for explicating its judgments as well as for managing the huge and growing scientific literature. Although it has not been easy, EPA appears to have finally developed a transparent process that produces analyses that are accessible to expert onlookers and that manages successfully to bridge science and policy in ways that appear worthy of replication.

Steps in the NAAQS Revision Process

To gain control over the sprawling NAAQS process and bring its NAAQS reviews back on schedule and limit future litigation, Administrator Johnson under President George W. Bush empaneled a "top-to-bottom review" of the NAAQS process in 2006.[53] The EPA staff recommendations from that initiative have now been largely implemented,[54]as illustrated in the figure below.[55]

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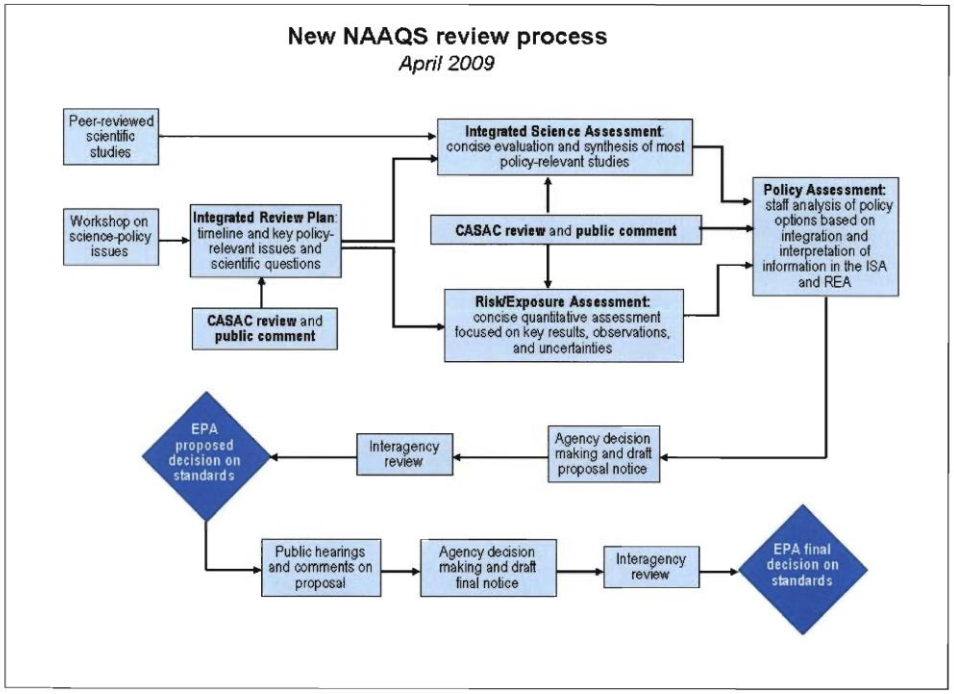
[52] Interview with EPA Staff, Office of Air and Radiation, July 26, 2011; Interview with EPA Staff, Office of Air Quality Planning and Standards, Jan. 17, 2012; Interview with EPA Staff, National Center for Environmental Assessment, Office of Research and Development, Jan. 18, 2012.

[53] EPA, Review of the Process for Setting National Ambient Air Quality Standards, March 2006, at E-1 [hereinafter EPA, NAAQS Review], available at http://www.epa.gov/ttnnaaqs/pdfs/naaqs_process_report_march2006.pdf. Although the primary impetus for this review was concern about the ability of EPA to meet its statutory (and judicial) deadlines, two of the four priorities were to improve the transparency of EPA's use of science, particularly in relation to policy. Specifically, among the four key charges, the team was asked to determine ways to clarify the distinctions between science and policy judgments and to identify and characterize uncertainties in scientific information. *See* Memo from George Gray and William Wehrum to Marcus Peacock, April 3, 2006, at page 1 (memo available at http://www.epa.gov/ttnnaaqs/pdfs/naaqs_process_report_march2006_cover.pdf); *see also* EPA, NAAQS Review, *supra*, at Appendix 2 (setting out more elaborate bullet points on the priorities for the review team) (appendices available at http://www.epa.gov/ttnnaaqs/pdfs/naaqs_process_report_march2006_attachments.pdf).

[54] EPA's own documentation of this process is somewhat patchy. For its public overview, see EPA, Process of Reviewing the National Ambient Air Quality Standards, last updated on August 25, 2011, available at http://www.epa.gov/ttnnaaqs/review.html. Beyond this general statement, the next best sources to understand EPA's process is the review report (which obviously was prepared prior to implementation), *see* EPA, NAAQS Review, *supra* note 53, and by accessing EPA's individual reports prepared after the 2006 review. (For particulates, for example, see EPA, Particulate Matter (PM) Standards, last updated on November 8, 2011, available at http://www.epa.gov/ttnnaaqs/standards/pm/s_pm_index.html. After the 2006 review, Administrator Jackson made some additional adjustments to implementation of the NAAQS process; the most significant change is discussed at the end of this Section and concerns authorship of the staff policy assessment. *See* Process for Reviewing National Ambient Air Quality Standards memorandum from Lisa Jackson to Elizabeth Craig and Lek Kadeli, May 21, 2009, available at http://www.epa.gov/ttnnaaqs/pdfs/NAAQSReviewProcessMemo52109.pdf.

[55] Excerpted from *id*. at 3.



As this flow chart shows, the current NAAQS decision-making process involves four separate staff-authored reports, each of which each constitutes a distinct stage in the process. This flowchart is a simplified representation of the process; the steps in the process are described in greater detail below (in some cases providing additional sub-steps not included in the flowchart). Cumulatively these reports evaluate the scientific evidence to determine whether a revised standard is needed. A discussion of each stage follows.

1. The Planning Report (Integrated Review Plan)

The first stage – the development of a planning report - begins with a "kick-off" workshop that solicits comments from the public and scientific community (including invited scientists) about developments in the science and policy that should frame EPA's review.[56] The workshop focuses specifically on scientific discoveries and related

[56] *See* EPA, Generic NAAQS Review Process, March 2007, available at http://www.epa.gov/ttnnaaqs/pdfs/peacock_4_17_07_attachment2.pdf.

developments occurring over the past five years that might suggest the need for a revised standard and hence deserve careful scientific review.

After the workshop, the EPA staff from the Office of Research Development (ORD) and the Air Office prepares an integrated review plan. The primary purpose of this planning document is to frame "key policy-relevant issues that would generally be used to frame the science assessment, risk/exposure assessment, and policy assessment." The report also sets a timetable for completing subsequent stages of the process.[57]

The planning report is integral to enhancing transparency of the NAAQS review.[58] By framing the relevant science-policy questions, the planning report provides a focus for the remaining four years of EPA's analysis.[59]

2. Integrated Scientific Assessment Report

At the next step of the NAAQS review, EPA compiles an integrated scientific assessment (ISA) of the existing scientific literature. This is effectively a review of all of the scientific evidence bearing on the discrete policy questions identified in the Planning Report.[60]

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[57] EPA, NAAQS Review, *supra* note 53, at 24.

[58] *Id*. The planning report is thus not a trivial step in the process; EPA allocates almost a year to its finalization and the planning reports alone are substantial in length – the particulates planning document was eighty-five pages in length, for example. A draft planning report is reviewed internally and then by CASAC and the public. Based on this feedback, EPA revises the planning document. For a sample planning document, see EPA, Integrated Review Plan for the National Ambient Air Quality Standards for Particulate Matter, March 2008, available at http://www.epa.gov/ttnnaaqs/standards/pm/data/2008_03_final_integrated_review_plan.pdf. See in particular pages 18-21 of *id* (stating policy-relevant questions for primary PM NAAQS that expand on the excerpts provided above in the text).

[59] It is hoped that "[i]n discussing policy-relevant issues, this plan could help clarify appropriate distinctions between science and policy judgments and/or elaborate on important concepts and terms that have both science and policy components." *Id*. Examples of policy-relevant questions identified by EPA for its particulate matter NAAQS process are:

- Has new information altered conclusions from previous reviews regarding the plausibility of adverse health effects associated with exposures to $PM_{2.5}$, PM_{10}, $PM_{10-2.5}$, or alternative PM indicators that might be considered?
- What evidence is available from recent studies focused on specific size fractions, chemical components, sources, or environments (e.g., urban and non-urban areas) of PM to inform our understanding of the nature of PM exposures that are linked to various health outcomes?
- To what extent is key scientific evidence becoming available to improve our understanding of the health effects associated with various time periods of PM exposures, including not only short-term (daily or multi-day) and chronic (months to years) exposures, but also peak PM exposures (less than 24-hour)?

Id. at 18-19.

[60] In stark contrast to EPA's earlier version of this assessment in previous NAAQS processes (i.e., the infamous "criteria document" that collapsed several of these now-separate reports into a single document and was renowned for its encyclopedic qualities), the new and improved integrated scientific assessment is

Generally, academics are contracted to draft the individual chapters of the integrated scientific assessment, with multiple points of review (at least three) from intra-agency reviewers, CASAC and the public before the ISA is considered final.[61] While the resulting ISAs are hailed as vastly more focused and concise than their predecessor (criteria) documents, they still are quite long and technical. In at least some cases these reports are more than 1000 pages in length, not counting the appendices.[62]

3. Risk/Exposure Assessment Report

Based on its analysis of the scientific evidence in the ISA, the EPA staff then prepares a separate risk assessment report that uses this evidence to predict the effects of alternate standards on public health. While these risk assessments are constrained by the available air quality data and concentration-response data, the goal at this stage of the process is to employ multiple models to produce quantitative risk estimates, accompanied by expressions of the underlying uncertainties and variability, for various endpoints, such as the impacts of a pollutant on susceptible populations and ecosystems.[63] The risk assessment process itself begins with a planning/scoping stage, which again involves CASAC review and public comment, followed by two more periods of intra-agency, CASAC, and public comment on the draft risk assessment reports.[64]

4. Policy Assessment Report

The last document in the process is a policy assessment that "bridges" these more science-intensive (ISA and risk assessment) reports to the policy questions at hand. The policy assessment is, in and of itself, an extensive document (in the EPA's review of the particulate matter standard, the policy assessment was over 450 pages in length, including appendices), but the discussion is written for nonscientists who do not have an extensive background in the relevant science.[65]

In this final staff report, the scientific literature is summarized in a way that relates to the overarching policy questions. The report then offers alternative health protection scenarios (and standards) that are supported by the evidence and risk

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more concise and focuses the assessment on the specific questions framed in the planning report. More detailed information is reserved for annexes, which can sometimes be longer than the body of the report.

[61] For a flowchart for production of the scientific assessment, see Figure 4.1 in EPA, Integrated Review Plan for the National Ambient Air Quality Standards for Particulate Matter, March 2008, at 25, available at http://www.epa.gov/ttnnaaqs/standards/pm/data/2008_03_final_integrated_review_plan.pdf.

[62] See, e.g., EPA, Integrated Science Assessment for Particulate Matter, Final Report Dec. 2009, available at http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=216546.

[63] *See, e.g.*, EPA, Planning report for Integrated Assessment, *supra* note 61, at 41 (describing this goal of the risk assessment).

[64] *See, e.g., id*. at 54.

[65] For a sample of a policy assessment, see EPA, Policy Assessment for the Review of the Particulate Matter National Ambient Air Quality Standards, April 2011, available at http://www.epa.gov/ttnnaaqs/standards/pm/data/20110419pmpafinal.pdf.

assessments. The policy analysis also provides a discussion of remaining questions and key uncertainties and identifies priorities for further data collection.[66]

The policy assessment is reviewed by internal EPA staff and by CASAC, sometimes several times, to ensure it is faithful to the scientific assessments and that important scientific information is not lost in translation.[67] It is worth noting that even at this late stage, CASAC review and comment is rigorous and extensive. For example, the second CASAC review of EPA's policy assessment for the review of particulate NAAQS consists of over 70 pages of single-spaced comments.[68]

5. Inter-agency Review

After completing this extensive analytical work-up, EPA officials select a proposed standard and write a proposed rule. The agency's proposed rule then goes to OMB. During this process EPA meets with OMB and other agencies and receives written comments on its proposal.

According to EPA staff, all of these communications are protected by the deliberative process privilege and are not made public.[69] The idea behind this exception to the Freedom of Information Act (FOIA) is to allow the free and uninhibited exchange of ideas and positions within government.[70] Thus, by its terms, deliberative process is a discretionary claim and is used only when the government can establish that it is in the government's interest to claim the privilege.[71] Over the last two decades, there have been shifts in the executive policies governing its use. Most recently, President Obama rejected President George W. Bush's policy of favoring the privilege and there appears to be a general presumption within the current Administration to release government

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[66] See Appendix C for an excerpt from a policy assessment report.

[67] For a very brief summary of CASAC input, see *id.* at 2-100 through 2-101 (summarizing CASAC advice).

[68] For the second CASAC review of EPA's policy assessment for particulates, see Letter from Dr. Jonathan M. Samet, Chair, CASAC, to Lisa P. Jackson, September 10, 2010, available at http://yosemite.epa.gov/sab/sabproduct.nsf/CCF9F4C0500C500F8525779D0073C593/$File/EPA-CASAC-10-015-unsigned.pdf.

[69] Interview with EPA Staff, Office of Air Quality Planning and Standards, Jan. 17, 2012.

[70] Although it was initially a common law creation, the deliberative process privilege is most commonly invoked as an exemption to FOIA, which allows an agency to withhold "inter-agency or intra-agency memorandums or letter which would not be available by law to a party other than an agency in litigation with the agency." 5 U.S.C. § 552(b)(5); *see generally* Shilpa Narayan, *Proper Assertion of the Deliberative Process Privilege: The Agency Head Requirement*, 77 FORDHAM L. REV. 1183 (2009) (describing the history and developing of the deliberative process privilege over time).

[71] The burden is on the government in this regard. As the Supreme Court has stated, FOIA's "basic policy of full agency disclosure unless information is exempted under clearly delineated statutory language, indeed focuses on the citizens' right to be informed about what their government is up to. Official information that sheds light on an agency's performance of its statutory duties falls squarely within that statutory purpose." U.S. Dept. of Defense v. Fed. Labor Relations Authority, 510 U.S. 487, 495-96 (1994). Indeed, the courts will require release of withheld deliberative documents if they find that the public benefits to disclosure outweigh the harm to the government. U.S. v. AT&T, 86 F.R.D. 603, 609 (D.D.C. 1979).

documents where possible.[72] Nevertheless, OMB currently appears to apply the deliberative process exemption to all of its interagency review processes.[73]

Since the NAAQS review rules are economically significantly, OMB uses its authority under Executive Order 12866 to hold the rule until it is satisfied with the package.[74] In the course of this largely nontransparent review, OMB not only offers comments and suggestions on the EPA's rule, but it determines the point at which a proposed or final rule responds adequately to all of the comments.

As a result of this interagency review process, the proposed rule ultimately published in the Federal Register may change and could even change significantly from the draft proposed rule drafted by EPA. Several EPA staff members suggested that some of these changes have impacted the characterization of the science in the proposed rule.[75] While theoretically the changes resulting from the deliberative process can be identified by comparing the EPA's draft proposed rule (which is placed in the docket) with the final proposed rule published in the Federal Register, such an analysis would provide little insight into why changes were made.[76]

6. The Final Rulemaking Process

EPA staff report that, after the notice and comment period has concluded, OMB can again influence how EPA responds to comments and alter the shape of the final rule, drawing on its authority under Executive Order 12866.[77] Staff report that these interactions with OMB are also protected by the deliberative process privilege.[78]

Other characteristics of the NAAQS Process

Beyond these basic steps to EPA's NAAQS decision-making process, there are other features of EPA's NAAQS process that deserve mention. These features bear on both the rigor and transparency of EPA's use of science in setting the NAAQS standards.

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[72] See President Obama, Memorandum for the Heads of Executive Departments and Agencies, Subject: Freedom of Information Act (Jan. 21, 2009); see also Narayan, *supra* note 69.

[73] Nina Mendelson, *Disclosing "Political" Oversight of Agency Decision Making*, 108 MICH. L. REV. 1128, 1157 (2010) (finding no reference to OMB review, even though it occurred and changes were made as a result); see also Stephanie Tatham, unpublished paper on OMB's Assertion of the Deliberative Process Privilege in Science-based Rulemakings (on file with author) (discussing OMB's extensive use of deliberative process privilege and finding that over 90% of OMB's denial of FOIA claims invoked this exemption); *see also infra* notes 513-514and accompanying text.

[74] Interview with EPA Staff, Office of Air Quality Planning and Standards, Jan. 17, 2012; Interview with EPA Staff, National Center for Environmental Assessment, Office of Research and Development, Jan. 18, 2012.

[75] *Id.*

[76] Interview with EPA Staff, Office of Air Quality Planning and Standards, Jan. 17, 2012.

[77] Interview with EPA Staff, Office of Air Quality Planning and Standards, Jan. 17, 2012; Interview with EPA Staff, National Center for Environmental Assessment, Office of Research and Development, Jan. 18, 2012.

[78] *Id.*

1. Attribution and authorship

One important feature of the NAAQS process is EPA's reliance on staff to author the analytical reports that inform its process. Specifically, teams of EPA staff produce the four reports that lead up to the proposed rule for a revised NAAQS.[79] While EPA management is briefed through "information sessions" on the contents of these reports, there is no editing of the report by management. (EPA staff could, however, point only to tradition and not to any rule that explicitly precludes this type of editing.)[80] Indeed, at least some of the draft NAAQS reports contain the disclaimer that the "findings, opinions, conclusions or recommendations" reflect those of the authors and do not necessarily represent the views of EPA.[81]

The team of staff authors is also listed by name in the acknowledgment section of the final report. This detailed acknowledgement section links each EPA staff to his/her specific contributions to individual chapters. It is not clear whether an agency staff member has the right to remove his/her name from this acknowledgement section if he/she disagrees with the final version of the chapter (presumably the issue has not yet arisen), but if a staff member can in fact withdraw his/her name from the report, then these acknowledgements provide an indicia of authorship.

2. Availability of the Supporting Literature

EPA is highly committed to making the literature upon which it relies publicly accessible. In the revisions to its NAAQS process in 2006, EPA developed an elaborate database (Health and Environmental Research Online or HERO) to make the scientific research used in the NAAQS reviews accessible. Peer reviewers can access the entire version of each of the tens of thousands of referenced studies used in NAAQS reviews through this database, including copyrighted publications.[82] The public can access at least summaries of these documents, as well as the full citations.[83] Providing this type of fingertip access to the enormous library of research that supports the NAAQS allows for

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[79] Interview with EPA Staff, Office of Air Quality Planning and Standards, Jan. 17, 2012.
[80] Interview with EPA Staff, National Center for Environmental Assessment, Office of Research and Development, Jan. 18, 2012.
[81] *See, e.g.*, EPA, Draft Policy Assessment for Particulate Matter, September 2009, available at http://www.epa.gov/ttn/naaqs/standards/pm/data/PreliminaryDraftPA091609.pdf. Note in this document that the names of individual staff are not listed, however. This is different from the final report which includes a detailed acknowledgement section that lists staff and reviewers by name and identifies their specific contributions to the report.
[82] Interview with EPA Staff, National Center for Environmental Assessment, Office of Research and Development, Jan. 18, 2012.
[83] See the Health and Environmental Research Online (HERO) Database, last updated on February 8, 2012, available at http://hero.epa.gov/.

more rigorous review of EPA's scientific work by those inside the agency, CASAC, and stakeholders.[84]

Summary and General Observations

The process that EPA has developed over the last forty years to review the standards for the NAAQS appears to be highly regarded.[85] As one interviewee stated, "It is a process that delivers a credible standard."[86] Another EPA staff remarked that, based on the current design, "I don't know how we could be more transparent." "In a general sense, the process serves the agency well."[87] The NAAQS process was also touted as a model of scientific transparency in a recent National Academy of Science report that suggested it should be adapted to other EPA programs.[88]

There are several features of the revised NAAQS process that offer useful insights to other agencies working to incorporate science into their decisions in a rigorous and transparent way. The first and perhaps most significant innovation is EPA's decision to break out the component parts of its analyses into separate steps (or in the case of NAAQS, actual reports) that can be reviewed on their own terms.[89] As just explained, there is a planning document that identifies the policy-relevant questions; an assessment of the available evidence in the ISA; an application of the evidence in the risk assessment; and a translation of the evidence and models, and their limitations, in the policy assessment.

A second, innovative feature of the NAAQS process is the iterative involvement of the CASAC, which is itself a prominent science advisory body.[90] In multiple, detailed reviews of each of the four EPA reports, CASAC scrutinizes the assumptions and alternate characterizations of the relevant scientific information. This provides rigorous external review of the agency's use of science.[91] CASAC also plays an important role in

[84] Interview with EPA Staff, National Center for Environmental Assessment, Office of Research and Development, Jan. 18, 2012.
[85] See also Interview with Staff of American Chemistry Council, July 29, 2011.
[86] Interview with EPA Staff, Office of Air and Radiation, July 26, 2011.
[87] Interview with EPA Staff, Office of Air Quality Planning and Standards, Jan. 17, 2012.
[88] *See* NAS, FORMALDEHYDE REPORT, *supra* note 2, at 120-121.
[89] See EPA, NAAQS Review, *supra* note 53, at 22 (see figure)
[90] Of all the science advisory bodies at EPA, CASAC seems to have consistently received the highest marks in terms of its balance, leadership, and quality of its work in the science-policy literature. *See, e.g.*, SHEILA JASANOFF, THE FIFTH BRANCH: SCIENCE ADVISERS AS POLICYMAKERS (1990) (discussing virtues of CASAC in a chapter-length case study); MARK R. POWELL, SCIENCE AT EPA: INFORMATION IN THE REGULATORY PROCESS 43 (1999) (reporting on how persons interviewed for the study on science at EPA 'gave SAB and CASAC credit for improving EPA's acquisition and use of science'); U.S. Envtl. Protection Agency, Safeguarding the Future: Credible Science, Credible Decisions 38 (1992) (noting positive effect of CASAC on EPA's decisions).
[91] CASAC, last updated on February 8, 2012, available at http://yosemite.epa.gov/sab/sabpeople.nsf/WebCommittees/CASAC.

determining when a revised report has adequately responded to comments, as elaborated below.[92]

Third, the NAAQS process is developed in a way that offers multiple opportunities (at least seven) for public comment. In such a process, there seems to be less chance of group think or tunnel vision emerging in EPA's assessment of the evidence. Because of these elaborate outreach efforts, EPA presumably also encounters few surprises during notice and comment on the proposed rule, at least to the extent that the proposed rule follows from the staff reports. From the standpoint of stakeholders, the iterative comment process on individualized stages of EPA's analysis would seem to make the commenters' work more manageable and focused.

Fourth, EPA has instituted the equivalent of "stopping rules"[93] that allow it to put an end to debate and close the record with regard to new scientific discoveries.[94] CASAC historically acted as the referee on when debate could effectively close by declaring an EPA report essentially ready for finalization after specific changes were made.[95] While this "closure" role was criticized by some EPA staff members and temporarily suspended, in recent reviews with EPA staff it appears that CASAC continues to identify when it believes that a report is nearly complete and can be finalized.[96] CASAC's ability to determine a convenient point for closing the record, or to set "stopping rules," is taken up again in the analysis section. EPA also has stopping rules for emerging science. If a new study emerges that is relevant to NAAQS, but it is not available until after the draft ISA has been peer reviewed, EPA will not consider it until the next NAAQS review five years later.[97]

Fifth, the current NAAQS reports provide attribution to named staff through a detailed acknowledgements section. While these staff are not listed as authors as is done on scientific publications, the acknowledgement section identifies their specific contributions to the report and, presumably if staff members disagree with the contents of the report they can ask that they not be acknowledged. There was a sense among agency

[92] Interview with EPA Staff, Office of Air Quality Planning and Standards, Jan. 17, 2012.
[93] For a discussion of "stopping rules" see *supra* notes 41-42 and accompanying text.
[94] Interview with EPA Staff, Office of Air Quality Planning and Standards, Jan. 17, 2012. Specifically, EPA will consider new studies up until the first ISA is revised by CASAC. After that point, all new evidence will be bracketed and reserved for the next five year NAAQS review. *Id.*
[95] *Id.*
[96] Cf. CASAC Draft Letter to EPA regarding Second Draft of ISA for Ozone, 2/8/12, at 1, available at http://yosemite.epa.gov/sab/sabproduct.nsf/264cb1227d55e02c85257402007446a4/FC9FAB17E2B06D4D8525799E0069EF5B/$File/draft+ozone+SERD+ISA+letter-020812.pdf (recommending that EPA prepare a revised draft of the ISA and submit it to CASAC for a third review opportunity).
[97] In cases of new scientific discoveries, EPA sometimes does prepare a "provisional science" report near the end of the NAAQS review that considers whether certain new and emerging science would have materially altered its analysis or conclusions. In cases where EPA has done this additional provisional science report, it has consistently concluded that the new science would not materially alter its assessment. One EPA staff scientist suggested that this is because the supporting studies are so numerous that additional research is unlikely to significantly alter the assessment's conclusions. Interview with EPA Staff, Office of Air Quality Planning and Standards, Jan. 17, 2012.

interviewees that it would make little sense *not* to acknowledge authorship. Doing so is believed to result in more robust and scientifically credible reports and to provide scientific staff with deserved credit for their work.[98]

Sixth and finally, the NAAQS process experimented with management or agency-authored reports (that are not prepared by staff), and the agency concluded from the experiment that staff-authored reports provided much more robust, nuanced, and complete statements of the scientific information as it informs policy. The use of staff to prepare all the foundational assessments is thus a deliberate feature of the design of the NAAQS decisionmaking process. Specifically, when for a short period of time responsibility for authorship of the policy assessment was shifted from EPA staff to management and published as an Advanced Notice of Proposed Rulemaking,[99] the first management-OMB-drafted policy assessment was harshly criticized by both EPA's Office of Research Development and by CASAC.[100] CASAC in particular noted that this policy assessment departed from and arguably ignored scientific recommendations of CASAC; did not connect the options suggested to the scientific literature; and presented options as equally plausible, despite their very different scientific underpinnings.[101] In response to this controversy, Administrator Jackson ultimately returned responsibility of the policy assessment to the staff.[102] Employees and CASAC report a high level of satisfaction with the change.[103]

In sum, there are a number of features of the NAAQS process that appear both innovative and promising for science-policy analysis.[104] While extrapolating from this expensive,[105] time-consuming,[106] and science-intensive NAAQS process to more mundane science-based regulatory projects is difficult, the process still appears to serve

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[98] Interview with EPA Staff, National Center for Environmental Assessment, Office of Research and Development, Jan. 18, 2012; Interview with EPA Staff, Office of Air Quality Planning and Standards, Jan. 17, 2012.

[99] Since the assessment was published as an Advanced Notice of Proposed Rulemaking, it required OMB-clearance.

[100] Interview with EPA Staff, Office of Air Quality Planning and Standards, Jan. 17, 2012.

[101] *See* Letter from Dr. Rogene Henderson, Chair of CASAC to Administrator Johnson, Jan. 22, 2008, at 1 (condemning the ANPR for lead prepared by EPA management as "unsuitable and inadequate" because it "does not provide the underlying scientific justification for the range of options for standard-setting that the agency is currently considering" and providing substantial details in the remainder of the letter regarding these concerns).

[102] *See* Jackson memorandum, May 21, 2009, *supra* note 54.

[103] Interview with EPA Staff, National Center for Environmental Assessment, Office of Research and Development, Jan. 18, 2012; Interview with EPA Staff, Office of Air Quality Planning and Standards, Jan. 17, 2012.

[104] Interestingly, none of these features of the NAAQS process was mentioned by the NAS panel in touting it as a model for IRIS assessments. *See* NAS, FORMALDEHYDE REPORT, *supra* note 2.

[105] Although cost estimates are not available, the staff suggested that the NAAQS revision process is likely quite expensive. Interview with EPA Staff, Office of Air Quality Planning and Standards, Jan. 17, 2012.

[106] Interview with EPA Staff, Office of Air Quality Planning and Standards, Jan. 17, 2012; Interview with EPA Staff, National Center for Environmental Assessment, Office of Research and Development, Jan. 18, 2012.

as a useful model for at least identifying the key steps necessary for the development of rigorous and transparent science-based regulation.

b. The Review of Conventional Pesticide Registrations

Much like the NAAQS standard-setting process, the review of existing, conventional pesticide registrations has undergone a major revision in the wake of the 1996 amendments to the Food Quality Protection Act.[107] Since its authorizing statute now requires EPA to review over 1000 pesticides every fifteen years,[108] the process EPA has employed to incorporate science into the revision process offers a useful point of comparison with the EPA's review of the NAAQS. To meet its deadline, the agency has set a goal of completing a review of approximately 60–70 pesticide products a year, as opposed to the review of about one NAAQS standard over the same time frame. The statutory mandate is also more open-ended and gives the agency discretion to consider both scientific and economic factors when making its decisions. Specifically, EPA may register a pesticide if the EPA is satisfied that the pesticide "will not generally cause unreasonable adverse effects on the environment."[109]

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[107] After a series of fits and starts, for more than two decades, EPA struggled to review and re-register "grandfathered" pesticides that had been on the market at the time the Federal Insecticide and Fungicide Act (FIFRA) was passed in 1972. The delays and unequal treatment of these old pesticides as compared to new pesticides not only sparked harsh criticism of EPA's pesticide program, but it prompted a series of congressional amendments intended to rectify the delay. Congress now requires EPA to review all the registrations (or licenses) of existing pesticides on the market every fifteen years. Specifically, amendments to FIFRA in 1996 require EPA to develop "a procedure for accomplishing the periodic review of registrations" and to ensure that "pesticide's registration [is reviewed] every 15 years." Section 3(g) of FIFRA, 7 U.S.C. § 136a(g). This statutorily mandated time frame is intended to ensure that pesticide registrations will not fall too far behind scientific and technological developments and that EPA provides all marketed pesticides with a rigorous review.

[108] EPA, "Registration Review Highlights", available at http://www.epa.gov/oppsrrd1/registration_review/highlights.htm. Specifically, EPA is reviewing the registrations of all pesticides registered at the time the law was passed, in August 1996. *See* EPA, "Agrichemicals: Food Quality Protection Act – Pesticide Reviews," www.epa.gov/agriculture/factsheets/epa-305-f-00-006ag.html. This requires EPA to review more than 50 chemicals a year in order to stay on schedule to complete the reregistration of 1100 pesticides by 2022. Interview with EPA Staff, Office of Pesticide Programs, August 5, 2011. *See also* EPA, "Accomplishments under the Food Quality Protection Act," http://www.epa.gov/pesticides/regulating/laws/fqpa/fqpa_accomplishments.htm.

[109] 7 U.S.C. § 136a(c)(5)(D). The pesticide must also satisfy several other statutory conditions, but they are not relevant to this Study. These additional requirements are that a) "its composition is such as to warrant the proposed claims for it"; b) "its labeling and other material . . . comply with the requirements of this subchapter"; and c) "it will perform its intended function without unreasonable adverse effects on the environment." *Id.*

Congress provided EPA with several additional tools to assist it in this science-based decision-making. First, EPA has the authority to require manufacturers to conduct additional testing needed to evaluate a pesticide registration (termed "call-in" authority). *Id.* at § 136a(c)(2)(b). In the data call, EPA can require manufacturers to submit (or, if necessary conduct) studies on a variety of effects, such as toxicological and ecological effects. *See, e.g.*, EPA Staff Background Paper #3.1, TRAC 5/27/98, available at www.epa.gov/oppfead1/trac/dci.htm. Second, EPA may solicit expert scientific advice from EPA's standing Science Advisory Panel (SAP), established under 25(d) of FIFRA and chartered under FACA.

Despite the very different workload, EPA's incorporation of science into its review of pesticide registrations tracks the NAAQS process in several important ways. First, like in NAAQS, EPA's pesticide office usually develops a series of separate reports – a planning report, a risk assessment report, and a proposed decision – for each pesticide reviewed. EPA also solicits public comment on each of these three documents. Finally, like NAAQS, EPA's analytical process stretches over five or six years for each pesticide.[110] In contrast to the NAAQS process, however, EPA does not engage external peer reviewers for individual pesticide registrations except in highly unusual cases.

The Steps to the Review of Pesticide Registrations

There are four steps to EPA's registration review process for each pesticide, three of these steps involve the preparation of a staff report that is subjected to notice and comment.

1. The Planning or Summary Document. This document describes the existing literature that bears on the pesticide under study and solicits additional information on it.[111] The

(For the 2006 charter of the SAP, see http://www.epa.gov/scipoly/sap/pubs/charter.pdf.) The SAP is statutorily required to review notices of intent to cancel or reclassify pesticide regulations, as well as other specifically identified regulations, but the Panel can also be used by EPA to evaluate other aspects of its decision-making, including difficult registration review decisions.

[110] Five or six years does not seem to be an unusually long time for the development of technically complicated informal rule at EPA. IRIS assessments, as described Section III.A.1.a. *infra*, can take a decade to finalize. MACT standards, which are technology-based emissions standards for air toxics promulgated for various individuals sectors of industry, take about 5 and half years, on average, to promulgate as final rules. *See* Wendy Wagner, Katherine Barnes, and Lisa Peters, *Rulemaking in the Shade: An Empirical Study of EPA's Air Toxic Emission Standards*, 63 ADMINISTRATIVE LAW REVIEW 99, 144-45 (2011). And of course at other agencies the informal rulemaking process for science-intensive regulations can stretch still longer. At OSHA, workplace standards are promulgated very slowly, if at all and appear to stretch over years or even decades. *See* OSHA Website, "History of Health Standards and Need to Revise PELs," available at http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=PREAMBLES&p_id=768 (conceding that "OSHA has issued only 24 substance-specific health regulations since its creation [in 1970]. It has not been able to review the many thousands of currently unregulated chemicals in the workplace or to keep up with reviewing the several thousand new chemicals introduced since its creation"). While there is no clear point for comparison at NRC, even the renewal of the license of a nuclear plant stretches to nearly two years per license. *See* OIG, Audit of NRC's License Renewal Program, Sept. 6, 2007, at 4. This offers a stark point of comparison with the FWS's very short deadlines for listing and habitat designation, discussed Section III.A.2, *infra*.

[111] This document is the rough equivalent of the planning document described above for NAAQS. In contrast to the NAAQS planning document, the precise questions in need of public input are not always identified explicitly or in an accessible way, although in some cases, the proposed work plan provides very specific questions for the subsequent scientific analysis. *See, e.g.*, EPA, Summary Report for Butylate, June 2009, downloadable at http://www.epa.gov/oppsrrd1/registration_review/butylate/index.html. EPA also provides a detailed fact sheet that summarizes the existing information available on the pesticide in the Summary Document. Although not all of these summary documents include complete citations or accessible links, they provide a basic overview of the information within the agency's files that is relevant to the pesticide review. For example, for Acephate, EPA's summary report does not always contain citations to the literature. There does not appear to be a link to all the underlying studies either. See EPA, Summary Report for Acepthate, available at at http://www.regulations.gov/#!documentDetail;D=EPA-HQ-

Summary Document also identifies in specific terms the data EPA needs to complete its assessment.[112]

2. The Data Call-in. EPA regulations establish the test protocols and risk assessment models it will use to evaluate each pesticide registration.[113] Since it is not uncommon for some of the information needed to complete these assessments to be missing, EPA issues a "data call-in" to the manufacturers that requires them to conduct this additional testing to fill the gaps.[114]

3. The Risk Assessment. Once the additional data has been submitted by the manufacturers, the EPA pesticide team conducts a risk analysis to assess the risks of the pesticides through various exposure pathways, from drinking water to worker exposure to food. The guidelines and models used for these assessment have been peer reviewed by

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OPP-2008-0915-0003;oldLink=false. Stakeholders did not seem to feel handicapped by the inaccessibility of the studies, even studies done by manufacturers that are not available. Interview with Pesticide Research Institute (a public interest organization), Aug. 1, 2011. This may be attributed in part to limited time and resources to review the studies, however. Finally, the work plan includes a timeline for the review.

[112] For a general description of the Summary Report see EPA's overview of the re-registration steps at http://www.epa.gov/oppsrrd1/registration_review/reg_review_process.htm. After soliciting public comment on the draft Summary Document, EPA prepares a final version of the Summary document or, in some cases, simply prepares a short addendum that summarizes the comments and EPA's responses. The final Summary document is posted in a pesticide's electronic file and serves as the work plan that guides the registration review process for a pesticide.

[113] For a web-based list of the test protocols, go to http://www.epa.gov/pesticides/science/guidelines.htm; for pesticide models, go to http://www.epa.gov/pesticides/science/models_db.htm.

[114] It appears from a cursory review of recent Summary Documents and staff interviews that the need for some data call-ins in the course of a registration review decision is not unusual, and may be the norm. Interview with EPA Staff, Office of Pesticide Programs, August 5, 2011. EPA's data call-ins require OMB clearance before they can be issued since they are considered "information collection requirements" under the Paperwork Reduction Act, 44 U.S.C. § 3501 et seq. While this OMB clearance can involve considerable transaction costs between EPA and OMB (for example, OMB currently reviews each individual data call-in before allowing it to be sent), EPA reports that to date the agency has succeeded in gaining authorization to request all of the data they deem necessary to conduct their risk assessment. Interview with EPA Staff, Office of Pesticide Programs, Jan. 27, 2012. Since OMB currently has decided it must review the call-ins individually, the process of working through the Paperwork Reduction Act with OMB can add as much as six months delay to the registration review and can involve considerable staff resources, however. *Id*. After a data call-in is issued, there is occasionally a second process of negotiation with the manufacturer with respect to satisfying the call-in demands. These settlements are similar to those occurring in civil enforcement cases. Rather than taking a manufacturer to court for noncompliance with a data call-in, EPA will agree to a somewhat different submission provided it generally meets EPA's data needs. *Id*.

Limited lab space and a variety of other factors constrain the manufacturers' ability to produce all of the requested data in a timely fashion. Manufacturers may also identify existing studies that appear to resolve some or even all of EPA's data needs. Interview with EPA Staff, Office of Pesticide Programs, Jan. 27, 2012. EPA may alter its call-in request based on these discussions, while ensuring that all basic data needs are satisfied. The resulting changes between what EPA initially requested in a call-in and what it ultimately received is detailed in the draft Risk Assessment. For a sample, see Appendix A.1. of the EPA, Chlorpyrifos Preliminary Human Health Risk Assessment for Registration, available at regulations.gov (document ID number: EPA-HQ-OPP-2008-0850-0025); Interview with EPA Staff, Office of Pesticide Programs, Jan. 27, 2012.

the Science Advisory Panel (SAP) or an equivalent peer review body (e.g., the NAS).[115] The draft risk assessment, prepared by staff, is again subject to public notice and comment, and in some cases may be subjected to multiple public comment periods.[116] The risk assessments can also be quite lengthy – 1200 or more pages in some cases - although the length of the assessment may vary considerably depending on the pesticide being reviewed.[117]

4. Proposed Decision on Registration. The pesticide team uses the risk assessment to draft a proposed decision with regard to registration of the pesticide.[118] The proposed decision summarizes the scientific evidence, EPA's assessment of the evidence, and provides a proposal for re-registration, which could involve changes to the label; the legally approved uses; partial or complete cancellation; or full registration of the pesticide.[119] This proposed decision is also subject to notice and comment. OMB is not

[115] Interview with EPA Staff, Office of Pesticide Programs, Jan. 27, 2012.

[116] For a sample, see, e.g., multiple references to various risk assessments in Readers Guide for Methyl Bromide, June 3, 2009, Docket EPA-HQ-OPP-2005-0123, available at regulations.gov; see also comments filed on multiple drafts of the assessment by industry association, the American Chemistry Council, at http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPP-2005-0123-0444.

[117] The EPA team follows the NAS Silver Book in conducting their risk assessments, which includes following NAS's recommendations for explicating uncertainty factors, assumptions and other important judgments. Interview with EPA Staff, Office of Pesticide Programs, August 5, 2011. In a recent draft risk assessment for Chlorpyrifos, for example, EPA provides a frank discussion of data needs, changes in information over ten years, uncertainty factors, and other assumptions in the first 10 pages of the risk assessment. Chlorpyrifos Preliminary Human Health Risk Assessment, *supra* note 114, at pages 2-16. It is not clear whether this type of accessible explication is unique in the agency's pesticide assessments, yet the format and approach in this sample risk assessment has the flavor of the NAAQS staff policy and planning reports with regard to more explicit and frank admissions of limitations in the available science.

[118] For some pesticide reviews, it is not necessary to conduct a new risk assessment (e.g., if a pesticide is withdrawn), in which case the staff skips the risk assessment step and moves straight to the proposed decision. Interview with EPA Staff, Office of Pesticide Programs, Jan. 27, 2012.

[119] This proposed decision is again subject to notice and comment. The format of the proposed decisions generally provides a discussion of the available information and then offers EPA's proposed decision based on that information. *See, e.g.*, outline in EPA, "Bromine Final Registration Decision," at http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPP-2009-0167-0010;oldLink=false. Unlike the NAAQS policy assessment report, however, the proposed decision does not include a section that bridges the scientific evidence with the overarching policy questions; instead the most important judgments and assumptions would seem accessible only to experts. *See, e.g., id.* (providing a sample of this technical quality of the assessments). EPA staff opined that the agency perhaps could do better in providing clearer discussions of its exclusion/inclusion criteria, uncertainties, and other technical discussions in this proposed decision, but they believe that much of these risk-related explications are provided in a clear format in the earlier, risk assessment document. Interview with EPA Staff, Office of Pesticide Programs, Jan. 27, 2012. Moreover, it would be costly for the agency to do this more elaborate discussion. Interview with EPA Staff, Office of General Counsel, Jan. 13, 2012. The staff also reiterated that pesticide assessments are much more complicated than most other risk assessments. In contrast to the NAAQS, for example, there are multiple endpoints in pesticide assessments, which include assessment workplace risks, bystander risks, risks on food, risks in drinking water, and a host of environmental impacts, including on plants, mammals, birds, fish, and endangered species. Human exposures, moreover, occur by ingestion, inhalation, and dermal exposure. Providing an accessible explanation of the estimates for all of these endpoints, with an explication of the accompanying uncertainties and assumptions, would be extremely costly and time-consuming. *Id.*

involved in reviewing these proposed rules, presumably because they are licensing decisions.

5. The Final Decision. EPA ultimately issues a final decision based on the additional information it receives through notice and comment. This final rule is signed by the EPA director of the pesticide registration review program (a career staff position), although in more complex or controversial cases, high levels of management, including the Administrator, may be briefed on the decision.[120] Like the proposed rule, the final rule does not require interagency clearance or OMB review.

Other Characteristics of Pesticide Registration Review

As with the NAAQS process, there are other features of pesticide registration reviews that deserve mention with respect to the integration of science into the decision.

1. Authorship

Much like the NAAQS process, a multidisciplinary team of EPA staff works together on all phases of the registration process, and authorship rights are afforded to these staff with respect to their analyses. Specifically, staff members are listed by name in the front matter of each of the pesticide registration reports.[121] Because EPA staff members serve as authors, they both gain credit and bear responsibility for the quality of the analysis presented in the document.[122]

While these documents are subjected to some intra-agency review before they are shared with the public, they are not subjected to management-initiated edits or revisions without the staff authors' assent.[123] EPA's approach to authorship in pesticide reviews thus seems to parallel the NAAQS process with respect to producing reports in a team or consensus-based fashion.[124]

2. Accessibility of the Literature

Also like the NAAQS process, EPA endeavors to provide a comprehensive bibliography of all the literature it relied upon in its draft risk assessment.[125] While the literature cannot be accessed through an internet database, as is the case with the HERO

[120] Interview with EPA Staff, Office of Pesticide Programs, Jan. 27, 2012.
[121] *See, e.g.*, Chlorpyrifos Preliminary Human Health Risk Assessment, *supra* note 114, at 1.
[122] Interview with EPA Staff, Office of Pesticide Programs, Jan. 27, 2012.
[123] *Id.*
[124] In contrast to NAAQS, in which the proposed and final rules are reviewed and potentially revised by management, the proposed and final decisions for pesticide review decisions are subject to a highly delegated decision making structure. The director of the conventional pesticide unit is the final signatory of all registration decisions. *Id.* Higher level management of EPA is not in the line of command and their assent is not necessary for pesticide approval.
[125] *See* Chlorpyrifos Preliminary Human Health Risk Assessment, *supra* note 114, at 102-110.

database used in NAAQS, EPA provides complete citations where possible.[126] EPA also prepares web pages for each pesticide[127] and a "readers' guide" to the docket to walk the reader through the various key decisions and stages of the registration review process.[128]

EPA does not make the manufacturers' data and studies publicly available in the course of its registration reviews because of a requirement in the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (Section 10(g)) that effectively precludes general public access to the data to ensure that the data are not released to pesticide manufacturers in other countries.[129] To gain access to this information, a person must certify that he/she does "not seek access to the data for purposes of delivering it or offering it for sale to any such business or entity or its agents or employees and will not purposefully deliver or negligently cause the data to be delivered to such business or entity or its agents or employees."[130] FIFRA also requires EPA to keep a record of the "names of persons to whom data are disclosed" and must "inform the applicant or registrant of the names and affiliations of such persons."[131] Most problematic, the information cannot be accessed until after a registration decision.[132] Because it is classified information under FIFRA, the data must also be viewed in EPA offices.[133]

In an effort to provide maximum transparency of this manufacturer data in spite of the restrictions of Section 10(g), EPA does post summary tables of each of these manufacturer-produced studies. It also employs teams of EPA scientists to ensure that the studies are done well.[134] These summary tables provide outsiders with at least some window into the nature of the scientific information supporting a decision.

3. External Peer Review

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[126] *See, e.g., id.*

[127] See http://www.epa.gov/oppsrrd1/registration_review/chlorpyrifos/index.htm for information on this pesticide, including the summary document and all other reports and decisions.

[128] *See, e.g.*, Readers Guide for Acephate, March 18, 2009, docket number EPA-HQ-OPP-2008-0915-0002, available on regulations.gov.

[129] 7 USC § 136h(g)(1).

[130] Interview with EPA Staff, Office of Pesticide Programs, Jan. 27, 2012. The person seeking access must certify that they are not an "employee or agency of any business or other entity engaged in the production, sale or distribution of pesticides in countries other than the U.S. . .". *Id.* Although this certification appears light for most persons, there is evidence that EPA may be denying FOIA requests for this information. A propublica investigation revealed that EPA denied 38 FOIA claims seeking this information from 2008-2009. Obviously further investigation is needed regarding the nature of these claims before it can be determined whether there is a relatively substantial impediment to accessing this information. *See* Jennifer LaFleur, FOIA Eyes Only: How Buried Statutes are Keeping Information Secret, available at http://www.propublica.org/article/foia-exemptions-sunshine-law. For the specific investigation under 136h(g), go to http://projects.propublica.org/foia-exemptions/statutes/113.

[131] 7 U.S.C. § 136h(g)(2).

[132] 7 U.S.C. § 136a(c)(2)(A).

[133] *Id*. at § 136h(g)(2).

[134] Interview with EPA Staff, Office of General Counsel, Jan. 13, 2012.

EPA does not routinely seek external peer review of its individual pesticide registration decisions or supporting risk assessments.[135] Instead, the opportunity for multiple points of public input, coupled with the interdisciplinary teams and intra-agency review processes, are believed to be sufficient to provide rigorous oversight of the agency's scientific assessments and analyses.[136]

EPA does consult its standing Science Advisory Panel (SAP) for particularly difficult scientific questions or for particularly difficult registration cases, such as was the case with atrazine.[137] The SAP also reviews all models and methods used by EPA in its pesticide reviews; in fact, this appears to be the primary source of external oversight over EPA's pesticide registration decisions.[138]

4. Inter-agency Coordination

The role of other federal agencies in pesticide decisions is different from the NAAQS in several ways. First, and as a point of sharpest contrast, OMB's involvement in pesticide registration reviews is limited exclusively to its data call-in oversight under the Paperwork Reduction Act. OMB is not involved in reviewing proposed decisions for registration, even in high level cases.[139] Also in contrast to NAAQS, USDA takes considerable interest in the review of at least certain pesticide registrations and is likely to be an active participant in these cases.[140] USDA occasionally files comments on pesticide registration reports and proposed decisions during notice and comment, although EPA staff report that USDA's involvement can also involve phone calls that are not recorded in the record.[141] Finally, because pesticides potentially affect endangered species, EPA must formally consult with the authorized agencies (National Marine Fishery Service and the U.S. Fish and Wildlife Service) if there is a possibility that a pesticide may adversely affect endangered or threatened species.[142] This consultation

[135] Interview with EPA Staff, Office of General Counsel, Jan. 13, 2012. When asked whether additional external review would be beneficial to EPA's process, one staffer vigorously defended the existing approach. Interview with EPA Staff, Office of General Counsel, Jan. 13, 2012. The staffer argued that to assemble peer review panels for each of the 1000 pesticide reviews would be very costly and would not have benefits that outweigh the costs of the panels, not to mention the potential added delays. *Id*. Panelists with the greatest knowledge are often conflicted out of serving, and more general reviewers may lack the needed familiarity with the research (much unpublished and provided by the manufacturer) to provide a robust review unless they actually reviewed all of the studies themselves. *Id*.
[136] Interview with EPA Staff, Office of General Counsel, Jan. 13, 2012.
[137] Interview with EPA Staff, Office of General Counsel, Jan. 13, 2012. One fact sheet suggests that EPA has consulted the SAP 58 times over the last ten years. EPA, "Accomplishments under the Food Quality Protect Act, Aug. 3, 2006," available at http://www.epa.gov/pesticides/regulating/laws/fqpa/fqpa_accomplishments.htm
[138] Interview with EPA Staff, Office of Pesticide Programs, August 5, 2011.
[139] Interview with EPA Staff, Office of Pesticide Programs, August 5, 2011.
[140] *Id.*; Interview with EPA Staff, Office of Pesticide Programs, August 5, 2011.
[141] Interview with EPA Staff, Office of General Counsel, Jan. 13, 2012.
[142] 16 U.S.C. § 1536.

step has been fraught with difficulty and delay and has sparked lawsuits and congressional oversight hearings.[143]

5. Transparency

Stakeholders were generally satisfied with the transparency of EPA's pesticide assessments.[144] Despite their praise for the transparency of EPA's reports, stakeholders still identified numerous contestable points in EPA's analyses. These disagreements with EPA often focused on one of the following: EPA's use of models (e.g., EPA ignored factors that should have been considered and included, such as temperature, wind speed, etc.); EPA's use of uncertainty factors (e.g., the agency erroneously considered some data and used it to adjust the uncertainty factors in contestable ways); or EPA's explanation of the results of studies (e.g., it misrepresented incident reports). These issues are considered again in more detail in the analysis section.

c. EPA's Integrated Risk Information System (IRIS)

The Integrated Risk Information System (IRIS) is a database of human health risk assessments that calculates "safe" doses for inhalation and ingestion for human exposure to hundreds of chemicals.[145] The assessments are not binding regulations, yet they can be

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[143] A review of the correspondence to date between FWS and EPA on individual pesticide decisions reveals credible and difficult technical disagreements over critical judgments that should be used in making these assessments. *See supra* notes 17-24 and accompanying text. For example, FWS questions the viability of models used by EPA to estimate risks to endangered species or to calculate their ranges, see Memo from Marjorie Nelson, FWS to EPA, 2/11/2008, available at http://www.epa.gov/oppfead1/endanger/litstatus/effects/atrazine/2008/fws-nonconcur.pdf, and EPA questions the basis for various conclusions in the Biological Opinion about adverse effects resulting from the use of pesticide products. *See, e.g.*, Memo from Stephen Bradbury, EPA, to NMFS, 8/16/2010, available at http://www.epa.gov/oppfead1/endanger/litstatus/effects/final-biop-ltr.pdf and Memo from Stephen Bradbury, EPA, to NMFS, 6/14/2011, available at http://www.epa.gov/oppfead1/endanger/litstatus/nmfs-draft-4-1comment.pdf. Some progress has been made in bridging these different risk assessment approaches. In at least one set of pesticide reviews, EPA adjusted its registration requirements in accord with these agencies' biological opinions. See Memo from Richard Keigwin, EPA, to NMFS, 7/10/2009 at http://www.epa.gov/oppfead1/endanger/litstatus/11-18-08-nmfs-biop.pdf. Additionally, the agencies collectively sent the NAS a set of questions regarding their differences. The National Academies, "Statement of Task: Ecological Risk Assessment under FIFRA and ESA," available at http://dels.nas.edu/resources/static-assets/best/miscellaneous/DELS-BEST-11-01-statement-of-task.pdf. There is some hope that the Academy can offer illumination that will begin to expedite future ESA consultations under FIFRA.

[144] They indicated that they were generally able to trace EPA's use of the available literature, understand the assumptions it was making, and could recreate the agency's analysis. In this regard, one industry stakeholder noted that "you can generally figure out how EPA used the science and got from one point to another." Interview with Staff of Exponent, an industry consulting group, Dec. 20, 2011. The public interest stakeholders generally agreed. For example, one public interest scientist said: "If you are a toxicologist, you can generally understand what EPA did with the science." Interview with Pesticide Research Institute (a public interest organization), Aug. 1, 2011.

[145] EPA, "Integrated Risk Information System: What is IRIS," available at http://www.epa.gov/IRIS/help_ques.htm#whatiris.

and are used by EPA and other federal and state governments to support regulation. For example, IRIS is used to assess residual risk in the air toxics program.[146] There is no statutory mandate under which EPA prepares these assessments, and thus there are effectively no mandated time frames or procedural or substantive directions on how the assessments should be conducted. At the same time, there is a great deal of interest in these risk assessments from a wide range of stakeholders because of their use in various regulatory contexts.

Background of IRIS

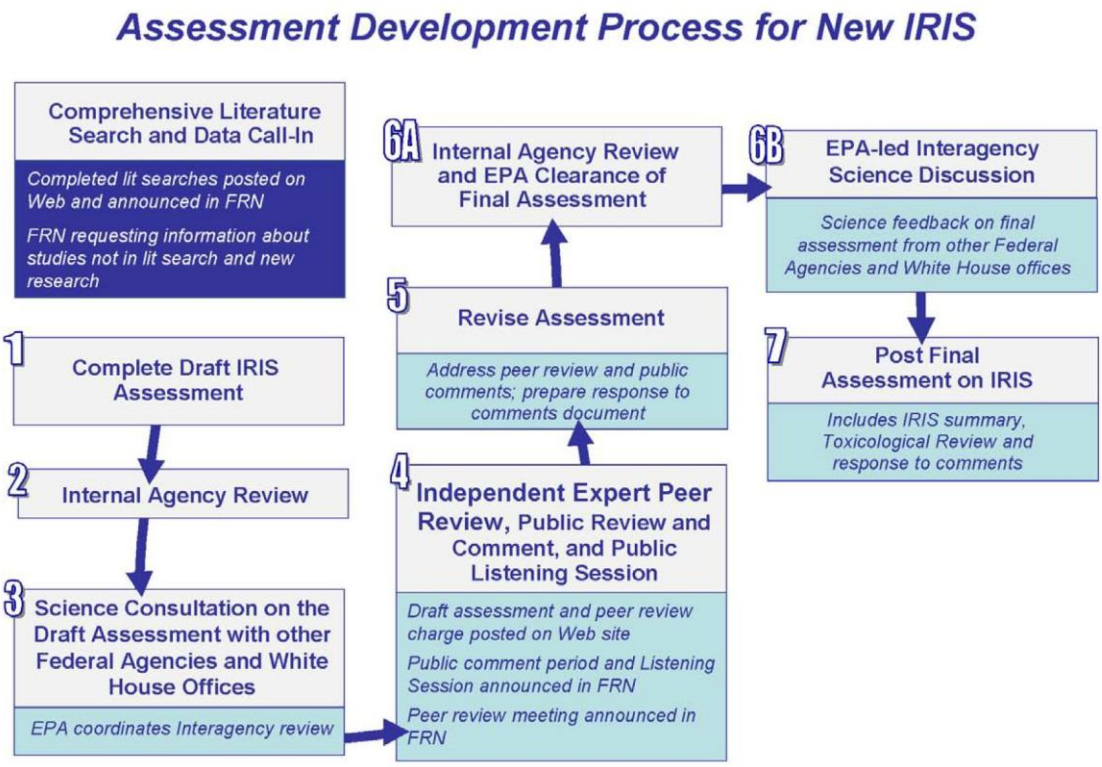
In IRIS assessments, EPA attempts to identify a quantitative reference (safe) dose for inhalation and ingestion for over 500 chemicals through a risk assessment.[147] The end goal for the "safe" dose is generally the "no observed adverse effects level," at which there is no biologically or statistically significant evidence of adverse effects in an exposed group as compared with a control group.[148] This well-defined objective makes completing IRIS assessments more straightforward than completing pesticide assessments, which must consider a number of different targets (e.g., workers, consumers, bystanders, plants, animals, and ecosystems) and endpoints (lethal and sub-lethal) that occur through multiple routes of exposure (e.g., water, air, dermal).[149] IRIS assessments are also more straightforward than the NAAQS standard-setting assessments for the same reasons (although there are fewer exposure routes and endpoints in NAAQS as compared to pesticides).

Over the last fifteen years, EPA's IRIS assessments have been criticized on several grounds.[150] First, EPA's progress in producing assessments has been very slow, averaging between six to eight years per assessment.[151] In fact, in 2009 GAO listed the IRIS program as one of the areas of high risk inside government for waste and mismanagement.[152] Second, IRIS assessments are subjected to two separate rounds of interagency review, with the scientific assessment sandwiched between these interagency

[146] GAO, CHEMICAL ASSESSMENTS: CHALLENGES REMAIN WITH EPA'S INTEGRATED RISK INFORMATION SYSTEM 6 (Dec. 2011).
[147] More specifically, EPA is only assessing the first two of four steps of risk assessment and does not attempt to develop risk management information.
[148] *See, e.g,* EPA, "Integrated Risk Information System: What is IRIS," available at http://www.epa.gov/IRIS/help_ques.htm#whatiris.
[149] Interview with EPA Staff, Office of General Counsel, Jan. 13, 2012.
[150] Some of these problems and EPA's reforms are further elaborated in Testimony by John Stephenson, Director of Natural Resources and Environment, GAO, Scientific Integrity: EPA's Effort to Enhance the Credibility and Transparency of its Scientific Process, June 9, 2009, available at http://www.gao.gov/assets/130/122677.pdf.
[151] Several stakeholders have criticized these delays, as has GAO in a series of reports. *See, e.g.*, GAO, CHEMICAL ASSESSMENTS, *supra* note 146, at 2-4 (summarizing this critical review), available at http://www.gao.gov/assets/130/122677.pdf.
[152] *See* GAO, HIGH-RISK SERIES: AN UPDATE, GAO-09-271 (Jan. 22, 2009).

stakeholder discussions.[153] Finally, the fact that OMB has historically managed the interagency review of IRIS assessment has led some to question the scientific credibility of the resulting assessments.[154]

In response to these concerns, Administrator Jackson made changes to the IRIS assessment decision-making process in 2009 with the dual goals of making the assessment process more transparent and reducing the time spent on IRIS reviews to less than two years per chemical.[155] Most significantly, as a result of these changes, EPA now takes the lead on the assessments; all written interagency comments must be submitted on the record.



[153] *See, e.g.*, GAO, CHEMICAL ASSESSMENTS: LOW PRODUCTIVITY AND NEW INTERAGENCY REVIEW PROCESS LIMIT THE USEFULNESS AND CREDIBILITY OF EPA'S INTEGRATED RISK INFORMATION SYSTEM 57 (March 2008), available at http://www.gao.gov/assets/280/273184.pdf. There are also indications that inter-agency review has influenced the assessment process, potentially significantly in some cases. *See* GAO, CHEMICAL ASSESSMENTS, *supra* note 146, at Appendix III (describing on a chemical-by-chemical basis the role of agencies like OMB and DOD on EPA's assessments).

[154] *See* GAO, LOW PRODUCTIVITY, *supra* note 153, at 56-58 (describing and criticizing OMB's role in IRIS assessments).

[155] See Appendix E for the evolution of EPA's current IRIS process through four separate flow charts. The revised process focuses primarily on limiting interagency review to two discrete points in the process and requiring that all comments from the agencies be formal and on the record, including comments from OMB. See EPA, IRIS Progress report, Aug., 2011, at 4, available at http://www.epa.gov/IRIS/pdfs/irisprogressreport2011.pdf; GAO, CHEMICAL ASSESSMENTS, *supra* note 146, at 10. Time limits were also placed on these interagency reviews. Administrator Jackson also was able to double the IRIS budget and add 25% more staff to the program. IRIS Progress report, *supra*, at 6.

Steps to an IRIS Assessment

An IRIS assessment follows several separate steps:

1. *Identification of relevant scientific evidence.* The first task, assigned to a contractor, is to collect all of the scientific research available on the chemical being assessed.[156] After the contractor completes its work, EPA issues a Federal Register notice ("FRN" on flowchart) that announces the availability of this contractor-prepared literature search for a chemical undergoing an IRIS assessment and solicits from the public additional information relevant to the assessment.[157]

2. *Preparation of the Draft Risk Assessment*. EPA then assembles an interdisciplinary team (paralleling the FIFRA process) that, with considerable help from the contractor, reviews the literature and prepares a draft risk assessment that identifies the "safe dose" or exposure level for a chemical. To provide a more robust internal scientific review, the draft risk assessment is then subjected to a staff level agency review using staff from appropriate offices and disciplines.[158] Based on this review, modifications are made, and the final draft assessment is made a part of the public record.

3. *Interagency Review*. EPA leads a process of interagency review on the draft assessment,[159] which includes not only written comments placed on the record

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[156] *See, e.g.*, EPA, NCEA Policy and Procedures for Conducting IRIS Peer Reviews 4 (July 30, 2009), available at http://www.epa.gov/IRIS/pdfs/Policy_IRIS_Peer_Reviews.pdf.

[157] *See, e.g.*, EPA, Announcement of availability of literature searches for IRIS assessments; request for information, 76 Fed. Reg. 13402 (2011). EPA does not provide a deadline for the submission of this information. See literature assessments posted at http://cfpub.epa.gov/ncea/iris_drafts/recordisplay.cfm?deid=187215. The literature assessments are arranged by topic (e.g., chemical properties, toxicokinetics) but do not contain narratives; simply a listing of relevant studies alphabetized by author. The literature assessments also generally cite to published literature or literature with links, although some studies are not publicly available and presumably must be acquired via FOIA. EPA is currently attempting to "HERO-ize" the IRIS literature database to make it more accessible. Interview with EPA Staff, National Center for Environmental Assessment, Office of Research and Development, Jan. 18, 2012.

While this first stage of the IRIS process – the assembly of relevant information -- is not as elaborate as the planning documents under FIFRA or NAAQS programs, this step does provide an initial opportunity for stakeholders and the general public to supplement the scientific record on a chemical. Note that GAO recommends that EPA give two years of advance notice of chemical review to provide private parties with opportunities to supplement the scientific record. GAO, CHEMICAL ASSESSMENTS, *supra* note 146. EPA has not yet implemented this step, but suggests it will. One can imagine both advantages and disadvantages to this advanced notice.

[158] The Chemical Manager, the Contractor, and these internal EPA reviewers are listed in the front of the draft assessment. *See, e.g.*, EPA, Toxicological Assessment of Acrylamide, March 2010, at xxi-xxiii, available at http://www.epa.gov/iris/toxreviews/0286tr.pdf.

[159] As mentioned, prior to 2009, OMB took the lead on soliciting interagency comments on the draft assessment and the entire inter-agency dialog, including changes, would be protected as deliberative process. *See* GAO, LOW PRODUCTIVITY, *supra* note 153, at 56-58.

but other discussions by phone and meetings that are not on the record.[160] EPA sets deadlines for these comments, and the entire review is scheduled to last no more than 45 days.[161] EPA then revises the assessment based on this review.

4. *External Peer review and Public Comment.* After completing an open meeting on the assessment, EPA subjects the revised draft assessment to public comment and external peer review (the latter process is elaborated below).[162]

5. *Revised Assessment and Second Round of Interagency Review.* Based on input from the peer reviewers and the public, EPA revises the assessment and subjects it to another round of internal peer review within the agency and then to interagency review. Written comments by other agencies, including OMB, are again incorporated into the public record.[163]

6. *Final Assessment*. Based on these comments, EPA revises its draft assessment and posts a final assessment.[164]

Characteristics of IRIS Assessments

1. The Transparency of IRIS Assessments

IRIS assessments are viewed as being less transparent than the NAAQS. This may stem in part from the fact that IRIS assessments are technical and are often quite long. For example, one of the recent assessments – on dichloromethane – was over 550 pages.[165] More important than their length, however, is the perception that the discussions are quite technical and not framed in ways that expose the major assumptions and alternative choices for nonscientists.[166] At least some of EPA's NAAQS reports, by contrast, are purposely designed to communicate the results of EPA's complex risk assessments in a way that makes them accessible to non-scientists.

Concerns about the transparency of IRIS assessments were raised more concretely in a spring 2011 NAS review of the EPA's IRIS formaldehyde assessment. Specifically,

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[160] Interview with EPA Staff, National Center for Environmental Assessment, Office of Research and Development, Feb. 3, 2012. Other agencies comment not only on the draft assessment, but the draft charge to the external peer reviewers. *See, e.g.,* EPA, EPA's Integrated Risk Information System: Assessment Development Process, May 2009, available at http://www.epa.gov/iris/pdfs/2009_IRIS_PROCESS_FINAL_05_19_09.PDF.
[161] *Id.*
[162] *Id.*
[163] *Id.*
[164] *Id.*
[165] *See* EPA, Toxicological Review of Dichloromethane (Methylene Chloride), Nov. 2011, at http://www.epa.gov/iris/toxreviews/0070tr.pdf.
[166] *See id.*

the panel observed that the assessments were unduly lengthy and repetitive and that it was difficult to understand EPA's assumptions and analysis at a number of points.[167] The NAS panel did not, however, offer comments on the EPA's overarching process for developing assessments, such as its use of peer review, public comment, or interagency review.[168]

A recent GAO report conducted six months after release of the NAS formaldehyde report provides a more favorable account of EPA's efforts to make its assessments transparent: " it appears that EPA has begun to enhance the readability of its assessments by making changes that appear to be in line with the suggestions made by the National Academies."[169] The GAO report was skeptical of EPA's ability to complete assessments within two years, however.[170] Indeed, much of the GAO report documented continued delays in EPA's assessment that nearly doubled the time originally allocated to the projects.[171] GAO also indicated that EPA may be experiencing delays and turf battles with OMB over the interagency review process, including the Data Quality Act.[172]

2. External Peer Review

As mentioned, after the draft assessment has been subjected to the first round of interagency review, it is then subject to some form of external peer review. The form of the external peer review depends on the level of controversy.[173] External peer review can be conducted by the NAS for highly controversial assessments; EPA's Science Advisory Board (SAB) for medium controversy assessments (this usually is limited to about 4

[167] *See* NAS, FORMALDEHYDE REPORT, *supra* note 2, at chapter 7.
[168] *Id.; see also* Section II.A., *supra.* In response to the NAS report, EPA agreed to make a number of changes to its future reviews to make them more transparent. *See, e.g.*, EPA, Progress Report, 2011, *supra* note 155, at 11. In future assessments, EPA plans to include a short (15 page) executive summary and short extended scientific summary (50 pages) to precede the longer report. Interview with EPA Staff, National Center for Environmental Assessment, Office of Research and Development, Jan. 18, 2012. EPA also intends to include graphics and other summary devices borrowed from the ISA of the NAAQS process. *Id*. One of the first IRIS assessments in this new format is trichloroethene TCE. *Id*. EPA is also investigating adding an early stage of external peer review and is developing a standing committee that operates like CASAC. *See, e.g.*, GAO, CHEMICAL ASSESSMENTS, *supra* note 146, at 44 (Letter from Paul Anastas, Assistant Administrator of EPA to GAO, Nov. 22, 2011).
[169] *See, e.g., id.* at 22.
[170] GAO noted that although EPA attempts to set rigid deadlines initially for these assessments, it appeared to have limited authority to enforce them, particularly against other agencies. *Id*. at 18. In its recent report, GAO also identified continuing, significant delays in IRIS assessments, although GAO also questioned whether EPA's two year goal was feasible, at least for moderately complex assessments. *See* GAO, CHEMICAL ASSESSMENTS, *supra* note 146, at 27-28.
[171] *See, e.g., id*. at 8
[172] Apparently, several Data Quality Act correction requests have been filed on draft IRIS assessments. Since these reports are subject to public notice in any event, EPA (and OMB) considers them effectively exempt from the DQA. Yet the GAO report suggests that OMB is still requiring EPA's responses to be cleared through it. *Id*. at 25-26.
[173] The Chemical Manager determines which level of peer review is needed and prepares a publicly available peer review plan. *See, e.g.*, NCEA Policy Report, *supra* note 156, at 5-6.

chemicals/year);[174] and contractor-selected individualized peer review panels for the remaining IRIS assessments (which one EPA official estimated covered about eighty percent of the total assessments).[175] Regardless of which group conducts the peer review, there are minimal standards for those serving as reviewers, such as standard conflict of interest requirements adopted by the agency.[176] The peer review contractor sets up and manages this external peer review when it is not conducted by EPA's SAB or the NAS.[177]

Of these three peer review processes, the most problematic (and the most common, because the SAB has limited time to conduct reviews) is the review by three external reviewers selected by an EPA contractor.[178] Since the comments come from three separate scientists who have not conferred, EPA finds that responding to the comments can be quite challenging.[179] It is not uncommon, for example, that one reviewer will offer suggestions on issues for which the other reviewers are silent (thus leaving open the possibility that the other reviewers would disagree). In addition, it is not uncommon for the three reviewers to offer comments that conflict with one another or to have reviewers focus on completely different feature of the assessment.

These problems are exacerbated because interagency review occurs after external peer review and the other agencies can seize on comments that favor their own positions and insist they be addressed.[180] The large range of individualized external review comments thus provides fodder for even more debate and discussion during the second stage of interagency review, with little hope of expeditious closure.

Thus, in contrast to CASAC's role in "closing" debate in the NAAQS process, the EPA faces a relatively large set of scientific questions and queries that seem to actually expand rather than narrow with each round of interagency review and peer review. EPA staff suggests that risk assessments for chemicals like formaldehyde (recall this assessment was the subject of a critical NAS report) are unwieldy and unfocused in large part because of this decision-making process. By subjecting assessments to multiple rounds of stakeholder and interagency discussion and depriving the agency of the

[174] Interview with EPA Staff, National Center for Environmental Assessment, Office of Research and Development, Feb. 3, 2012.
[175] *See, e.g.*, GAO, CHEMICAL ASSESSMENTS, *supra* note 146, at 8.
[176] *See, e.g.*, *id*. at 5-6 and 7-10.
[177] *See id.* at 7. For a list of "highly influential assessments" under IRIS, see EPA, Peer Review Agenda, at http://cfpub.epa.gov/si/si_public_pr_agenda.cfm.
[178] For an example of external peer review comments, see the Consolidated Comments from External Peer Review for Acrylamide, posted (with other items) at http://cfpub.epa.gov/ncea/iris_drafts/recordisplay.cfm?deid=187729.
[179] Interview with EPA Staff, National Center for Environmental Assessment, Office of Research and Development, Feb. 3, 2012.
[180] Interview with EPA Staff, National Center for Environmental Assessment, Office of Research and Development, Feb. 3, 2012.

authority to effectively "close" the debate, agency reports can be filled with "facts that go nowhere" and "hypothetical analyses that don't need to be run."[181]

3. Interagency Review

EPA staff report that interagency review remains a significant feature of the IRIS process.[182] The GAO report and interviews indicate that other agencies take a keen interest in EPA's IRIS assessments because of their potential liability and compliance costs, which can hinge on IRIS values. As a result, interagency review generally comes much closer to supplementing the public comment from stakeholders rather than serving as a form of expert peer review.[183] In contrast to public commenters and even external peer reviewers, however, EPA is expected – perhaps by OMB or as a matter of interagency courtesy – to provide responses to all of these federal agency comments and concerns in the assessment itself. Indeed, one EPA staff suggested that this need to respond to the extensive interagency comments causes EPA to drill down into details at the expense of dedicating staff resources to providing a strong, coherent draft on the most important issues.[184]

As the decision process outlined above indicates, EPA dedicates two separate windows of time to interagency review – one before EPA's draft assessment is released for public comment and peer review and a second after both peer review and public comment have concluded. In other agency decision-making processes, by contrast, interagency review is merged with the public comment process. Moreover, although OMB historically managed the interagency review process, EPA now manages this review, and the agencies' comments are placed in the record.[185] Considerable interagency review still takes place by phone and meetings, however, and these discussions are protected as deliberative and are not on the public record.[186]

4. Access to the Literature

EPA posts a list of references for each of the chemicals going through the assessment process. EPA also includes this reference list in its draft assessments, and in the most recent assessments even includes hyperlinks to each study cited in the reference

[181] Interview with EPA Staff, National Center for Environmental Assessment, Office of Research and Development, Feb. 3, 2012.
[182] Interview with EPA Staff, National Center for Environmental Assessment, Office of Research and Development, Feb. 3, 2012. .
[183] Although some health agencies were initially involved in interagency discussions, they have largely dropped out of the process. *Id*.
[184] Interview with EPA Staff, National Center for Environmental Assessment, Office of Research and Development, Feb. 3, 2012.
[185] *Cf*.., GAO, CHEMICAL ASSESSMENTS, *supra* note 146, at 19 (NASA requested OMB to hold an interagency workgroup to discuss EPA's short comment deadlines).
[186] Interview with EPA Staff, National Center for Environmental Assessment, Office of Research and Development, Feb. 3, 2012. .

list.[187] Although it is still being developed, EPA is attempting to build a web database of these studies, modeled after the NAAQS HERO database. When completed, this database will facilitate public and peer reviewer access to the literature that forms the basis for IRIS decisions.[188]

5. Authorship and Attribution

The EPA and EPA-contractor authors, EPA internal reviewers, and external peer reviewers are each listed by name in the first section of an IRIS assessment.[189] Attribution and authorship rights are considered a basic feature of the IRIS assessment process.[190] EPA staff report that this authorship gives staff credit for their work while ensuring that they are accountable for the same. The list of internal and external reviewers also gives these scientists a stake in the assessment. While not formally stated, it is generally understood that, if the authors are not comfortable with the document, they can remove themselves as authors and simply be acknowledged as contributing to the report.[191]

2. The Department of Interior's Fish and Wildlife Service: Listing Endangered and Threatened Species and Designating Critical Habitat

Although the U.S. Fish and Wildlife Service (FWS) engages in a number of science-based decisions,[192] this study focuses entirely on the FWS' species listing and critical habitat determinations. Species and habitat designation decisions – the primary tools for preventing species extinction – were selected in part because they attract more public attention than other science-based decisions, and consequently more information is available on them. These decisions also appear to be fairly representative of other FWS science-based processes with respect to how science is incorporated into policy.[193]

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[187] *See, e.g.*, EPA, "IRIS Agenda and Literature Searches," avaialable at http://cfpub.epa.gov/ncea/iris_drafts/recordisplay.cfm?deid=187215.

[188] *See, e.g.*, EPA, "IRIS Progress Report 2011," Aug., 2011, at 6, available at http://www.epa.gov/iris/pdfs/irisprogressreport2011.pdf.

[189] *See, e.g.*, EPA IRIS Home Page, available at http://www.epa.gov/IRIS/ (providing links to recent assessments with this attribution in the front matter of the assessment).

[190] Interview with EPA Staff, National Center for Environmental Assessment, Office of Research and Development, Feb. 3, 2012.

[191] Interview with EPA Staff, National Center for Environmental Assessment, Office of Research and Development, Feb. 3, 2012.

[192] These include five-year reviews of threatened and endangered species, emergency listings, the development of recovery plans, interagency consultations regarding jeopardy, delisting species, and the development of habitat conservation plans.

[193] It should be noted that the OIG report of Julie MacDonald identifies irregularities across a number of different programs. *See generally* OIG, MacDonald Report, *supra* note 10. The discussions of transparency problems in the listing and habitat designation decisions thus seem to carry over to these other areas.

The approach to science-policy decision-making used by the FWS to list species and critical habitat under the Endangered Species Act[194] is a very different approach from that of the EPA. As described above, the NAAQS reviews begin with staff-authored documents (with attribution to individual scientists in the acknowledgement section) that undergo multiple points of contact with the public and peer reviewers before the proposed rule is published.

The FWS's approach to species listing and habitat designations, by contrast, is much more abbreviated, limits authorship, and is less transparent. The FWS's assessment of the evidence, its technical analysis, and its decision in terms of applying the policy factors to the scientific evidence is contained in a single proposed rule that is drafted by staff and management working together. In addition, instead of listing individual scientists as authors, attribution for the technical analysis is generally given to a field staff office.[195] Furthermore, virtually all internal drafts and assessments supporting this single decision document, with a few exceptions discussed below, are classified as deliberative privilege until the proposed rule is published.[196]

Endangered Species Act (ESA) Listings and Critical Habitat Determinations: The Law

The FWS and the National Marine Fisheries Service (NMFS) (which was not included in the study), are responsible for determining whether a species or subspecies is endangered or threatened under the Endangered Species Act. If based "solely on the basis of the best scientific and commercial data available,"[197] a species is threatened or endangered with extinction (or likely to be so) "throughout all or a significant portion of its range," then the FWS must list the species. [198]

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[194] 16 U.S.C. § 1533.

[195] *See* Attribution subsection on FWS, *infra*.

[196] This truncated approach to listing is an explicit policy of the FWS. As the Director instructed staff in 2006:

> Premature release of drafts, scientific information or briefings can significantly undermine the confidence in the process by the public (through the Administrative Record) as well as our ability to have free and open debate on data interpretation. Failure to maintain a culture of "in Service scientific debate" prior to forming conclusions can significantly undermine the credibility placed with the science as we and the Department engage in policy or decision-making discussions. In order to ensure the integrity of this process, it is imperative that all documents, assessments and drafts remain inside the Service, except for discussions as appropriate with your recognized federal and state peers. Any requests for such release or premature briefings should be forwarded to this office for appropriate action.

Memorandum from FWS Director H.Dale Hall to FWS Directorate, Feb. 3, 2006, at page 1, available at http://www.fws.gov/endangered/esa-library/pdf/Science_in_DecisionMaking_2_3_06.pdf.

[197] 16 U.S.C. § 1533(b)(1)(A).

[198] *Id*. at § 1532(6).

In making this determination, FWS is statutorily required to consider five factors, any of which can trigger listing.[199] Much like the NAAQS determinations, the FWS is prohibited from considering economic impacts in listing species.[200] The designation of critical habitat, however, must take economic and related considerations into account as required by statute.[201]

Steps for Listing and Habitat Designations

A listing/habitat decision typically follows a three-step process, with each step published in the Federal Register:

1) *A 90-day decision on a petition*. Listing analyses are often triggered by citizen petitions that demand that a particular species be listed as a threatened or endangered species.[202] The FWS has only ninety days by statute to determine whether a petition presents "substantial scientific or commercial data that the petitioned action may be warranted."[203] The FWS's decision typically involves a relatively extensive scientific analysis that relies largely on evidence submitted by a petitioner.[204] The FWS details its analysis with respect to each of the five statutory factors and publishes its full analysis and decision in the Federal Register.[205]

2) *A 12-month finding that listing is not warranted or that proposes listing and solicits notice and comment on that proposal*. After completing the 90 day

[199] *Id*. at § 1533(a)(1)(A)-(E). The 5 factors are: a) "the present or threatened destruction, modification, or curtailment of its habitat or range;" b) "overutilization for commercial, recreational, scientific, or educational purposes;" c) "disease or predation;" d) "the inadequacy of existing regulatory mechanisms;" or e) "other natural or manmade factors affecting its continued existence." *Id.*

[200] *Id*. at §1533(b)(1)(A).

[201] *Id*. at § 1533(b)(2) (in making critical habitat designations the Secretary shall take into consideration "the economic impact, and any other relevant impact, of specifying any particular area as critical habitat").

[202] In recent years, the FWS reports that its priorities are largely driven by petitions filed by nonprofit groups for the simple reason that the agency's resources are very limited and the agency's response to petitions is statutorily required. Interview with FWS Staff, Endangered Species Program, Jan. 9, 2012.

[203] 16 USC § 1533(b)(3)(A); 50 CFR § 424.14(b). This is a lighter evidentiary standard than a conclusion (during the next review) that listing is ultimately warranted based on the "best scientific and commercial data" standard. *Id*. at § 1533(b)(1)(A).

[204] In ruling on this petition, the FWS relies primarily on "the information provided by the petitioner", FWS, Endangered Species Petition Management Guidance 10 (July 96), available at http://www.nmfs.noaa.gov/pr/pdfs/laws/petition_management.pdf, with attention to ensuring the reliability of that information, *id*. at Appendix A, but it also considers "information already available in the Service's files." *Id*. at 10.

[205] 16 U.S.C. § 1533(b)(3)(C)(ii). For a sample, see FWS, Endangered and Threatened Wildlife and Plants; 90-Day Finding on a Petition To List the Humboldt Marten as Endangered or Threatened, 77 Fed. Reg. 1900, 1904-08 (2012) (undertaking this analysis). At this point, the FWS will also include a notice in the same published decision that solicits from the public information on the species and its habitat, often including very specific questions for which it seeks information. *Id*. at 1900-01. Much like the approach in all the other agencies, this initial solicitation of information is intended to ensure that the agency's files are as complete as possible.

decision the FWS then has twelve months (by statute) to issue a proposed finding with regard to whether a listing is warranted.[206] The analysis in the 12-month finding (whether it be to list or not to list) is based on a comprehensive analysis of the best available evidence.[207] This analysis in the proposed rule is conducted by staff and management working together.

If the FWS concludes that listing is warranted,[208] then its decision takes the form of a proposed rule upon which it solicits public comment. As described below, with the help of a contractor, the FWS also solicits external, independent peer review on its proposal. In the same proposed rule, the FWS is required by statute to propose the designated critical habitat for the species.[209] Although the listing proposal does not require OMB review, the critical habitat designation must be cleared by OMB.

3) *A final rule*. Like the proposed rule, the final rule is the result of a collaboration between staff and management within the FWS and the Department. Also like the proposed rule, for critical habitat designations the final rule must be cleared by OMB.

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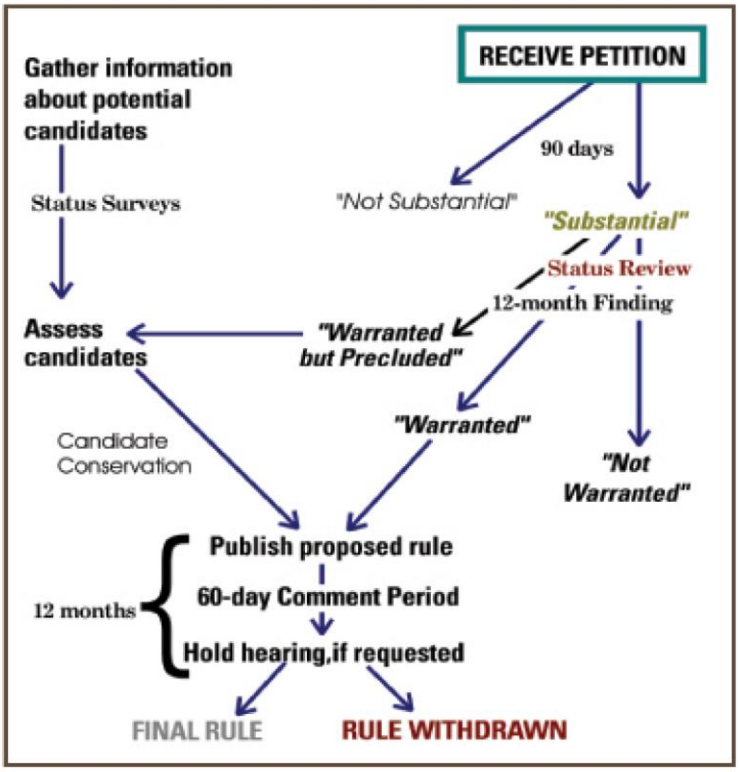
[206] 16 U.S.C. § 1533(b)(5)(A)(i). A six month extension can be justified based on "substantial disagreement regarding the sufficiency or accuracy of the available data." *Id*. at § 1533(b)(6)(B)(i). The FWS has been held to these timelines in litigation by nonprofit group. For a list of judicially imposed deadlines for critical habitat designations, see http://www.fws.gov/endangered/esa-library/pdf/ch-actions.pdf.

[207] 16 U.S.C. § 1533(b)(1)(A).

[208] If the FWS concludes that listing is not warranted or is warranted but precluded, the FWS issues its decision as a finding without notice and comment. A negative decision (i.e., "not warranted") is considered a final action subject to appeal. *Id.* at § 1533(b)(3)(A). The FWS will conclude that a listing is not warranted if "convincing data on biological vulnerability and threat are not available to support a proposed to list." Petition Guidance, *supra* note 204 at 13-14. By contrast, listing is warranted when there is "convincing evidence" in its favor. *Id*. There is also a third, "warranted but precluded" category in cases where there are inadequate resources to list relative to other, higher priority species. *Id.* Species falling into this category are reconsidered annually. *Id.*; *see also* 16 U.S.C. § 1539(j)(2)(C)(i). For the priority system that the FWS has developed, see FWS, 1983 Priority Guidelines, 49 Fed. Reg. 43098 (1983). The cutoff for where how these priority rankings affect whether a species is in the warranted but precluded category are variable and depend in part on workload and resources. See Stanford Environmental Law Society, The Endangered Species Act 47-49 (2001) (describing this feature in more detail with examples). The statute is read to create a presumption in favor of listing. Interview with FWS Staff, Endangered Species Program, Jan. 9, 2012.

[209] The critical habitat designation includes areas considered necessary to protect survival at status quo levels and does not include what may be necessary for recovery. 16 U.S.C. § 1532(5); 50 C.F.R. § 424.12(b). As mentioned, critical habitat designations must include economic considerations to the extent that the habitat extends beyond a biologically determined "core" area essential to prevent extinction. 16 U.S.C. § 1533(b)(2). Although habitat designations are required to be issued with the species listing decisions, the statute does allow the FWS to delay the decision if the designation at the time is "not determinable" and to avoid it altogether if the designation is "not prudent." *Id.*



From FWS, Listing a Species as Threatened or Endangered, June 2011.

General Characteristics of Listing and Habitat Designations

1. Public access to technical assessments supporting FWS decisions

As mentioned, the FWS follows an abbreviated process for incorporating science in which both management and staff work together to produce the analysis that supports a decision.[210] The proposed rule and accompanying technical documents that comprise the

[210] An email from Dale Hall, the FWS Director in 2006, posted on the FWS site in its ESA policy library fleshes out the agency's expectations regarding this collaboration between staff and management in formulating listings and other decisions in the FWS. *See* email from Dale Hall to FWS Directorate and Deputies, dated Feb. 8, 2006, available at http://www.fws.gov/endangered/esa-library/pdf/Directions_for_Directorate.pdf. In listing and related decisions, the Director will become involved early in the process. "[A] written briefing" to the FWS director is required just at the point that the "field is beginning to write the document". "The real value here is to give advice and suggestions to the field so they can assist in providing information in the draft to answer expected questions." Hall's directions conclude with:

> "(6) The discussions between you in the A/S [Assistant Secretary] office and me will focus on policy direction or policy decision-making. Identification of other weaknesses in the draft are welcomed, but will be given to me as the responsible person in the Service to make necessary corrections or improvements. . . . This will be tricky until we get better at it, but we will keep working it until a solid process emerges."

In this directive, Hall is attempting to separate and protect the field's scientific analysis from the policy decisions made in the Assistant Secretary's office based on that analysis. See OIG MacDonald Report, *supra* note 10, at 15 (citing FWS employee as saying that Hall drew a "line in the sand" that

listing and critical habitat packages originate with field staff but are then reviewed and revised by a number of regional and Washington offices and ultimately are sent to the DOI Office of the Solicitor, the FWS Director, and the Assistant Secretary for Fish, Wildlife, and Parks.[211]

In theory, the extensive review of the proposed rule by management creates opportunities for the scientific analysis to be altered, although whether or how much this occurs cannot be determined. An IG report produced to investigative the misuse of authority by Assistant Secretary Julie MacDonald did criticize the FWS for not having guidelines relating to how scientific evidence and technical analysis should be incorporated into decisions during this internal review process.[212] In the case of critical habitat designations, for example, the IG identified 14 different versions of a FWS policy that purported to guide critical habitat designations over a three year period (between 2003 and 2006).[213] Because the guidelines to FWS personnel on how to assess and report on scientific evidence are so ambiguous, the IG concluded that the transparency and scientific rigor of the FWS's supporting analyses were at risk of being compromised.[214]

Although the internal deliberations of the FWS are protected as deliberative process before the proposed rule is published, after the rule is published, the FWS does typically make the administrative record available from its field office.[215] A FWS staff

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MacDonald could not change the science coming from the field). To the extent that this approach prevails, it would seem to improve the scientific integrity of the decision-making within the Department. Yet the informality of Hall's directions (an email) leaves open the possibility that future FWS Directors may take the opposite tack. The Hall email openly concedes in fact that "There is almost never one clear answer to ESA, FERC or other questions, and our objective is to ensure we have as clear of an understanding of the range of options as we can have." Hall, *supra*. Yet how those range of options is to be expressed as against the evidence and interpretation of that evidence is not spelled out.

[211] Interview with FWS Staff, Endangered Species Program, Jan. 9, 2012.

[212] Assistant Secretary MacDonald allegedly bullied staff and manipulated the scientific record in order to undermine recommendations for listing; as a result of her activities, a number of proposals for listing were dropped. In investigating her case, the Office of the Inspector General concluded that the FWS's own lack of guidelines was partly to blame for her ability to abuse this authority. OIG MacDonald Report, *supra* note 10, at 7. Specifically, the OIG found:

> While the ESA affords the Secretary great discretion in several areas – exclusions of habitat being one example – the absence of policy guidelines in exercising that discretion has resulted, in MacDonald's case, in a wholesale lack of consistency, a process built on guess-work, and decisions that could not pass legal muster. [Indeed, the resulting ambiguity created "an enormous policy void, which MacDonald was able to readily exploit."] This dearth of policy and guidance seems less than coincidental. For many years, through several administrations, this appears to be an area of intentional failure to clarify, in order to maximize the agenda *du jour*.

OIG MacDonald Report, *supra* note 10, summary letter at 2, available at http://www.lb9.uscourts.gov/webcites/10documents/HomeBuilders_conflict.pdf

[213] OIG MacDonald Report, *supra* note 10, at 130.

[214] *Id*.

[215] No documents, except for a possible bibliography and two critical habitat reports, required under NEPA and Executive Order 12866, are posted online. One of the two critical habitat reports is a supporting environmental assessment that explores the consequences of the critical habitat designation, required under NEPA. The second is a draft economic assessment of alternative critical habitat designations. The

member indicated, however, that there can be considerable variation in how these records are prepared. To the extent that there is guidance to assist with this task, it is badly dated.[216] Thus some administrative records that support listing will be carefully prepared to include the full range of documents that led up to the FWS' proposed rule, including significant changes and discussions.[217] Other administrative records may be less comprehensive, mostly because drafts are not saved or collected and the record is generally prepared at the end of the process.[218] A staff member also indicated that the agency's approach to claiming deliberative process protections for internal documents has varied over time and generally lacks clear guidance.[219]

2. External Peer Review

The FWS voluntarily solicits independent peer review relating to its proposed listing decision from at least three independent specialists.[220] While the reviewers are invited to comment on any issues in FWS's analysis, they are asked in particular to provide opinions on the species' taxonomy and biology.[221]

The FWS's decision to solicit external peer review on its species listing decisions is the result of formal FWS policy, but it is not legally required. [222] Perhaps in part because it is discretionary, FWS's decision to use external peer review for listings, as well as its selection of reviewers, has been controversial. The FWS's actual selection of reviewers in individual cases has been criticized by members of Congress, who, for example, argue that the FWS selects reviewers in ways that stack the deck in favor of a desired outcome.[223] Other stakeholders question whether peer review is even necessary at all and have expressed concern that it might reduce the FWS's discretion, delay the

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economic assessment of critical habitat designations not only informs the Secretary regarding the benefits and costs of alternative habitat designations as required by the ESA, but also allows the Service to address the requirements of Executive Orders 12866 and 13211, and the Regulatory Flexibility Act (RFA), as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA). Both of these additional assessments are made available, with the proposed rule, for public viewing and are considered part of the larger package subjected to notice and comment. It is not clear whether they must also pass through the same proposed rule review chain or whether they are considered the equivalent of staff documents that support a larger critical habitat designation.

[216] Interview with FWS Staff Member, Field Office, Feb. 15, 2012.

[217] *Id*.

[218] *Id*.

[219] *Id*.

[220] *See, e.g.*, Joy Nicholopoulos, *The Endangered Species Listing Program*, 24 ENDANGERED SPECIES BULLETIN, Nov./Dec. 1999, at 5, 9.

[221] *Id.* at 9.

[222] FWS, Endangered and Threatened Wildlife and Plants: Notice of Interagency Cooperative Policy for Peer Review in Endangered Species Act Violations, 59 Fed. Reg. 34270 (1994). A search through past FWS proposals reveals that this peer review is also occasionally sought for critical habitat designations. See FWS Letter soliciting external peer review on the Gopher Frog, Nov. 11, 2011, Document Number FWS-R4-ES-2010-0024-0024, available at regulations.gov.

[223] Interview with FWS Staff, Endangered Species Program, Jan. 9, 2012.

listing process, and tax the limited resources of staff.[224] According to FWS officials, however, peer review has been helpful and provides a robust check on the FWS's scientific and technical analyses.[225] This peer review can occasionally alter the FWS's analysis in substantive ways.[226]

3. Attribution and the Release of Staff Reports

Attribution for the FWS's technical analysis is given to a field office at the end of the Federal Register publication (e.g., "The primary authors of this notice are the staff members of the [fill in the blank] office."). According to FWS staff, there is no individualized attribution or scientific authorship for the analyses that support the proposed rule, as is the case at EPA.[227] This is likely due in large part to the collaborative nature of the FWS's analysis and the fact that it is reviewed and edited by multiple offices as a draft proposed rule.[228]

4. Bibliography and Public Access to the Supporting Literature

The extent to which the bibliographic information on which decisions are based is publicly available is inconsistent. For example, while references in abbreviated form are cited in the FWS's Federal Register preamble, the full bibliography is not published in the proposed rule and is not always posted on regulations.gov.[229] In cases when the bibliography is not posted, commenters are invited to contact the designated contact person in the appropriate field office. It appears that external peer reviewers must follow this same process to acquire the literature supporting the FWS's analysis.[230]

In the bibliographies that were available online,[231] only some of the cited literature was published. Other references included unpublished studies and internal

[224] *See* STANFORD ENVIRONMENTAL LAW SOCIETY, *supra* note 208, at 53 (reporting on this).
[225] Interview with FWS Staff, Endangered Species Program, Jan. 9, 2012.
[226] *Id.* The FWS ultimately revises the proposed rule and reopens public comment after explaining the changes it made in response to peer review. *See, e.g.*, FWS, Endangered and Threatened Wildlife and Plants: Designation of Critical Habitat for Mississippi Gopher Frog, 77 Fed. Reg. 2254 (2012).
[227] Interview with FWS Staff, Endangered Species Program, Jan. 9, 2012.
[228] *Id.*; Interview with FWS Staff Member, Field Office, Feb. 15, 2012.
[229] *See, e.g.*, Proposed Endangered Status for the Chupadera Springsnail (Pyrgulopsis chupaderae) and Proposed Designation of Critical Habitat, 76 Fed. Reg. 46218, 46233 (2011) (guiding readers to regulations.gov for the bibliography).
[230] In at least one solicitation to peer reviewers pulled from a docket, the reviewers were given only the published federal rule. *See, e.g.*, Letter to Peer Reviewers for the Gopher Frog, *supra* note 222, at 2 (advising reviewers that "[a] list of the References Cited in the proposal- Copies of the references cited are available from our files if you wish to review them.").
[231] *See, e.g.*, Reference List for the Chupadera Springsnail, Document ID FWS-R2-ES-2011-0042, available at regulations.gov.

memoranda. Presumably these documents would also need to be requested from the field office that serves as the designated contact point for listings.[232]

5. The Role of OMB and Interagency Review

As discussed, OMB does not review listing decisions,[233] but decisions regarding critical habitat designations do require OMB clearance.[234] As with OMB's review of EPA's proposed rules, the internal deliberations, reviews, and changes made as part of this review are considered deliberative process and are therefore privileged.[235] Note that while critical habitat designations are often published in the same proposed rule as species listings, these two elements of the rule are discussed separately in the preamble. Therefore, it is presumably not difficult for these two types of decisions to be separated for the purposes of OMB review.

3. A Birds' Eye View of the Nuclear Regulatory Commission's Incorporation of Science into its Regulatory Decision-making

The Nuclear Regulatory Commission (NRC) provides yet a third point of contrast to the FWS and EPA regulatory programs. As discussed in Section II, *supra,* the primary reason that NRC was selected for study is that the NRC is independent and thus presents a slightly different regulatory process. Rather than responding to Executive Branch appointees and undergoing mandatory OMB clearances (as well as other methods of coordination), NRC is governed by a five member board of Commissioners appointed by the President for five year, staggered terms. At least two of the Commissioners must be affiliated with the Democratic Party, and two must be affiliated with the Republican Party.[236] As a consequence, the NRC is a bipartisan body. The internal politics and

[232] Given the limited timeframe and resources of the FWS, it might not be possible to make supporting documents more readily available. However, in a policy email from Dale Hall to the FWS Directorate, *supra* note 210, point 3 at page 1, Hall indicates that: "If literature cited in the document is in electronic form in the field office, that will be forwarded with the draft [to the Director]. If not, we agreed that an intern could be assigned to find the citations and either print them off or put them in electronic form." It is not clear why this internally collected research cannot be made available in the docket, but this was not asked of the interviewees in this study.

[233] Interview with FWS Staff, Endangered Species Program, Jan. 9, 2012. Officials in FWS were not sure why OMB refrains from reviewing species listing decisions.

[234] *Id.*

[235] A review of the critical habitat designations cleared through OMB over the last few years (since 2009) on reginfo.gov reveal that every critical habitat designation cleared through OMB involved some change as a result of OMB review, although the designation decisions were not held up for more than about two weeks in most cases. *See* http://www.reginfo.gov/public/do/eoAdvancedSearchMain (using the advanced search terms of "critical habitat" as subject, and FWS as the subagency for concluded rules). Beyond this limited information, virtually nothing was learned about the substance of OMB's involvement in critical habitat designations.

[236] Under the Energy Reorganization Act of 1974, Sec. 201, "not more than three members of the Commission shall be members of the same political party."

external mechanisms of pressure at the NRC are thus different than at an Executive Branch agency.

The NRC's technical decisions are generally based on more limited scientific information than the information upon which EPA and the FWS typically rely. For example, NRC regulatory issues often concern technical issues and modeling assumptions that require considerable engineering expertise.[237] Grounded operational experience is also viewed as a necessary disciplinary perspective to include on most expert advisory groups because the technical issues can be closely tethered to specific, applied issues and challenges.[238]

Finally, NRC's statutory mandates generally do not impose many deadline-forcing requirements on NRC. Consequently, NRC is not subject to the deadline pressure that appears to be a significant factor in EPA's NAAQS and pesticide reviews and in FWS's ESA determinations.

Roland Frye, a Senior Attorney at NRC, was conveniently on detail to ACUS during the preparation of this report. Mr. Frye contributed most of the information detailed in this and the next section on NRC. Specifically, Mr. Frye conducted all of the interviews with NRC personnel and contributed virtually all of the documentation and other substantive information used in this report on informal rulemakings and on NRC's scientific integrity programs. Mr. Frye also prepared two stand-alone white papers on NRC's use of science advisory bodies and its use of expert elicitation, which are available in Appendices A and B. Any errors in transcribing and analyzing this information for purposes of the report, however, are attributable solely to the author.

a. Informal Rulemakings

The NRC engages in a diverse set of rulemakings and licensing decisions, but most of the NRC's regulatory activities involve some form of oversight or restrictions on nuclear operations, such as waste disposal, worker safety, or operations and maintenance.[239] This study placed primary, but not exclusive, emphasis on examining NRC's informal rulemaking projects (particularly in nuclear material and waste rulemakings) so that these processes can be compared with EPA's NAAQS review process.[240]

NRC's actual process or flowchart for undertaking its technically-based, informal rulemakings is not explicated in NRC fact sheets, on the NRC's webpage, or even in

[237] Interview with NRC Staff, Office of General Counsel, Nov. 15, 2011.
[238] *Id.*
[239] See first four horizontal tabs on NRC's home page at U.S. NRC, last visited on February 2, 2012, available at http://www.nrc.gov/ (list).
[240] Since the processes examined in the FWS and other program offices of EPA were relatively product- or issue-specific (e.g., akin to a licensing decision), the NRC's broader rulemaking orientation also provides a more diverse view of rulemaking activities in different agencies.

technical documents or directives (at least that the author could find). Like the other agency programs studied in this report, NRC's process for promulgating technical rules was reconstructed from interviews with staff and stakeholders, the synthesis of various documents, and sampling ongoing and concluded rulemakings posted on several tabs of the NRC website.[241] While the process outlined below for technical rulemakings may not describe all NRC rulemakings, it appears to be the general approach used in most cases.

In general, NRC's informal rulemaking for technical rules proceeds as follows:

1. *Trigger for Action.* The need for a rule or guidance is generally triggered by a statute or by Commission priority, a staff recommendation, a recommendation from the Advisory Committee on Reactor Safeguards (ACRS), or a petition from the outside.[242] In some cases, the decision to proceed with a regulatory project, in and of itself, may result from give-and-take between staff and the Commission.[243]
2. *Possible Workshop.* Staff or the Commission occasionally suggest a stakeholder workshop early in the rulemaking process. These workshops are public and in some cases are lengthy in duration and broad in scope.[244] In the workshops, the staff solicits information and guidance on the rulemaking project.
3. *Staff Analysis.* The staff then provides the Commission with one or more technical papers (called a Commission or SECY paper)[245] that offer analysis and sometimes

[241] The following rulemakings were selected from the NRC's website, in part because they are currently ongoing or recently concluded: a) a revision of 10 CFR Part 61 (low level nuclear waste), see U.S. NRC, Potential Revision of 10 CFR Part 61, last updated on April 6, 2011, available at http://www.nrc.gov/about-nrc/regulatory/rulemaking/potential-rulemaking/potential-part61-revision.html#background; b) U.S. NRC, Specific Analysis Rulemaking (Unique Waste Streams), last updated on June 20, 2011, available at http://www.nrc.gov/about-nrc/regulatory/rulemaking/potential-rulemaking/uw-streams.html; c) rulemaking regarding uranium mill tailings, see U.S. NRC, Docket Folder Summary, No. NRC-2010-0075, available at http://www.regulations.gov/#!docketDetail;dct=SR%252BFR%252BPR;rpp=10;po=0;D=NRC-2010-0075; d) U.S. NRC, Requirements for Maintenance of Inspections, Tests, Analyses, and Acceptance Criteria, No. NRC-2010-0012, available at http://www.regulations.gov/#!docketDetail;rpp=10;so=ASC;sb=postedDate;po=0;D=NRC-2010-0012; e) U.S. NRC, Proposed Security Rulemaking for Independent Spent Fuel Storage Installations, last updated on September 16, 2011, available at http://www.nrc.gov/about-nrc/regulatory/rulemaking/potential-rulemaking/isfsi-security.html; f) U.S. NRC, Options to Revise Radiation Protection Regulations and Guidance, April 9, 2011, available at http://www.nrc.gov/about-nrc/regulatory/rulemaking/potential-rulemaking/opt-revise.html.

[242] Interview with NRC Staff, Nov. 2011.

[243] Interview with NRC Staff, Office of General Counsel, Nov. 15, 2011.

[244] *See, e.g.*, U.S. NRC, Potential Revision of 10 CFR Part 61, last updated on April 6, 2011, available at http://www.nrc.gov/about-nrc/regulatory/rulemaking/potential-rulemaking/potential-part61-revision.html#background (includes discussion of public workshop); U.S. NRC, Site-Specific Analysis Rulemaking (Unique Waste Streams, last updated on June 20, 2011, available at http://www.nrc.gov/about-nrc/regulatory/rulemaking/potential-rulemaking/uw-streams.html (includes a public meeting at the beginning of the process); U.S. NRC, Options to Revise Radiation Protection Regulations and Guidance, last updated on April 9, 2011 available at http://www.nrc.gov/about-nrc/regulatory/rulemaking/potential-rulemaking/opt-revise.html (same).

[245] *See, e.g.*, NRC, Commission Papers (SECY), available at http://www.nrc.gov/reading-rm/doc-collections/commission/secys/. It is not clear from NRC's website whether "SECY" is an acronym or simply the proper name for the papers.

options for the regulatory project in question.[246] SECY papers used to be extremely long and detailed. As these staff analyses generally grew in size and became increasingly complicated, the Commission demanded that they be shorter and more succinct. SECY papers now are relatively short and to the point,[247] although the technical rulemakings often include multiple attachments.[248] In some cases, documents are also included in the record that either precede or follow issuance of the SECY papers.[249]

4. *Draft proposal.* If the Commission decides to move forward, it directs the staff to draft a proposed rule and also a preamble, which is termed a "Statement of Consideration."[250] This draft Statement of Consideration is deliberative and the Commission therefore does not, at least initially, make it available to the public.[251] The proposed rule and its accompanying Statement of Consideration are circulated internally to the Office of General Counsel (OGC) for legal concurrence.[252] Once OGC states that it has "no legal objection" to this package of documents, they are then submitted to the Commissioners, who may edit and revise the documents. The Commissioners' alterations to the draft proposed rule and Statement of Consideration are also considered part of the deliberative process and are therefore exempt from public release, although the Commissioners' decisions on staff papers are made public.[253]
5. *No OMB Clearance.* Because the NRC is an independent agency, the proposed rule does not need to be cleared through OMB. OMB's role is limited primarily to its statutory responsibilities in authorizing information collection requirements under the Paperwork Reduction Act[254] and in determining whether an NRC

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[246] Interview with NRC Staff, Office of General Counsel, Nov. 15, 2011. For samples, *see supra* note 241. *See also* U.S. NRC, Proposed Security Rulemaking for Independent Spent Fuel Storage Installations, last updated on September 16, 2011, available at http://www.nrc.gov/about-nrc/regulatory/rulemaking/potential-rulemaking/isfsi-security.html; U.S. NRC, Docket Folder Summary, No. NRC-2010-0012, available at http://www.regulations.gov/#!docketDetail;rpp=10;so=ASC;sb=postedDate;po=0;D=NRC-2010-0012; U.S. NRC, Docket Folder Summary, No. NRC-2010-0075, available at http://www.regulations.gov/#!docketDetail;dct=SR%252BFR%252BPR;rpp=10;po=0;D=NRC-2010-0075.

[247] Interview with NRC Staff, Office of General Counsel, Nov. 15, 2011.

[248] *Id.*

[249] *See, e.g.*, US. NRC, Docket Folder Summary, No. NRC-2011-0012, available at http://www.regulations.gov/#!docketDetail;dct=FR%252BPR%252BN%252BO%252BSR;rpp=10;so=ASC;sb=postedDate;po=0;D=NRC-2011-0012; U.S. NRC, Docket Folder Summary, No. NRC-2010-0075, available at http://www.regulations.gov/#!docketDetail;dct=SR%252BFR%252BPR;rpp=10;po=0;D=NRC-2010-0075; U.S. NRC, Docket Folder Summary, No. NRC-2010-0012, available at http://www.regulations.gov/#!docketDetail;rpp=10;so=ASC;sb=postedDate;po=0;D=NRC-2010-0012.

[250] Interview with NRC Staff, Nov. 2011.

[251] *Id.*

[252] *Id.*

[253] Statement of NRC Staff, Feb. 1, 2012. For the Commission decisions, see the Staff Requirements Memoranda recording these decisions, available by data at http://www.nrc.gov/reading-rm/doc-collections/commission/srm/.

[254] 44 U.S.C. § 3501, et seq.

regulation constitutes a "major rule" under the definition section of the Congressional Review Act.[255]

6. *Notice and comment and possible external peer review.* The proposed rule is published in the Federal Register and is subject to notice and comment. It might also be subject to external peer review, particularly if it falls under the jurisdiction of one of the Commission's expert advisory panels.
7. *Final rule.* The development of the final rule follows an internal review process very similar to the one outlined in the steps above and is published in the Federal Register.[256]

The Availability of Initial, Staff Analyses

Most of NRC's technical analyses are contained, or at least summarized, in the SECY papers, which provide the equivalent of EPA's staff analyses.[257] In virtually all cases, except when the papers expose personnel, proprietary information, or security

[255] 5 U.S.C. § 804(2). NRC's Office of General Counsel report that "neither OMB nor the White House has served as a general-purpose editor/reviewer of NRC regulations (in contrast to their review of regulations from Executive agencies). Nor does OMB resolve disputes between the NRC and other agencies with respect to the issuance of NRC regulations." Statement of NRC Staff, OGC, Jan. 25, 2012.

[256] Interview with NRC Staff, Nov. 2011.

[257] The importance of these staff analyses as providing a backdrop and information foundation to Commission decisions is reinforced by a decision-making structure that attempts to maintain a relatively strict separation between the Commissioners and the general NRC staff (those staff who do not serve Commissioners directly). While there is still give-and-take between staff and Commissioners, NRC processes are relatively hierarchical and arranged to generally make it clear where staff analyses leave off and the Commissioner decision-making begins.

There have been some interactions that potentially blur these traditionally distinct roles of staff versus the Commissioner, however. Paralleling the Julie MacDonald scandal in DOI, see supra, there are current allegations that Commission Chairman Jackzo pressured staff on at least one occasion to withhold and/or "clear" a SECY paper through him before the paper could be shared with the other Commissioners. While the staff papers at issue were not concerned exclusively with technical issues, the unorthodox process of intervening in communications between the staff and other Commissioners set off a firestorm within NRC. As discussed below, the noncurrence process brought some of these staff-management disagreements to light. These allegations of interference have triggered an OIG report, *see* NRC OIG, "NRC Chairman's Unilateral Decisoin to Terminate NRC's Review of DOE Yucca Mountain Repository License Application," Report No. 11-05 (Jun. 6, 2011); a congressional hearing, *see* House Committee of Oversight and Government Reform, "Hearing on 'The Leadership of the Nuclear Regulatory Commission'", Dec. 14, 2011, available at http://oversight.house.gov/index.php?option=com_content&view=article&id=1536:12-14-2011-qthe-leadership-of-the-nuclear-regulatory-commissionq&catid=12&Itemid=1; an investigative report authored by Congressman Darrell Issa (R-CA), *see* Majority Staff Report, U.S. House of Representatives, Committee on Oversight and Government Reform, "A Crisis of Leadership" (Dec. 13, 2011), and media coverage. A report by Congressman Ed Markey (D-MA) attempts to rebut the allegations. *See* Edward J. Markey, Regulatory Meltdown (Dec. 9, 2011). See also Appendix D, nonconcurrence statement on Yucca Mountain; Press Release, Barbara Boxer, U.S. Sen., Boxer Opening Statement on NRC Hearing, December 15, 2011, available at http://epw.senate.gov/public/index.cfm?FuseAction=Majority.PressReleases&ContentRecord_id=426c2a48-802a-23ad-432a-c3b0a1258452&Region_id=&Issue_id.

information, SECY papers are available to the public.[258] Outsiders interested in NRC policies can thus track the scientific assumptions and use of the technical literature in virtually all NRC rulemakings by comparing the staff report (and potentially other technical documents) with the proposed rule. The NRC also generally includes other technical documents and reports in its public docket before the proposed rule is published.

Attribution and Authorship

NRC does not appear to give attribution or authorship rights to the staff preparing the staff SECY papers. A review of SECY papers in recent years reveals that the papers are signed by higher level supervisors, without acknowledgement or attribution to staff.[259] Presumably this practice is intended to signal to the Commissioners that the papers have been reviewed rigorously within the agency and approved (and hence) signed by a higher-level supervisor. Perhaps like the FWS, the tendency to resist staff attribution is thus balanced against the need to provide the decision-makers with a document that formally represents the agency's final technical position on a particular matter. It is not clear, however, whether listing the individual staff as contributors or in an acknowledgement section would impede these goals. At the same time this gesture towards authorship could produce countervailing benefits, a possibility that is considered again in the analysis section.

Availability of the Supporting Literature

To supplement the references cited in the preamble of the proposed rule, the NRC maintains a public database (Agency wide Documents Access and Management System or ADAMS) that is available on its website. The documents cited in the literature reviews for SECY Papers and other technical documents are, according to NRC staff, generally available in this docket or on ADAMS.[260]

b. Overview of NRC's Licensing Renewal Decisions

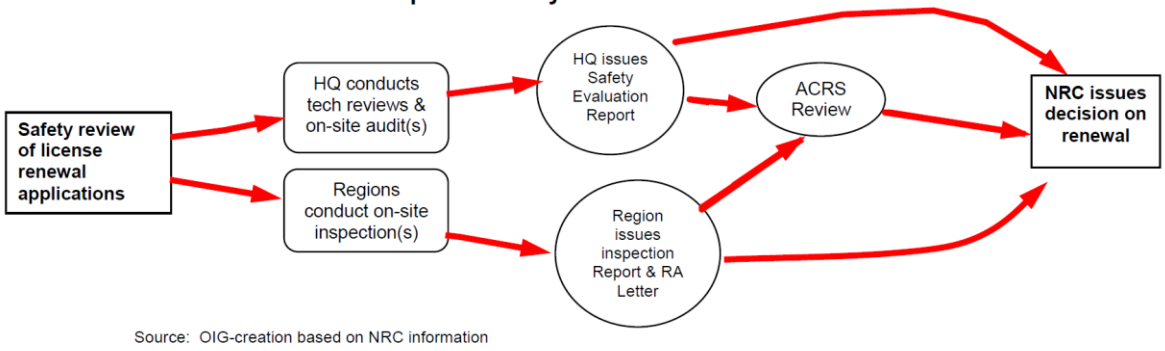
Public interest stakeholders identified NRC's licensing process, such as the licensing renewal process, as more problematic in ensuring rigorous and transparent regulatory products as compared with NRC's informal rulemakings. While an examination of NRC's entire licensing program is beyond the scope of this study, two

[258] U.S. NRC, Commission Papers (SECY), last updated on January 9, 2012, available at http://www.nrc.gov/reading-rm/doc-collections/commission/secys/. The NRC website also provides an accessible portal to these SECY papers. *Id.* See also Statement of NRC Staff, Feb. 1, 2012.
[259] This statement is based on a review of ten different SECY papers posted in 2011 at http://www.nrc.gov/reading-rm/doc-collections/commission/secys/.
[260] Statement of NRC Staff, Feb. 1, 2012.

Office of the Inspector General (OIG) reports deserve mention because they document problems with the NRC's use of technical information.[261]

NRC must renew some operator licenses and make amendments to other licenses over time and as the need arises. With regard to license renewal, although a nuclear reactor operating license expires in forty years, NRC can extend this license for an additional twenty-years if it believes the plant can continue to be operated safely.[262] NRC has developed technical directions for reviewing these license renewal applications.[263] NRC's flow chart for this decision-making process is provided below. [264]

Figure 1
Simplified Safety Review Process



Source: OIG-creation based on NRC information

The OIG's review, which focused on the second and third steps (columns) of Figure 1 (i.e., the staff's technical reviews, on-site inspections and audits, and resulting staff evaluation reports and letters), found the staff analyses to lack scientific and technical rigor.[265] For example, more than thirty-five percent of the more than 450 passages examined by the OIG lacked specific support for the conclusions or a mention of the methodology used to conduct the technical review,[266] and more than sixty percent of the passages simply repeated the operators' technical and factual assertions in support of staff conclusions, without any indication of independent validation.[267] OIG found that the lack of guidance to staff in conducting the assessments, coupled with inadequate quality control, to be at the root of much of this lack of rigor and transparency in the NRC's safety evaluations.[268] The OIG also found that inspectors and auditors were

[261] The first of these two reports was mentioned by a public interest stakeholder in interviews as representative of larger problems at the NRC. Interview with Staff, Beyond Nuclear, Jan. 23, 2012.
[262] 10 C.F.R. Part 54.
[263] See OIG, Audit of NRC's License Renewal Program, Sept. 6, 2007, at 1 (summarizing these regulations).
[264] *Id*. at 3.
[265] The OIG performed a content analysis of randomly selected audit reports, inspection reports, and safety evaluation reports in license renewal applications over a six-year period. *Id*. at pp. 45-47 in Appendix C.
[266] An explicit methodology was also found lacking for the post-renewal inspection process. *See id*. at 29.
[267] In addition, less than three percent of the passages contained detailed information to support the conclusions. *Id*. at 46-47.
[268] *Id*. at 11-13. The NRC auditors and inspectors also were not instructed on how and whether to seek verification of operator-supplied information, and thus they tended to accept this operator-supplied

prohibited from removing operator documents on-site, which made it more difficult for them to conduct the analysis and write the report.[269] This prohibition also made it effectively impossible for others in or outside the agency to validate or even spot-check the quality of these foundational reports used to renew licenses for aging reactors.[270]

A second OIG report is less overtly critical of the technical rigor and transparency of NRC's licensing decisions, but identifies similar types of problems in NRC's safety evaluations of the operators' applications for license amendments.[271] In reviewing these license amendments, the OIG found that NRC's licensing process was not supported by sufficient documentation or validation of the applicant's statements.[272] While the OIG found no instances of flawed safety evaluations, the underlying absence of documentation would seem to limit the OIG's ability to evaluate whether the safety evaluations were in fact robust and reliable.

Public stakeholders suggested that NRC's incomplete documentation and explanation of its methods and technical conclusions, spotlighted in these two OIG reports, has been a continuing source of concern, not only in licensing decisions but in its enforcement of regulations.[273] In essence, these concerns translate to a lack of rigor and transparency in the documentation and explanation of agency decisions. In the case of license renewals and amendment decisions, moreover, it is difficult to imagine how the public or even those within the agency could oversee the licensing decisions when the

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information without critical scrutiny. There were various examples in the OIG report of how this information required cross-checking and follow-up inquiry regarding past lapses in operator performance, *Id.* at 18-23, and how accepting the operators' generic statements missed a number of important safety concerns.

[269] *Id.* at 14-17

[270] *Id.*

[271] U.S. Nuclear Reg. Comm'n, Review of NRC's License Amendment/Safety Evaluation Process, September 18, 2001, available at http://pbadupws.nrc.gov/docs/ML0127/ML012770353.pdf. The OIG report was commissioned by Congress in 2000 after the failure of a steam pipe that had been approved one year earlier. *Id.* at 1. Since nuclear reactor licenses are very specific, virtually any change to a plant, even simple changes in the organizational chart, requires an approval of an amendment to a license. At the time of the OIG report, in 2001, the NRC was receiving 1,500 applications per year for the review and approval of these amendments. *Id.* at 1.

[272] Specifically, the OIG found that NRC's "process does not provide adequate controls to ensure that all process steps are completed and supported by adequate documentation." *Id.* at i-ii. The OIG did note, however, that the NRC's assessment process was "well-thought out, thorough and provides all the necessary steps for ensuring the staff perform the required technical reviews," id. In their examination of four requested amendment approvals, for example, NRC staff had failed to provide any documentation for "defin[ing] regulatory requirements, policies [and] applicable precedents." In three of the four cases, there was no documentation for the step "Notify public and complete no significant hazards signification." *Id.* at 6.

[273] *See, e.g.*, Inspector General, NRC's Regulation of Davis-Besse regarding Damage to the Reactor Vessel Head, Dec. 30, 2002, at 14 (describing the failure of NRC to document its controversial decision to reverse course and decline to shut down Davis-Besse in light of evidence of significant safety concerns); *see also* GAO, NRC Needs to More Aggressively and Comprehensively Resolve Issues Related to the Davis-Besse Nuclear Power Plant's Shutdown, May 2004.

underlying documents are not available and the methods and technical bases for the conclusions are generally not explained.

c. External Peer Review

Science advisory groups appear to play an important role in a number of NRC rulemaking processes. In some cases these groups even have the authority to suggest projects and comment on NRC's priorities. Although it is not clear whether the advisory groups are realizing their full potential in ensuring that NRC's use of science is rigorous and transparent, their heavy engagement in NRC's work[274] suggests that they are a critical feature of the decision-making structure, at least for science-intensive issues.[275]

In some rulemaking settings and in virtually all license decisions, peer review by one of the two expert advisory groups is required by statute.[276] In other cases, NRC requests an existing expert advisory group to review a rule or otherwise provide guidance on a regulatory project. In either case, when this review of a rulemaking occurs, the review is generally conducted by either the NRC's Advisory Committee on Reactor Safeguards (ACRS)[277] or the Advisory Committee on Medical Uses of Isotopes (ACMUI), both of which are chartered under FACA.

The advisory group with the most expansive jurisdiction is ACRS, which was established by the Atomic Energy Act of 1954 to provide advice to the NRC on licensing, with particular attention to nuclear reactor safety.[278] NRC by rule has charged ACRS with a number of responsibilities.[279] Among these responsibilities is the mandatory

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[274] Members also commit to considerable service on these committees. ACRS requires 100-120 days a year from each member, with full committee meetings running three days and with 2-3 subcommittee meetings each month. Interview with NRC Staff, Oct. 26, 2011.

[275] *See* Roland Frye, The United States Nuclear Regulatory Commission's Use of Scientific and Technical Advisory Committees, Dec. 2011, at Appendix B.

[276] As detailed below, the jurisdiction of these two advisory groups is focused on the topic areas denoted in their respective names, although the ACRS in particular appears to have an increasingly expansive jurisdiction, which now includes radioactive waste. *See Id.* at 3. In cases where there is not a requirement for peer review, NRC staff and the Commission can still assemble a panel of independent reviewers or experts who are not full-time employees of the NRC for these other regulatory projects. It is not clear whether or how often this type of additional peer review occurs or whether the experts are convened under FACA, however. Interviews also revealed that for at least some of these more specific issues, it was difficult to identify neutral reviewers (this is a problem that EPA staff also suggested could occur in pesticide peer review). Interview with NRC Staff, Office of General Counsel, Nov. 15, 2011. As mentioned at the end of this report, however, the challenges associated with developing robust peer review are left for future ACUS projects.

[277] The ACRS is comprised of a maximum of fifteen members, who consist primarily of academics, scientists and regulated parties in the private sector with diverse, relevant expertise. Interview with NRC Staff, Oct. 26, 2011. Members are selected to provide broad expertise, and some attention is also given to ensuring that at least some members have actual operational experience. *Id.*

[278] 42 U.S.C. § 2039. For fuller discussion of the creation and history of this advisory committee, see Frye, *supra* note 275, at 3-5.

[279] 10 C.F.R. § 1.13 (listing the responsibilities). The responsibilities include, for example, reviewing and reporting on "[e]ach application for a construction permit or an operating license for a facility which is of a

review of all informal rules on nuclear safety. ACRS typically reviews the proposed rules either after public comment or simultaneously with public comment and then again, as an optional matter, once the final rule is drafted.[280] NRC staff typically provides a written response to each of the advisory committee's comments, although historically this was not always the case.[281] Both the ACRS review and staff responses are generally placed in the public record.

Over the more than 50 years of interaction between ACRS and NRC staff, there have been some vigorous disagreements. [282] In several cases, in fact, the NRC staff did not agree with or accept ACRS' recommendations.[283] Interviewees report, however, that ACRS has never disagreed with staff with regard to the granting of a license or construction permit.[284]

Beyond its formal role in reviewing staff rules, technical documents, and licenses, the ACRS also reports to the Commission at least annually.[285] The ACRS may also, on its own initiative, "conduct reviews of specific generic matters or nuclear facility safety-related items."[286] It may even recommend that the Commission initiate a rulemaking – a formal recommendation that requires a response from the Commission in 90 days.[287] ACRS's scope of powers thus appears quite expansive and may be broader than EPA's CASAC.

The second advisory committee, ACMUI,[288] plays an important but narrower role in NRC decision-making as compared with ACRS. ACMUI was created an NRC

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type described in [10 CFR] 50.21(b) or 50.22, or for a testing facility." *Id.* at § 50.58(a). NRC regulations also require the staff to involve ACRS in informal rulemakings regarding nuclear safety. NRC, Final Rule, ACRS Participation in NRC Rulemaking, 46 Fed. Reg. 22,358 (1981), *as amended*, NRC, Electronic Availability of NRC Public Records and Ending of NRC Local Public Document Room Program, 64 Fed. Reg. 48,948 (1999).

[280] Interview with NRC Staff, Office of General Counsel, Nov. 15, 2011. For technical rules, the ACRS either reviews proposed rules and provides detailed comment simultaneously with public comment or it provides its review on the proposed rule after the NRC has responded in a draft to public comment. *Id.* ACRS also reviews license decisions, including license renewals, based on the staff's safety reports. These ACRS reviews can be detailed and are always part of the public record. *Id.*

[281] *Id.*

[282] *See* Frye, *supra* note 275, at 6-7.

[283] For instance, in 1959, the ACRS adamantly opposed a staff recommendation regarding standards for locating nuclear power reactors in or near population centers. Similarly, in 1965, the ACRS opposed a related recommendation by the regulatory staff to prohibit the location of power reactors in metropolitan areas. *Id.* at 7.

[284] Interview with NRC Staff, Oct. 26, 2011.

[285] 10 C.F.R. § 1.11(c); Interview with NRC Staff, Oct. 26, 2011. For example, the ACRS makes occasional oral presentations directly to the Commission. *See* Frye, *supra* note 275, at 7.

[286] 10 C.F.R. § 1.13.

[287] *Id.* at § 2.809.

[288] Members of ACMUI come from diverse sectors and appear selected to ensure broad disciplinary representation. Although they were originally expected to include only physicians and scientists, disciplinary representation is much broader in practice. *See* Frye, *supra* note 275, at 10.

regulation[289] and reports to staff as needed on medical questions that are referred to it.[290] The Commission may also request advice and expert opinions from this body.[291] The ACMUI receives informational copies of all proposed regulations under its purview,[292] yet unless specifically requested, the ACMUI is not expected to conduct reviews of these rules, although it is allowed to do so. Like the ACRS, there are occasions on which ACMUI and NRC staff disagree on key issues.[293]

Since the 1980's, the NRC has also employed expert elicitation to develop expert recommendations on particularly difficult technical issues.[294] Unlike peer review or expert advisory boards that comment on technical analyses, expert elicitation involves the selection of experts who attempt to arrive at empirical estimates based on very limited information and often in circumstances where even computational models cannot be developed to handle relevant variables in a robust way.[295] Roland Frye has prepared a memo providing a detailed analysis of that program, which is included in Appendix B.

B. Agency Efforts to Improve the Scientific Integrity of their Processes

In recent years, the suppression and editing of staff technical analyses by political appointees in ways that substantially change the analyses have received a great deal of attention.[296] Much like the more general criticisms of agency transparency, however, these politicization problems with agency science are not well characterized. To be sure, there are publicized accounts of staff suppression and the editing of technical memoranda by agency management in ways that alter the characterization of the scientific information, but they are relatively few in number.[297] Likely more pervasive, but even more difficult to document, are concerns by agency personnel and outsiders that there is a risk of group think and the discouragement of dissenting views in some agency settings. This type of group think or top-down narrowing of acceptable views may not be

[289] 10 C.F.R. § 1.19(a).
[290] Interview with NRC Staff, Office of General Counsel, Nov. 15, 2011; Interview with NRC Staff, Oct. 26, 2011.
[291] *Id.*
[292] Interview with NRC Staff, Office of General Counsel, Nov. 15, 2011.
[293] *See* Frye, *supra* note 275, at 11-12.
[294] Roland Frye, Use of Expert Elicitation at the Nuclear Regulatory Commission, Feb. 16, 2012, included as Appendix B.
[295] NRC identifies expert elicitation as "a well-recognized technique for quantifying phenomenological knowledge when modeling approaches or data are insufficient." NUREG-1829, Vol. 2, Estimating Loss-of-Coolant Accident (LOCA) Frequencies through the Elicitation Process: Appendices A through M (Apr. 2008) (ML081060300), at v (cited in Frye, *supra* note 294, at 1).
[296] *See, e.g.*, *supra* note 6; Testimony of Jeff Ruch, PEER, Endangered Species Act Implementation: Science or Politics, before the House Natural Resources Committee, May 9, 2007, available at http://www.peer.org/news/news_id.php?row_id=854.
[297] *See, e.g.*, Doremus, *supra* note 6; OIG MacDonald Report, *supra* note 10.

malicious or even conscious, but if it occurs it can impair the quality of the underlying technical analysis by limiting the vigorous skepticism afforded the agency's analysis.[298]

The President's directive on scientific integrity identifies all of these scientific challenges, but it focuses most intently on the need to halt the overt manipulation of agency science by supervisors and political appointees. [299] According to one former Office of Science and Technology Policy (OSTP) official, there was strong support within all the agencies for this narrower focus. Agency scientists were purportedly "jubilant" at the prospect of finally addressing this issue formally within the Executive Branch.[300] Not surprisingly, the agencies' science integrity guidelines promulgated in response to the President's and OSTP's directives primarily address the "science politicization" problem and defer or only lightly address the challenge of encouraging diverse views and internal skepticism. In particular, the signature feature of most of these agency and departmental scientific integrity guidelines is the establishment of a scientific misconduct process. A number of agencies' scientific integrity guidelines also include codes of conduct and communications policies, so that agency scientists can publish, speak with the press, and express their views without clearance requirements.[301]

A review of these recent scientific integrity policies, as well as other relevant programs in place at DOI and EPA at the time of the study, is provided below. The final section then considers NRC's approach to these problems, which have been evolving for several decades and have been implemented independently of the recent White House initiative.

1. Scientific Integrity Policies in response to the White House Initiative

a. The Department of the Interior

DOI was the first agency to develop a final science integrity policy in response to OSTP Director John Holdren's memorandum requesting these polices. DOI officials indicate that this integrity policy is only the first in a series of policies that they intend to promulgate to address issues of scientific integrity.[302] DOI is currently working on a

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[298] *See infra* Section IV.B.3.

[299] Interviews with past OSTP employees confirmed that the laser-like focus from the Obama Scientific Integrity directive was on this politicization of science, with less focus on other problems with regulatory science that were known to be problematic, including regulatory review, the quality of regulatory science, and how to set policy on scientific communications from an agency. Interview with former OSTP employee, Feb. 14, 2012; Interview with former OSTP employee, Jan. 23, 2012.

[300] Interview with former OSTP employee, Jan. 23, 2012.

[301] *See generally* OSTP, Scientific Integrity Policies Submitted to OSTP, available at http://www.whitehouse.gov/blog/2011/08/11/scientific-integrity-policies-submitted-ostp.

[302] Interview with Department of Interior Staff, Aug. 29, 2011. There was some internal disagreement about the strategy of developing guidelines that addressed only one issue at a time. A decision was ultimately made to start with the low hanging fruit and gradually develop policies on these other, more difficult areas as consensus builds. Without this more incremental approach, there was also a concern

communications policy in response to the scientific integrity initiative and has plans to address a succession of other issues over time.[303]

The goal of DOI's current integrity policy, which is focused primarily on policing misconduct and establishing codes of conducts, is to provide agency scientists with autonomy and the support of the organization if they believe they have been coerced or otherwise bullied in ways that go beyond basic minimum standards of scientific integrity.[304] The hope is that this policy will allow problems within the Department to be identified and corrected at an early, internal stage of the deliberations, before they grow into larger public controversies.[305]

In its initial scientific integrity policy, DOI has established a relatively elaborate scientific misconduct process.[306] Under the policy, DOI staff and outside parties can make allegations of scientific misconduct against a staff or official within DOI.[307] The scientific misconduct process thus provides a mechanism that is new to DOI policy for formally reporting and punishing scientific fabrication, including editing technical reports in ways that are not supported by the evidence.[308] While the definition of misconduct is relatively narrow and includes only intentional or reckless "fabrication, falsification, or plagiarism" in scientific activities,[309] DOI's policy also encompasses "intentionally circumventing policy that ensures the integrity of science and scholarship" or in ways that "compromise scientific and scholarly integrity."[310]

DOI's process involves the initial submittal of a non-anonymous allegation of misconduct by anyone, including persons outside the agency.[311] If the allegation is

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about paralysis and/or extended delays in which the DOI would operate with absolutely no integrity guidelines in place. *Id.*

[303] *Id.*

[304] *Id.*

[305] *Id.*

[306] Department of Interior, Departmental Manual 305 DM 3, Jan. 28, 2011, available at http://www.whitehouse.gov/sites/default/files/microsites/ostp/DOI-DM-sci-integ.pdf [hereinafter DOI Scientific Integrity Guidelines]. A critical OIG report, published in April 2010, undoubtedly provided an added urgency; this April 2010 report focused exclusively on the failure of the DOI to develop a scientific misconduct program and was published only one year after the large, OIG investigation of the Julie MacDonald case. OIG, DOI, Evaluation Report: Interior Lacks a Scientific Integrity Policy, Report No. WR-EV-MOA-0014-2009 (April 2010).

[307] DOI Scientific Integrity Guidelines, *supra* note 306.

[308] DOI's misconduct provisions borrow from the HHS, Office of Research Integrity regulations on scientific misconduct, 42 C.F.R. Part 93. It may be the case that at least some of the DOI's integrity regulations were overdue. In 2000 OSTP issued a policy requiring federal agencies to adopt scientific misconduct regulations following ORI's model for extramural and intramural research. *See* http://ori.hhs.gov/federal-policies. The extent to which DOI's 2011 policy simply satisfies this earlier 2000 command would benefit from further research.

[309] DOI Scientific Integrity Guidelines, *supra* note 306, at 3.5M; *see also id.* 3.8A (adding the intentional and reckless requirement and cautioning against using the process for honest differences of opinion).

[310] *Id.*

[311] *Id.* at 3.8A(1).

determined to be credible, then an inquiry will be conducted.[312] If it is ultimately determined that intentional or reckless misconduct occurred, then sanctions – spanning the range from termination to reprimand – may be issued.[313] As mentioned, DOI's integrity policy also offers codes of conduct and principles to guide staff behavior, although these objectives do not appear enforceable.[314]

DOI's scientific integrity policy has been criticized by several public interest groups for failing to establish a public tracking system for the misconduct complaints filed in the Department.[315] DOI has also been criticized for failing to address other important science integrity issues in its first set of guidelines, such as enhanced whistleblower protections.[316] DOI admits that its first policy has a limited range in

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[312] This inquiry is conducted by the Department or Bureau Scientific Officers working with the responsible manager and an assigned Servicing Human Resources Officer. *See id*. at 3.8B through F

[313] Sanctions are issued at the discretion of by the manager and the Servicing Human Resources Officer. *See id*. at 3.8G. DOI is currently developing a training and outreach program to educate staff about the program and how they can report misconduct within the Department. Interview with Department of Interior Staff, Aug. 29, 2011. Within the Department, there is a collaborative learning network (not available to those outside the agency) that provides staff with an online training tool, including case studies and other features. The training is considered a key feature of the new integrity initiative at DOI. *Id*. Presumably broad outreach also helps deter abuses of scientific integrity within the agency by advertising the potentially high costs of this abuse.

[314] For example, one provision directs staff to "[d]ocument the scientific and scholarly findings considered in decision making and ensure public access to that information and supporting data through established Departmental and Bureau procedures – except for information and data that are restricted from disclosure under procedures established in accordance with statute, regulation, Executive Order, or Presidential Memorandum." DOI Scientific Integrity Guidelines, *supra* note 306, at 3.4.C. Other, even more ambitious (but unenforceable) goals include a requirement that employees commit to "clearly differentiate among facts, personal opinions, assumptions, hypotheses, and professional judgment in reporting the results" and to "fully disclose methodologies used, all relevant data, and the procedures for identifying and excluding faulty data." *See id.* at 3.7A.(7) and 3.7.B.(3). *See also id.* at 3.7A.(9) and 3.7.B. (1)-(4). The DOI integrity rules close with guidelines for staff serving on the boards for professional societies. Employees serving in these roles in their personal capacity do not appear to require approval, but they are urged to consult with ethic's officers to ensure their compliance with conflicts of interest and ethical standards. *Id.* at 3.9.B.(1). Approval is required of employees who wish to engage in these activities in their official capacity. *See generally id*. at 3.9.

[315] Interview with Staff, Union of Concerned Scientists, June 28, 2011; Interview with Staff, PEER, July 27, 2011; Interview with Department of Interior Staff, Aug. 29, 2011. Currently, all of the misconduct proceedings remain internal to the agency and are not publicly available or summarized. Interview with Department of Interior Staff, Aug. 29, 2011. DOI defends its position as necessary to protect the confidentiality of the accused and as a way to encourage employees to feel freer to identify problems early in the process, before they become media events. *Id.*

[316] Stakeholders argue that a fundamental mechanism for ensuring that the misconduct program will actually be utilized is the institutionalization of parallel protections for complainants through heightened whistleblower protections. Without heightened protections against retaliation, there are substantially reduced incentives for employees to report misconduct and a corresponding risk that the complaint process will be underutilized. See, e.g., Statement of Francesca Griffo, UCS, Interior Department's New Scientific Integrity Policy Must Trigger Significant Changes To Be Effective, Feb. 1, 2011, available at http://www.ucsusa.org/news/press_release/interior-departments-new-SI-policy-0495.html. Even in universities, incidents of research misconduct are grossly under-reported, presumably because of scientists' fears of retaliation as well as a perception of being viewed as non-collegial. See, e.g., Bob Montgomerie & Tim Birkhead, *A Beginner's Guide to Scientific Misconduct*, 17 ISBE Newsletter, May 2005, at 16. Finally, the public interest groups have criticized DOI for failing to adopt a more liberal communications

addressing problems of scientific integrity.[317] However, DOI officials maintain that if one must start with the most serious problems, this policy is a first, strong step in the right direction.[318]

It is worth noting that after publication of the DOI policy, the National Oceanic and Atmospheric Administration (NOAA) published a parallel scientific integrity policy that is generally viewed as similar, but more beneficial.[319] Although NOAA is not within the three agencies under study here, because its guidelines build heavily on DOI's guidelines, and because they are viewed by public interest groups as considerably more effective, they are discussed briefly in closing.[320] NOAA's policy, like DOI's, establishes a scientific misconduct program,[321] but NOAA ultimately departs from DOI's policy in several important ways. First, NOAA commits to an annual, public reporting of misconduct allegations and proceedings occurring within the agency.[322] This addresses

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policy that allows Department staff and officials to publish studies or speak with the media. They point to the FWS's more liberal publication policies, which allow FWS to speak openly provided they include a disclaimer that they are not speaking for the agency. FWS allows its scientists to publish without management approval provided they add a sentence that the contents "do not necessarily represent the views of the U.S. [FWS]." Fish and Wildlife Service, Information and Expression: Part 117 Communicating Scientific Information, January 26, 2010, at § 1.4, available at http://www.fws.gov/policy/117fw1.pdf. The FWS' policies, they maintain, should serve as an example of what the entire Department of Interior should develop for staff scientists. DOI officials indicate that they are currently working on such a policy. Interview with Department of Interior Staff, Aug. 29, 2011.

[317] Specifically, misconduct is narrowly defined. Suppression of science and even bullying of staff to alter their findings or analysis might not be covered by the policy if these acts are not clearly intentional or reckless, yet these negligent acts are likely to be more prevalent than outright misconduct. The policy also does nothing to encourage good faith disagreements and debates among scientists within the Department.

At the time of this report, there was only one known allegation and it was filed by PEER, a watchdog group, based on personnel actions taken against a scientist researching the Arctic polar bear (dubbed Polarbeargate). Suspended Polar Bear Research Defended by Advocates, ScienceInsider, July 29, 2011, available at http://news.sciencemag.org/scienceinsider/2011/07/suspended-polar-bear-researcher.html. This incident is still under investigation by the Department's OIG. For a recent critical account of that investigation, see PEER, Polar Bear Probe Careens in New Directions, Oct. 26, 2011, at http://www.peer.org/news/news_id.php?row_id=1527. The allegations in PEER's case do not concern management's manipulation of the technical or scientific analysis, but rather the halting of a research biologist's work without cause and stigmatizing his research through a criminal investigation of undisclosed "integrity" issues. See PEER complaint, available at http://www.peer.org/docs/doi/7_28_11_Scientific_Misconduct_Complaint.pdf.

[318] Interview with Department of Interior Staff, Aug. 29, 2011.

[319] See, e.g., UCS, NOAA Boosts Scientific Integrity with New Policy, Dec. 7, 2011, available at http://www.ucsusa.org/news/press_release/noaa-boosts-scientific-integrity-1357.html. It is not clear why NOAA, rather than the Department of Commerce, developed these guidelines. The most likely answer is that NOAA was determined to put into place integrity guidelines and did not want to wait for the Department's leadership on this issue.

[320] In the development of its scientific integrity policy, NOAA solicited and responded to more than one thousand different, substantive comments on its draft policy. *See* NOAA's Disposition of Comments Received on Draft Scientific Integrity Guidelines 3 (Nov. 21, 2011), available at http://nrc.noaa.gov/Public_Comments_Disposition.pdf.

[321] *See* NOAA Scientific Integrity Policy, NAO 202-736D, Dec. 7, 2011, available at http://www.corporateservices.noaa.gov/ames/administrative_orders/chapter_202/202-735-D.html.

[322] *See* § 10.04 of *id.* ("NOAA's Chief Scientist . . . will provide annual public reporting . . . of the aggregate number of misconduct cases, the areas of concern, the affiliation of the individuals involved, how

some of the most vigorous public interest group complaints regarding DOI's policy. Second, NOAA attempted to draft its policy in a way that not only develops ambitious codes of conduct, but makes them enforceable.[323] Finally, NOAA's integrity policy references a parallel communications policy that should allow agency scientists to speak and publish freely, provided they provide disclaimers when they are not acting in their professional capacity.[324]

b. EPA

In contrast both to NOAA and DOI, EPA has had a scientific misconduct program in place since 2000 (EPA's program was established in response to an OSTP federal policy).[325] A detailed line-by-line comparison of EPA's program with those developed more recently by DOI and NOAA was not attempted in this study, but EPA's program appears relatively complete[326] and the Health and Human Services (HHS) Office of Research Integrity site refers to EPA's program as a finalized program.[327]

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much accusations were investigated, and the number of findings of misconduct."). NOAA staff indicates that ultimately, because of the lack of a Chief Scientist, "the Chair of the NOAA Research Council will make this annual reporting available." Statement of NOAA Staff, Jan. 26, 2011.

[323] Violations must be intentional and reckless and constitute some form of scientific misconduct to be enforceable. *See* §§ 1.01(b) and 8.01 of NOAA Scientific Integrity Policy, *supra* note 321. Nevertheless, NOAA evinces an intent to include as scientific misconduct, violations of its code of conduct. See § 5.01 of *id.* (stating that "[a]ll staff identified in Section [3].02 *must* uphold the fundamental Principles of Scientific Integrity [Section 4], the Code of Scientific Conduct [Section 6], and the Code of Ethics for Science Supervision and Management [Section 7] . . .") (emphasis added); *see also* § 1.01 of NOAA, Procedural Handbook for Scientific Integrity, available at http://www.corporateservices.noaa.gov/ames/administrative_orders/chapter_202/Procedural_Handbook_NAO_202-735D_31Jan_2012.pdf (noting that "[a] finding of Scientific and Research Misconduct requires a determination by the Determining Official"; and under § 1.01(a), the determination is based on significant departures from the Code of Scientific Conduct or Code of Ethics for Science Supervision and Management). Since NOAA's policy contains ambitious principles for its code of conduct, this is an important feature of the guidelines. See NOAA Scientific Integrity Policy, §§ 4-7, *supra* note 321.

[324] *See id.* at § 4.05 (noting that "NOAA scientists may freely speak to the media and the public about scientific and technical matters based on their official work"); *id.* at § 4.06 (stating that "NOAA scientists are free to present viewpoints . . . that extend beyond their scientific findings to incorporate their expert or personal opinions, but . . . must make clear they are presenting their individual opinions").

[325] Apparently, neither NOAA or the DOI complied with this 2000 policy, although presumably their recent programs now satisfy this directive. See HHS, Summary of Agency Misconduct Policies, available at http://ori.hhs.gov/federal-research-misconduct-policy. EPA simply cites to this existing program in its draft guidelines. EPA Scientific Integrity Policy at 10, available at http://www.epa.gov/osa/pdfs/epa_scientific_integrity_policy_20120115.pdf.

[326] EPA Scientific Misconduct Policy, available at http://ori.hhs.gov/sites/default/files/epapolicy.pdf

[327] HHS Summary of Misconduct Policies, available at http://ori.hhs.gov/federal-policies. EPA's misconduct program was criticized in July 2011 by EPA's OIG, however, for inadequate training of EPA staff and insufficient updating and monitoring of the program. *See* EPA Office of Inspector General, Office of Research and Development Should Increase Awareness of Misconduct Policies (July 2011), available at http://www.epa.gov/oig/reports/2011/20110722-11-P-0386.pdf. Although EPA reports that it receives very few allegations of misconduct from within the agency, the OIG warned that this low rate could well be due to this insufficient outreach and training by the agency. *Id*. at 8.

Also in contrast to DOI and NOAA, EPA has not been as diligent in preparing its science integrity guidelines. EPA's guidelines were distributed in draft in August 2011, six months after DOI's guidelines were final.[328] It is worth noting that there are relatively few accounts of overt suppression and scientific manipulation at EPA,[329] at least as compared with DOI's travails.[330] Although it may not fully explain EPA's apparent apathy with regard to complying with the White House's scientific integrity initiative, EPA may in part lack a sense of urgency with respect to this particular problem.

2. NRC's Procedures to Enhance the Scientific Integrity of its Decisions and its Staff

The NRC has had relatively elaborate policies in place for several decades to preserve the scientific integrity of its decision-making process and staff; these policies were thus developed completely independently from President Obama's scientific integrity initiative.[331] The policies include opportunities for the airing and resolution of internal disagreements through informal and formal channels.[332] As elaborated below,

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[328] While the fate of these guidelines is an open question, the draft guidelines are very general and do not appear to create enforceable responsibilities or provide meaningful additions to EPA's existing commitments to scientific integrity, except perhaps for the appointment of a Scientific Integrity Officer and committee within the agency. EPA Scientific Misconduct Policy, *supra* note 326, at 2 and 9-10. EPA's draft policy also seems to studiously avoid offering specifics on communications and whistleblower policies, although there is a reference to the ability of EPA staff to publish and speak to the press, provided they indicate that it does not state the views of the agency. *See id*. at 5.

[329] EPA staff was apparently prevented from conducting an assessment of the adverse consequences of coal ash, for example. Interview with PEER Staff, July 27, 2011. See EPA OIG, Agency Handling of Coal Ash, Sept. 8, 2008, available at http://peer.org/docs/epa/7_18_11_EPA_sci_suppression.pdf; (discussing EPA staff that report that EPA suppressed the risks of coal ash and lacked a robust process for reviewing drafts on the subject posted); see also EPA OIG Audit Report, EPA Promoted the Use of Coal Ash Products with Incomplete Risk Information, March 23, 2011, available at http://www.epa.gov/oig/reports/2011/20110323-11-P-0173.pdf; and PEER press release on the issue. http://www.commondreams.org/newswire/2011/07/18. Sixty Minutes also ran an investigation of these and related issues concerning the lax regulation of coal ash. See video clip at http://www.huffingtonpost.com/2009/10/04/coal-ash-on-60-minutes-un_n_309268.html.

[330] Interview with Former EPA Staff, Dec. 21, 2011. Note that "interference" with EPA science from OMB is, however, considered a potentially significant problem. *See infra* Section IV.A.1.

[331] Recall that as an independent agency, the NRC is not bound by the President's scientific integrity initiative; NRC has in fact indicated it will not issue its own scientific integrity policies in response to the OSTP memorandum. Interview with NRC Staff, Oct. 26, 2011.

[332] Although communications policies and whistleblower protections were not studied here because they are significant enough issues to warrant a separate study of their own, it is worth noting in passing that NRC also appears to have a relatively liberal communications policy. According to interviewees and written (but somewhat ambiguous) policies, members of the NRC staff are allowed to speak with the media and publish their work without clearance, provided they do not ascribe their private views to NRC. Interview with NRC Staff, Oct. 26, 2011. The applicable Directive – Directive 3.9 -- is unclear on this point, however. It suggests clearance is needed to discuss NRC work, but then provides a disclaimer in settings where the publication or speech is not cleared by NRC. *See* NRC Management Directive 3.9 Handbook at 6, available at http://pbadupws.nrc.gov/docs/ML1100/ML110070679.pdf. NRC Management Directive 7.3 Handbook, at 7, available at http://pbadupws.nrc.gov/docs/ML0414/ML041410583.pdf only further muddies the waters. It states "All speeches, papers, or journal articles prepared by an employee for a professional organization that relate to

the NRC's approach to scientific integrity may well provide a model or best practices that could be used by other agencies for a broader range of issues, particularly with respect to encouraging diverse views and skepticism within the government.[333]

a. Encouraging Dissenting and Diverse Views

In order to facilitate the free exchange of ideas from within the agency, NRC has developed an elaborate "Collaborative Work Environment Program." This program consists of three separate policies, two of which are more than three decades old. These cumulative policies are intended to create an environment in which employees can disagree and publicly question decisions by those higher in the chain of command.[334]

Open Door Policy

NRC's first initiative in this program – the open door policy – was initially created in 1976[335] to provide staff with an opportunity to meet with supervisors beyond their immediate supervisor to discuss disagreements over technical issues and other matters.[336] The current directive provides that "[a]ny employee may initiate a meeting with an NRC manager or supervisor, including a Commissioner or the Chairman of NRC, to discuss any matter of concern to the employee."[337] Managers are required to honor an employee's request for confidentiality unless the manager is a Commissioner or unless specific explicit exceptions make the promise of confidentiality impracticable.[338]

NRC technical, legal, or policy issues should be reviewed in accordance with MD 3.9.(a)." This includes information about technical issues unless the information is deliberative or confidential. By contrast, if staff members purport to speak on behalf of NRC, their statements must be cleared through the agency. Management Directive 3.9. Staff members are also encouraged to participate in professional societies and other similar activities, although participation through NRC (under salary) requires supervisor approval. See Handbook for Directive 7.3 at p.6. In cases when employees participate in their private capacity, they may again proffer whatever technical or opinion statements they wish, provided they "make clear to the organization that the views expressed by the employee in the course of participation are not necessarily those of the NRC." *Id*.

[333] The DOE appears to have a differing professionals program as well, at least for technical issues. See DOE P 442.1 "Differing Professional Opinions on Technical Issues". Before concluding that the NRC program provides the most complete model, further research is recommended into both DOE and other agencies not studied in this report.

[334] The NRC has a webpage dedicated to this Collaborative Work Environment Program. The website states that "[i]n some organizations, being a "team player" means accepting management's preliminary views during the decision-making process and not "rocking the boat." Being an NRC Team Player does not mean those things. NRC holds its employees to a higher standard of involvement and responsibility for the decisions that are made." http://www.nrc.gov/about-nrc/values/open-work-environment.html.

[335] NRC Office of Enforcement, Review of the NRC Differing Professional View/Opinion Program, ML082190414, at 1 (2007) [hereinafter DPO 2007 Review].

[336] NRC, Management Directive 10.160, "Open Door Policy", available at http://pbadupws.nrc.gov/docs/ML0414/ML041490186.pdf. The policy indicates it was approved in 1991 and revised in 1997.

[337] NRC, Open Door Policy, Handbook 10.160, at 1, available at http://pbadupws.nrc.gov/docs/ML0414/ML041490186.pdf.

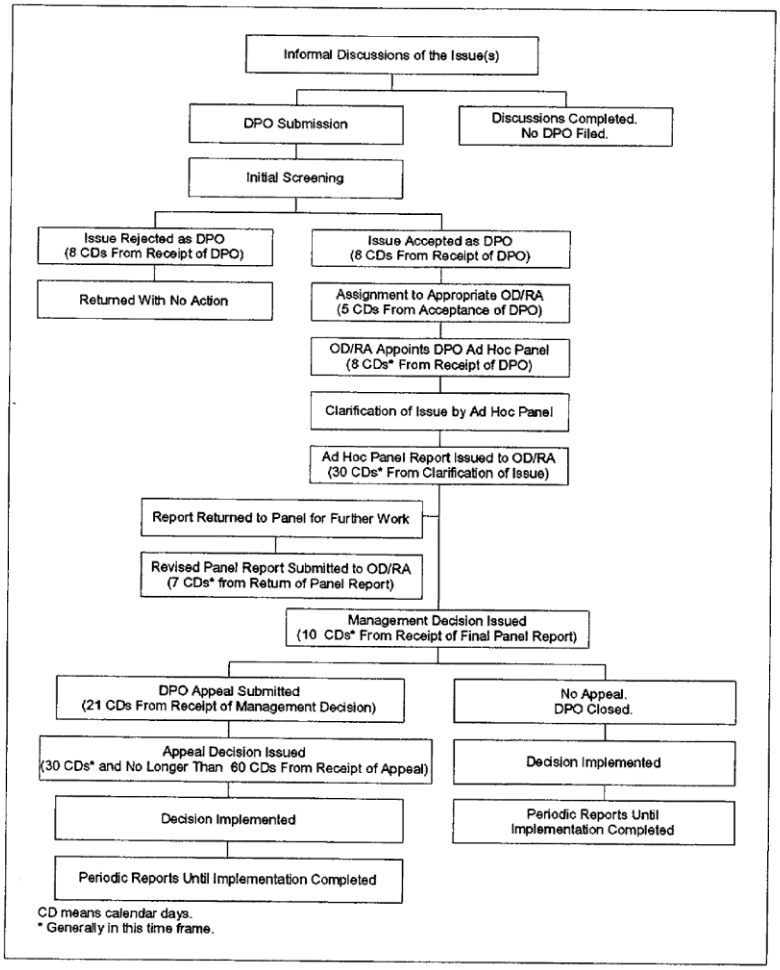
[338] *Id*.

Managers are also prohibited from retaliating against employees who utilize the program.[339] There is no formal tracking of the use of this policy, but there are now relatively vigorous agency efforts to educate staff about its existence.

Differing Professional Opinions

In 1980,[340] NRC developed the "differing professional opinions" (DPO) program[341] to provide a formal process for "expressing differing professional opinions . . . concerning issues directly related to the mission of NRC" and to provide prompt resolution of these disagreements through an impartial review by knowledgeable personnel.[342] Staff members are allowed to prepare formal statements of dissent against decisions that have already cleared staff review and are effectively conclusive decisions of the NRC.[343] The dissent is not only placed in the record, but it is actually adjudicated to determine whether the official position of the agency should be adjusted.[344] This adjustment occurs through a formal hearing as well as an appeal process. A flow chart provides the numerous, discrete steps for the process (CDs=calendar days).[345]

[339] Open Door Policy, Directive 10.160, *id.*, at 2.
[340] DPO 2007 Review, *supra* note 335, at 1.
[341] NRC Management Directive 10.159, Differing Professionals Opinions Program [hereinafter DPO Program]. This Directive indicates it was initially approved in 1999 and revised in 2004.
[342] *Id.* at 1 of Directive.
[343] NRC Management Directive 10.158, Non-concurrence Process, at 1 of the Handbook [hereinafter NCP] ("The DPO Program applies only to positions that are no longer under staff review, and has certain prerequisites and exclusions that do not apply to the NCP."). The DPO process is only available to those who make the case that the issues cannot be resolved through informal channels and also cannot be used to raise grievances covered under other programs. DPO Program, *supra* note 341, at 2 of DPO Handbook (listing "issues that do not qualify" for DPOs). There is a formal screening step that involves culling out the nonqualifying DPOs by NRC staff. *Id.* at 4-5. While there are provisions for protecting the confidentiality of the submitter of a DPO, *id.* at 4, the DPO process is not available to anonymous filers. *Id.* As with the open door policy, users of the DPO program are supposed to be protected from retaliation. *Id.* at 14-15. DPO submitters may also receive a certificate of appreciation at the end of the year for raising issues of concern. DPO 2007 Review, *supra* note 335, at v.
[344] Not surprisingly, the composition of this panel remains controversial in individual case and appears to be a continuing challenge in implementation of the program. *Id.* at 8-9. The DPO submitter recommends potential candidates for this ad hoc panel, but panels are ultimately selected by the Office Director or Regional Administrator of the office of the submitter under guidelines that require one of the panelists to be an employee recommended by the submitter. DPO Program, *supra* note 341, at 6-7 of Handbook.
[345] The figure was copied from *id.* at Exhibit 2. While the DPO process is designed to allow issues to move expeditiously through the agency, in practice the process can take much longer. Generally, the process takes over six months and in at least one case dragged out over nearly two years. DPO 2007 Review, *supra* note 335, at 5 and 10-11. The extended time frame for resolving DPOs is a continuing problem for the program. *See also* NRC OIG, Review of NRC's Differing Professional View/Differing Professional Opinion Program, OIG-00-A-07, Sept. 20, 2000, at 15-17 [hereinafter OIG Report on DPO]. Appeals then can take another six months, more or less. *Id.*



Although the volume of DPOs in NRC is not terribly high,[346] NRC appears to take the program seriously and has struggled over the years to make it credible. An audit report by the NRC Office of the Inspector General in 2000 produced a relatively critical evaluation of the program.[347] The OIG concluded that there was underutilization of the program due to fears of retaliation and a perceived lack of effectiveness of the program.[348] Multiple subsequent assessments of the DPO program,[349] including the NRC

[346] A 2007 assessment by NRC reports that no DPOs were filed in that calendar year, although a handful worked their way through the resolution and appeal process. DPO 2007 Review, *supra* note 335, at v.
[347] The Report was initiated in part based on general reports by NRC employees that they did not in fact feel free to voice dissenting opinions despite the DPO policy. OIG Report on DPO, *supra* note 345, at 3-4.
[348] *Id.* at 9. The OIG found that more than fifty percent of the (27) DPO submitters that OIG interviewed believed that some form of retaliation had occurred after filing a DPO. *Id.* at 18. Additionally, the guidelines for filing DPOs retained the submitter's supervisors in the chain of command, which was problematic in terms of chilling engagement, increasing the risk of retaliation, and impairing the fair resolution of the disagreement. *Id.* at 10.
[349] The agency has conducted its own internal evaluation of the program over the years, including annual reviews. The DPO program requires that NRC conduct an in-depth annual program review, including audits of office and regional performance records. DPO 2007 Review, *supra* note 335, at 3. For a summary of the more extensive reviews of the program, see *id.* at 1. There are some boilerplate similarities

OIG report published in 2000, have resulted in a number of changes to the program following the OIG's recommendations.[350]

Non-concurrence Process

Finally, in 2006 NRC developed a Non-concurrence Process (NCP) that provides a formal mechanism for those in the line of concurrence (and even those employees not in the line but well-versed in the relevant issues) to formally lodge their non-concurrence with draft policies or draft documents.[351] The NCP is a complement to DPO since it applies to decisions that are still in draft and acknowledges that employees will not always concur and thus should be provided with a process to either opt out of concurrence or to file a statement of non-concurrence.[352]

The NRC's NCP process is not as process-intensive as the DPO process. The submitter first drafts a non-concurrence, the non-concurrence is shared with the document sponsor who then describes any action taken, and both forms are then shared with the document signer for his/her consideration.[353]

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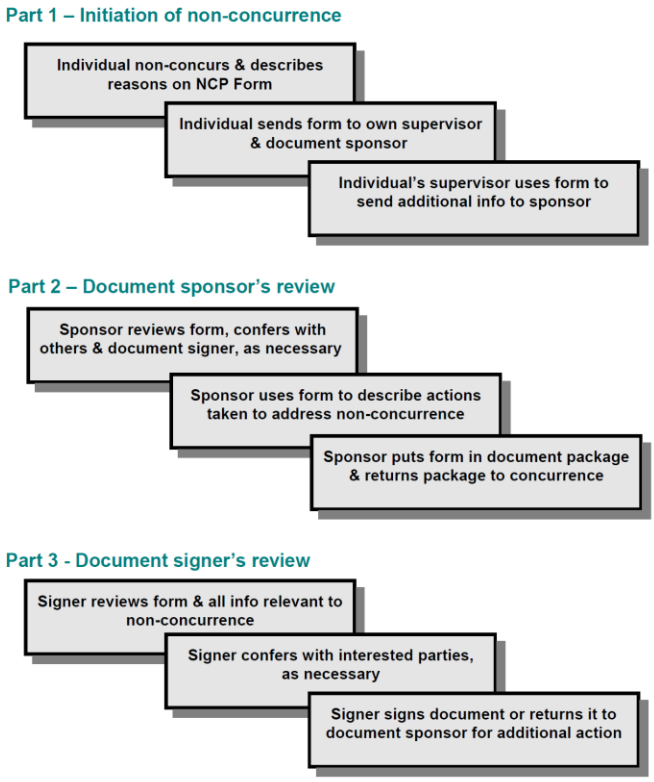
between these annual reports, but the NRC does collate the data from the prior year and summarize at least the nature of the DPOs and their disposition, as well as identify areas for ongoing improvements and reform.

[350] These changes include improving employee understanding of and comfort with the program, broadening the scope and coverage of the protections (e.g., to contractors), and building in more sources of feedback and tracking of the programs. See DPO 2007 Report, *supra* note 335; NRC, Differing Professionals Opinions Program 2006 Program Review, ML071160295 [hereinafter DPO 2006 Report]. Employee outreach and training appear to be the highest priorities. DPO 2007 Report, *supra* note 335, at v; DPO 2006 Report, *id*., at v. To that end, NRC has established DPO liaisons in each office to facilitate use of the program. DPO 2007 Report, *supra* note 335, at 22. In the annual review process, NRC also surveys DPO submitters, panel members, and office members for feedback on the process and includes this information in the annual assessment, *see id.* at 4 and Appendix C, although the results of this information were difficult to trace in the written annual report. NRC annually also provides a brief summary of each of the DPOs that have been filed and their current status in its annual, public report. This information provides a valuable window into the nature of the disagreements that are emerging through this program. See Appendix D and E of the 2007 and 2006 Review reports, *supra* note 335 and *id.,* for example.

[351] NPO, *supra* note 343.

[352] *Id.* at 1 of Handbook. A sample of a Non-concurrence statement is provided at Appendix D.

[353] The Figure is from *id*. at Exhibit 1. *Id*. at 2-3 of Handbook; *see also id*. at 6-11 (providing more complete guidelines on the process).



Retaliation is explicitly discouraged in this policy by threats of disciplinary action in accordance with NRC policy. Employees are also provided a mechanism for submitting grievances if they perceive they have been retaliated against.[354]

[354] *Id.* at 13. A 2010 OIG report on the non-concurrence process identified several ways that the process could be improved. As an introductory matter, OIG noted that the NCP program was still in an interim status, despite the initial intention of NRC to finalize it within a year after adoption (i.e., 2007). OIG Audit of NRC's Non-Concurrence Process, OIG-11-A-02, Oct. 7, 2010, at 1-2, 10, and 28. The OIG also noted that NRC had dedicated very little in the way of staff or resources to either the DPO or NCP programs. "[T]he fiscal year 2010 budget is $3000 for the entire Differing Views Program [Open Door, DPO, and NCP programs], and 1.5 full-time equivalents are designated to collectively support the Differing Professional Opinions Program and the nonconcurrence process." *Id.* at 1. The crux of its review , however, highlighted the need for clearer guidelines for how employees could use the process. OIG reported, for example, that "[i]nterview results revealed that 70 percent of filers, document sponsors, and document signers did not understand their respective rights, roles, and responsibilities in relation to the non-concurrence process as compared to that described in [the NCP] policy." *Id.* at 7. Clearer guidelines and more effective employee training constituted the primary recommendations for remedying the shortcomings in the program. *Id.* at 10-12. OIG noted that the fact that the NCP was suspended in interim status for years may have aggravated these problems since NRC did not develop a tracking system to identify problems during this transitional period. *Id.* at 13-16. This extended interim status may also send a signal to employees that NRC does not take the program seriously.

NRC's Office of Enforcement appears to be addressing each of the recommendations, although the NCP program is still not finalized. *See, e.g.*, Letter from Stephen D. Dingbaum to R. William Borchardt re Status of Recommendations, Sept. 9, 2011; see also Letter from Roy P. Zimmerman, Director of Office of Enforcement to Stephen Dingbaum, July 27, 2011, reporting on status of OE's response to the OIG's

b. Continuing Challenges

The most substantial impediment to NRC's efforts to provide an open workplace stems from employees' concerns about possible retaliation[355] and perhaps a natural inclination of employees to seek to "get along" and not anger colleagues or (even more so) supervisors.[356]

NRC has taken a number of actions to address these concerns, including issuing awards to DPO submitters,[357] publicizing success stories,[358] buttressing its anti-retaliation oversight processes and policies,[359] and attempting to publicize the successes of DPO submitters.[360] The NRC also has policies that deter retaliation by levying sanctions against those who retaliate against another employee for expressing his/her concerns.[361] And NRC offers redress to employees who have been retaliated against.[362]

There is also evidence that the processes are being used. For example, a nonconcurrence filing served as one of the triggers for the recent controversy over NRC Commissioner Chairman Jackzo's management style.[363] Indeed, in his statements in response to a recent congressional investigation, Chairman Jackzo reiterated the usefulness of these submissions, reporting that two DPOs and twelve formal nonconcurrences had been filed within NRC during 2011.[364] While this highly publicized nonconcurrence statement may not be typical, and in any event did not involve disagreements over technical issues, it provides a formal mechanism for staff to publicly question management that appears to be unusual in the federal government.

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recommendations. It appears that NRC also has not developed a tracking system for the non-concurrences and DPOs, and thus the availability of a public tracking system seems even more remote. DPO Review 2007, *supra* note 335, at 11-12. Some of these NCP documents are nevertheless available through searching the ADAMs document retrieval system on the internet. Filers can indicate that they wish their filings to be made public, and it appears that by checking this box, the non-concurrence is then shared more generally through ADAMs (with the appropriate redactions for confidential information). *See* page three of the Non-Concurrence Process Form, NRC Form 757.

[355] In its review, NRC reports that "[t]he OIG 2005 NRC Safety Culture and Climate Survey (referred to as the safety culture survey) found that approximately one-third of employees believe submitting a DPO has a negative effect on career development at the NRC." DPO 2007 Review, *supra* note 335, at 15.

[356] In the controversial decision to over-ride a technical decision that Davis-Besse should be shut down, for example, several employees expressed their support for a [employees don't vote, only Commissioners do that at the NRC] shut-down, but indicated that they did not feel strongly enough to file a DPO. NRC OIG, NRC's Regulation of Davis-Besse Regarding Damage to the Reactor Vessel Head, Dec. 30, 2002, at 13. It is not clear from the OIG report whether they were pointedly asked whether they would file a DPO. It is also not clear what these employees would consider significant enough to warrant filing a DPO.

[357] DPO 2007 Review, *supra* note 335, at 14.

[358] *Id*. at 23.

[359] *Id*. at 14-15.

[360] *Id*.

[361] NRC Management Directive 10.99, cited at p.2 of the Open Door Policy Handbook, *supra 336*.

[362] These employees have remedies through either a negotiated or a formal grievance procedure. Management Directive 10.101, cited at *id*.

[363] *See* Appendix D for a copy of this nonconcurrence filing.

[364] Jackzo letter to Issa, dated Dec. 12, 2011, at p.1.

However, in at least some other settings where these open processes should, in theory, have been useful to elevate staff concern about technical issues embroiled in NRC decisionmaking, they were not used.[365] A focused study of the underutilization of these processes at past, critical points in NRC decision-making might provide added valuable information about how to reinforce the effectiveness and use of these programs.[366]

C. Summary of the Findings

Rather than attempting to summarize this section through text, a summary table is provided below that provides a thumb nail sketch of the findings with respect to a number of process-related factors. The analysis section then attempts to draw lessons from these various agency processes.

	EPA NAAQS	**EPA Pesticide**	**EPA IRIS**	**FWS listing**	**NRC informal rules**
# of chemicals/species/ rules	6 chemicals	1000 chemicals (50/year)	500 chemicals	Dozens species/year	Unclear how many rules/year
Nature of the scientific evidence	Large and robust body of relevant research; mostly academic and published; publicly available in journals	Generally heavily industry-based; sometimes quite limited, but meets minimum standards of information necessary for an assessment	Often industry-based; sometimes quite limited	Usually considerably more limited than the evidence available in EPA's program and some of it is not published	Engineering and technical; Operational information is often critical
Statutory Constraints on Decision	5 year review period; must use FACA science advisory board for review	All pesticide registrations must be reviewed every 15 years	None	Response to petition in 90 days; proposed decision within 1 year	Mandatory review by science advisory boards for some licensing and informal rulemakings
PreNPRM comment opportunities	Generally 8 separate public comment periods on 4 documents	Typically 2 documents, each subjected to public comment before the proposed decision	One public comment period; the recommended dose is not a rulemaking, however	None	In some informal rulemakings, there is an extensive workshop. There may be other outreach activities as well, depending on the regulatory decision.
Are scientific analyses and related technical documents that support proposed	Yes. Multiple drafts of 4 consecutive reports; external peer review	Yes. Planning and risk assessment drafts; summary of comments; EPA's response	Draft assessment and revised assessment; all comments, including	Yes, but only after the proposed rule is published	Yes. Commission papers prepared by staff and other supporting documents are

[365] *See supra* note 356.

[366] From the research conducted for this report, there was no specific lessons learned study of why these open workplace programs were not used in some of the more publicized incidents that question the technical veracity of NRC decision-making. A lessons learned report that specifically examines why DPOs were not filed in Davis-Besse, etc. might shed light on these fundamental questions.

decision publicly available?	comments; EPA responses to all comments		interagency comments; EPA response to all comments		almost always publicly available
Internal peer review	Yes	Yes	Yes	Staff and management collaborate on final product	Appears yes; supervisory chain reviews and signs staff paper
External Peer review	Multiple reviews by mandatory advisory body	Generally no	Yes, but level of peer review depends on size of assessment	Yes, individual peer reviewers	Often yes, standing advisory bodies required by statute; One standing body has broad authority to recommend projects
Role of OMB	Yes, it clears the proposed and final rules	OMB only involved to the extent the Paperwork Reduction Act is triggered	Yes, 2 rounds of comments on assessment	Yes, but OMB clears the proposed and final rules for critical habitat only	OMB only involved to the extent the Paperwork Reduction Act is triggered
Role of interagency review	Included during public comment	Included during public comment and informal contacts	Two dedicated stages to interagency review	Included during public comment	No evidence; presumably included during public comment
Stopping rules for emerging science	Yes, formal policy	No	Yes, generally closed after draft assessment	Unclear, but short timeframe likely makes stopping rules unnecessary	Unclear; Commissioner structure likely facilitates authoritative decisions
Stopping rules for debate	Informal closure by advisory board	EPA determines as needed	Complicated by interagency review	Short timeframe makes it non-problematic	Unclear; See above re Commissioner structure
Authorship or attribution of staff-authored reports	Yes - dedicated acknowledgements on reports; authorship types of rights	Yes - team authorship on reports	Yes - dedicated acknowledgements on reports; authorship types of rights	Limited - attribution to field office	Minimal - Manager signs staff papers
Reference list provided to peer and public reviewers	Yes	Yes	Yes	Yes, although reference list may need to be requested from agency contact in Fed. Reg.	Yes, included in staff papers, technical documents, and proposed rules
Availability of supporting literature to public	Studies available through an electronic database	Limited availability: Unpublished studies by manufacturers require pre-clearance and cannot be viewed until after the registration decision has been made	Generally available, although availability of the unpublished studies was not investigated	Generally available, although availability of the unpublished studies was not investigated	Mixed availability: 1) Yes, in general for informal rulemakings; 2) No (or limited) for license decisions, at least with respect to operator information
Ability to compare changes in proposed decision against	OMB review can obscure this to some extent	Yes, although it is not clear that all policy-relevant choices are	Generally yes; although no to the extent that interagency review	It depends on the analyses included in the administrative record	Yes, for informal rulemakings

underlying scientific analysis		accessible to the nonscientist	impacts the initial scientific analysis		
Dissent policies for staff scientists	Informal, in part built into authorship	Informal, in part built into authorship	Informal, in part built into authorship	Informal, but dissents have been placed in the record in one case	Yes, formal program
Misconduct policies	Yes	Yes	Yes	Yes	Does not appear there are misconduct policies, although they would seem to be almost completely covered by broader dissent and nonconcurrence policies

IV. Analysis and Recommendations

Despite a wealth of bad publicity, the evidence in this study reveals that agencies have made considerable strides in ensuring the rigor and transparency of their integration of science into regulation. Some agencies are explaining how policy and science intersect in their regulatory projects in sophisticated, yet accessible ways.[367] Likewise, some agencies are establishing processes that ensure both expert and internal review of their work, and, in connection with these processes, are providing a public record of the changes they make in response to peer review and public comment.[368] Agencies are also establishing integrity policies that allow their staff to raise scientific differences with supervisors through various informal and formal mechanisms.[369] Finally, agencies increasingly use the Internet to post the reference list used in their decision-making and even to make copies of documents consulted during that process readily available through databases and hyperlinks.[370]

This study also reveals features of agency decision-making processes that would benefit from further improvements. 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 scientific integrity initiative. A Clinton Executive Order caps the number of discretionary advisory committees that agencies can form; statutory barriers impede the public's access to studies that informed the agencies' scientific analysis; presidential review processes can alter the science underlying a rule

[367] This is exemplified by the policy assessment in the NAAQS process, see Section III.A.1.a., *supra*.
[368] In the IRIS assessment, interagency comments as well as peer review and public comments are all placed in the record and EPA provides a response to all of these comments in appendix A of its assessment. See Section III.A.1.b., *supra*.
[369] The NRC's collaborative workplace program provides a model example. *See* Section III.B.2, *supra*.
[370] EPA has established a large database of all of the studies used to conduct the NAAQS review. *See* Section III.A.1.a., *supra*.

but are protected as deliberative process; and abbreviated statutory deadlines for rulemakings 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.

Second, while some agencies are innovating 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 other agencies in a mechanical way, certain best practices can and should be adopted by all agencies engaging in scientific decision-making.

Third, the findings clearly reveal the need for additional study of regulatory science. The agencies' use of external peer reviewers, for example, is vital to ensure both the rigor and transparency of the integration of science into policy, yet very little is understood about this feature of agency decision-making. This and other research topics are integral to both an understanding and reform of the agency's use of science for policy. A few future topics emerging from this study are listed in the final section.

A. Addressing External Constraints

Various external constraints substantially limit the ability of the agencies to "be transparen[t] in the preparation, identification, and use of scientific and technological information in policymaking."[371] The first constraint is the agencies' inability to ensure the transparency of its decision-making process during OMB review. Currently OMB review of science-intensive rules is protected as deliberative process, and there is no publicly available log or record of OMB's changes or why they were made.[372] This expansive claim of deliberative process appears to be in direct conflict with the Presidential directive for the transparent use of science.

Second, even though OMB appears to be playing a significant role in making changes to science-intensive rules, it has not adopted scientific integrity policies, unlike many other regulatory agencies,. It is thus important that this final clearance agency ensure the scientific integrity of its decisions in keeping with the President's directive.

Finally, a variety of congressional and executive branch constraints on agency decision-making processes impede the ability of the agencies to make their processes more rigorous and transparent. Although this study focused only on five programs in

[371] Obama Memorandum, *supra* note 7.

[372] See Interview with former OMB Staff Member, Jan. 9. 2012; Interview with former OMB Staff Member, Feb. 3. 2012; Interview with EPA Staff, Office of Air Quality Planning and Standards, Jan. 17, 2012; Interview with EPA Staff, National Center for Environmental Assessment, Jan. 18, 2012; Interview with EPA Staff, National Center for Environmental Assessment, Feb. 3, 2012; Interview with FWS Staff, Endangered Species Program, Jan. 9, 2012.

three agencies, there are reasons to believe that the impediments identified here are not the only ones that limit agencies in their effort to develop rigorous decision-making processes for the integration of science into regulation. These impediments should be cataloged more systematically, and an agency like OSTP should develop a plan for removing or eliminating these constraints.

This section provides an analysis of these external impediments to agency decision-making processes and offers recommendations for reform.

1. OMB Clearance Processes Can Obscure the Role that Scientific Analysis Plays in Informing Decisions

Executive Order 12866 directs OMB to review economically significant rules, but as currently practiced its oversight role is largely shrouded from public view under a broad invocation of the deliberative process privilege.[373] With regard to science-intensive rulemakings, OMB review thus puts an abrupt end to "transparency in the preparation, identification, and use of scientific and technological information in policymaking" as commanded by the President.[374] This secrecy, moreover, is a discretionary choice; there is no law that requires OMB to exert such a broad claim of Executive privilege and recent court cases take OMB to task for doing so.[375]

OMB's nontransparent review makes it impossible for the public to compare an agency's policy choices against a rigorous scientific record since key decisions made during the deliberative process remain unidentified and unexplained.[376] EPA NAAQS

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[373] OMB does provide general information on whether some changes were made in the course of its review at www.reginfo.gov. The nature and reason for the changes are not explained, however. For arguments OMB's deliberative process claims are overbroad, see GAO, Low Productivity and New Interagency Review Process Limit the Usefulness of EPA's Integrated Risk Information System 54, 73, 80-83 (March 2008); *infra* notes 513-514 and accompanying text; *see also* Mendelson, *supra* note 73, at 1164-67.

[374] See Obama Memorandum, *supra* note 7, at 1. A less expansive use of the deliberative process privilege does not affect the "functions of the Director of OMB" in his/her review of agency regulations. *See id.* at 2. Although this boilerplate reference to "functions of the Director of OMB . . . relating to . . . administrative . . . proposals," which is copied into a number of Executive Orders, *see, e.g.*, Executive Orders 13366 and 13547, is somewhat ambiguous, it does not appear to encompass basic process values as applied to OMB operations, such as fidelity to the President's scientific integrity principles. Instead it refers to the authority granted the "OMB Director" to review specific "proposals" of the Executive Branch. Indeed, in response to the President's memorandum, OMB promptly developed scientific integrity guidelines governing its review of legislative testimony prepared by the Executive Branch, thus signaling its own acknowledgement that it is expected to comply with the President's scientific integrity guidelines. *See* Holdren memorandum, *supra* note 8, at 4 (discussing OMB's "guidelines to OMB staff concerning the review of draft executive branch testimony on scientific issues")

[375] *See supra* notes 69-73 and accompanying text (discussing these discretionary features of the deliberative process claim) and *infra* notes 513-514and accompanying text (discussing the courts' recent rulings on the subject); *see generally* Narayan, *supra* note 69.

[376] *See, e.g.*, Section III.A.1.a., *supra*; *see generally* Mendelson, *supra* note 73, at 1146-59 (2010) (discussing the lack of transparency of OMB review); Heidi Kitrosser, *Scientific Integrity: The Perils and Promise of White House Administration*, 79 FORDHAM L. REV. 101, 117 (2011) (discussing secret role of OMB in agency oversight).

staff, in particular, note how following their seven plus stages of public comment and peer review, their proposed rule then falls into a secret process at OMB where EPA can no longer publicly account for changes made to the proposed rule.[377] While FWS staff did not share the details of the nature of OMB's review of critical habitat designations, it appears from reginfo.com that OMB has also been making changes to each of the FWS's critical habitat designations since at least 2009.[378] These programs are not unique. OMB currently classifies its review of all economically significant rules under the deliberative process privilege,[379] and a good many of these economically significant rules appear to involve scientific analyses.[380]

In fact, OMB's secret oversight role occurs not only for economically significant rules cleared under Executive Order 12866, but also for a number of other regulatory projects as well. For example, while the IRIS program is technically outside of OMB's formal jurisdiction, OMB not only plays a vigorous role in offering comments on the agency's risk assessments in this program (a change from its previous role, which involved managing the entire process of interagency review under the veil of the deliberative process privilege),[381] but may even be exerting an authoritative clearance role for some of the assessments, despite EPA's public statements to the contrary.[382] Moreover, while OMB comments appear in the record, the telephone calls and meetings are all considered deliberative process.[383] The literature reveals that IRIS is again not unusual. OMB's involvement in regulatory projects that are not economically significant outnumbers the rules for which its review is required under Executive Order 12866.[384]

Because it is protected as privileged information, it is impossible to tell the significance of the changes made by OMB to an agency's draft proposed rule or other regulatory project,[385] but evidence collected in this study indicates that at least some of

[377] Interview with EPA Staff, Office of Air Quality Planning and Standards, Jan. 17, 2012; Interview with EPA Staff, National Center for Environmental Assessment, Jan. 18, 2012.
[378] *See supra* note 235 and accompanying text (reporting that all recent critical habitat designations involved some changes at OMB).
[379] *See, e.g.*, Mendelson, *supra* note 73, at 1157 (finding no reference to OMB review in Federal Register searches, even though it occurred and changes were made as a result); *see also* Stephanie Tatham, *supra* note 73.
[380] *See, e.g.*, Mendelson, *supra* note 73, at 1152-57; Tatham, *supra* note 73, at 19-31.
[381] *See* Section III.A.1.b., *supra*.
[382] *See id*.
[383] *See id*.
[384] *See* Rena Steinzor, Michael Patoka, and James Goodwin, Behind Closed Doors at the White House: How Politics Trumps Protection of Public Health, Worker Safety, and the Environment at 34-37 (Nov. 2011) (reporting from an empirical investigation that the majority of rules reviewed or coordinated through OMB are not economically significant; "of 409 rules . . . the subject of at least one OIRA meeting from Oct. 16, 2001 to June 1, 2011, 161 of them (39 percent) were economically significant, while 248 of them (61 percent) were non-economically significant").
[385] OMB's own site indicates that changes are generally being made during the course of their review; one can view the OMB recorded action taken on a concluded rule at http://www.reginfo.gov/public/do/eoAdvancedSearch. If the OMB's action was "consistent without change", then OMB did not alter the agency's decision. If the action was "consistent without change",

OMB's comments and suggested changes are directed at the agency's interpretation and characterization of the relevant science. OMB's recent comments on IRIS assessments, which are now part of the public record at EPA's request, for example, reveal that OMB is more than willing to offer detailed, lengthy comments on scientific issues.[386] This general, science-intensive role of OMB in reviewing agency's regulatory work is reinforced by interviews with non-IRIS agency staff members from OMB, OSTP and EPA. Two former OMB employees and a number of EPA staff in the NAAQS program, for example, recounted how OMB can get "deep" into the science (and associated policy) of a regulatory project.[387] One EPA staff member suggested that many of OMB's comments were actually useful in tightening the scientific analysis, but they were often not material enough to justify the extended delay and added transaction costs. The EPA scientist noted that because OMB has final clearance authority over the proposed rule, the agency is at its mercy; OMB typically requires the agency to make every change it suggests, whether major or minor before it will clear the rule for publication.[388]

A number of published accounts in the literature also reveal evidence of OMB's willingness to delve into all features of an agency's science-based decision in carrying out its review of rules and other regulatory projects.[389] Surveys of EPA employees conducted by the Union of Concerned Scientists provide still more evidence of "OMB's meddling in EPA decision making [in a way that constitutes] . . . a major hindrance to the agency's scientific integrity."[390]

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some change (s) were made to the agency's decision as the result of OMB review. What these changes were, however, is not capable of being determined.

[386] It is possible to access the interagency discussions for some IRIS chemicals by visiting http://cfpub.epa.gov/ncea/iris_drafts/archiveDrafts.cfm#C_form and accessing interagency comments (the last column). For a sample of these OMB comments, see, e.g., OMB Staff Comments on Acrylamide, available at http://cfpub.epa.gov/ncea/iris_drafts/recordisplay.cfm?deid=22440; OMB Comments on Carbon Tetrachloride, available at http://cfpub.epa.gov/ncea/iris_drafts/recordisplay.cfm?deid=56725. See Appendix F for a sample OMB comment letter.

[387] Interview with former OMB Staff Member, Jan. 9. 2012; Interview with former OMB Staff Member, Feb. 3. 2012; Interview with EPA Staff, Office of Air Quality Planning and Standards, Jan. 17, 2012; Interview with EPA Staff, National Center for Environmental Assessment, Jan. 18, 2012.

[388] *See* Interview with EPA Staff, National Center for Environmental Assessment, Jan. 18, 2012. Moreover, in some rulemakings OMB solicited and collated comments from other agencies, yet it does not attribute the comments to the agency making the comments. *Id.*

[389] *See, e.g.*, GAO, Chemical Assessments, *supra* note 146, at Appendix III (discussing OMB's role in several EPA IRIS assessments); Kitrosser, *supra* note 376, at 2407 (discussing OMB's potentially negative role in compromising scientific integrity of publicly provided information in the BP oil spill); Mendelson, *supra* note 73, at 1152-57; Rena Steinzor, *The Case for Abolishing Centralized White House Regulatory Review*, 1 MICH. J. OF ENVTL. & ADMIN. LAW 247-68 (forthcoming 2012); Steinzor et al., *supra* note 384; Peter L. Strauss, *Possible Controls over the Bending of Regulatory Science, in Anthony, et. al eds.*, VALUES IN GLOBAL ADMINISTRATIVE LAW 126-27 (2011) (discussing OIRA's role in the NAAQS ozone standard and referring a similar episode with respect to a proposed regulation to protect an endangered whale from collisions with larger boats); Tatham, *supra* note 73.

[390] Union of Concerned Scientists, Interference at the EPA at 28 (2008) (reporting this finding in nearly 100 surveys conducted of employees in 2007, out of a total of 1586 surveys that were returned).

At the same time that there is growing evidence that OMB's current approach to deliberative process privilege is problematic, there is little evidence of corresponding benefits to government processes. Deliberative process is a privilege that exempts or classifies government discussions from discovery and FOIA in order to promote free and open exchanges and deliberations among government employees.[391] Yet, as one former OMB employee and an EPA staff member observed, with the appropriate software and time one can ultimately isolate the changes made by OMB to a draft proposed rule by going through various extraction procedures.[392] If the changes made as the result of these deliberations are capable of being re-engineered by interest groups with time and resources, there appears to be no legitimate basis for shrouding the nature of the changes made by OMB in secrecy. The lack of transparency only serves to block the less well-financed groups from tracking the role that OMB plays in regulatory decisions while advancing no apparent governmental interest.

Technically, in fact, OMB should be providing greater transparency for at least its review of economically significant rules, since under Executive Order 12,866 OIRA is required to "[i]dentify for the public, in a complete, clear, and simple manner, the substantive changes between the draft submitted to OIRA for review [of an economically significant rule] and the action subsequently announced" as well as "[i]dentify for the public those changes in the regulatory action that were made at the suggestion or recommendation of OIRA."[393] Executive Order 12866 also requires that OIRA "make available to the public all documents exchanged between OIRA and the agency during the review by OIRA" once the rule is published.[394] Yet even these basic requirements appear not to be followed by OMB, at least not regularly.[395] In any event, these mandated disclosures provide no information on why the changes were made; do not extend to rules that are not economically significant; and occur only after the final rule is promulgated.

In order to ensure the transparency of agency science-based rules, the President should supplement the transparency provisions of Executive Order 12,866 by issuing another Executive Order directing OMB to refrain from applying the deliberative process privilege to its review of economically significant, science-intensive rules unless there is an overwhelming national benefit to such secrecy, such as protecting national security, privacy, or significant trade secrets.[396] The President's science integrity directive already

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[391] *See, e.g.*, GAO, LOW PRODUCTIVITY, *supra* note 153, at 54 ("[O]ne official told us that generally OMB believes that effective deliberations among federal agencies are important and that if agencies' deliberative comments are part of the public record, agency officials will not be as frank and candid as they would be under the protection of confidentiality.").

[392] Interview with former OMB Staff Member, Feb. 3. 2012; Interview with EPA Staff, Office of Air Quality Planning and Standards, Jan. 17, 2012.

[393] Exec. Order No. 12,866 §§ 6(a)(3)(E)(ii)–(iii), 58 Fed. Reg. 51,735, 51,742 (Oct. 4, 1993).

[394] *Id.* § 6(b)(4)(d).

[395] *See, e.g.*, Mendelson, *supra* note 73, at 1149.

[396] Note that this study did not explore similar types of White House review processes, such as CEQ's review under NEPA, OMB's other review processes under the Data Quality Act or the Paperwork

makes it clear that at least with regard to the agencies' science-based rules, broad deliberative process claims are inappropriate. But since deliberative process continues to be widely applied by OMB to all features of its review process, it is necessary for the President to provide more specific instructions to OMB regarding the need for transparency in its review of science-intensive rules.[397]

In the alternative, the President should issue an Executive Order that requires, at the very least, that either the OMB or the agency originating the rule provide an accounting of each of the material changes made during OMB review and explain each change.[398] This log should be placed in the public record at the time the deliberations take place or shortly thereafter. The fact that OMB already submits its comments on IRIS assessments on the record reveals that this type of transparent communication can and is occurring in some regulatory areas and that it does not jeopardize government functions.[399]

Finally, the President should require that when OMB is engaged in interagency review or coordination of regulatory projects that are not economically significant as defined in Executive Order 12866, OMB should ensure that all of its communications with the agency are submitted in writing and placed in the public record.

> **The President should issue an Executive Order directing OMB to refrain from applying the deliberative process privilege to its review of agencies' science-intensive regulations unless there are overwhelming national interests at stake, such as national security, personal privacy, or substantial trade secrets. In the alternative, the President should require by Executive Order that OMB or the agency originating the rule create a log of all changes made to an agency's draft rule during the course of OMB review and provide a reason for each change. This log and explanation of changes should be promptly placed in the administrative record.**

Reduction Act, or even OSTP's review process under the President's scientific integrity initiative or other programs.

[397] An argument can of course be made that the privilege should not be used in a broader number of rules, see generally Mendelson, *supra* note 73, but that is beyond the scope of this study.

[398] This recommendation thus goes beyond the requirements of Executive Order 12,866 insofar as it: 1) requests that OMB or the agency explain the basis for each change; and 2) requires OMB or the agency to produce the changes after the deliberation, which is at a point before the final rule is promulgated. As discussed supra, since there is little evidence that this portion of Executive Order 12,866 is being followed, it also reminds OMB to create this log of changes in the first place. *See also id*. at 1164 (recommending that OMB review should be made transparent and that to accomplish this the agency would "need to summarize the critical details of, say, executive review positions and explain the extent to which those positions are connected to the agency's ultimate decision"); *id.* at 1167 (recommending that "at the time the agency publishes its proposed or final rule, the agency would have to summarize the final position reached in the executive review process.").

[399] *See id*. at 1164 (suggesting that the President could order OMB to communicate with agencies only in writing and the written communications would be put in the record).

The President should also require by Executive Order that when OMB is engaged in the review of agency regulatory projects that are not economically significant as defined in Executive Order 12866, OMB should ensure that all of its communications with the agency are submitted in writing and placed in the public record.

2. OMB should develop a scientific integrity program as directed by the President

As just discussed, OMB appears to exert an important oversight role on some agency science-intensive policies, but it has no internal scientific integrity program itself as required by the President's directive.[400] This deficiency is still more problematic since OMB is not considered a scientific expert, but it nevertheless plays a critical clearance role for science-intensive regulations. OMB's very small scientific staff,[401] coupled with its own statements that eschew its role as a scientific expert,[402] strongly suggest that its review occurs primarily with policy considerations in mind. When OMB raises questions about the scientific analysis, those inquiries are typically directed at acquiring a better understanding of and perhaps questioning an agency's assumptions or other choices that fill in various gaps in the scientific record.[403] OMB should establish rigorous scientific integrity programs to ensure that it does not inadvertently step over the line and interfere with the underlying scientific evidence in conducting this oversight role.

To meet the President's directive and maintain symmetry with the integrity programs in the other agencies for which it reviews rules, OMB should develop its own scientific integrity program.[404] The content of OMB's integrity policies should at least meet OSTP's minimum standards as set forth in John Holdren's memorandum.[405] To expedite OMB's effort to develop a scientific integrity program (since the deadline for these programs has passed), OMB could, for example, adapt NOAA's integrity policy to

[400] As mentioned in *supra* note 374, OMB has already developed some scientific integrity guidelines and does not attempt to make the expansive argument that ensuring the basic scientific integrity of its operations, like other Executive Branch agencies, would affect the "functions of the Director . . .relating to . . . administrative . . . proposals". *Id*.
[401] OMB appears at present to have only one scientist on staff, Margo Schwab, although this requires verification.
[402] One OIRA official maintains that "[w]ith regard to the use of science in the regulatory process, this is fundamentally a question for the regulatory agencies" and not OMB's responsibility. Email from OMB Official, Jan. 30, 2012.
[403] Interview with former OMB Staff Member, Feb. 3. 2012.
[404] There is some evidence that OMB may have protected its deliberative, clearance role vigorously in the development of OSTP's scientific integrity guidelines. *See* Kitrosser, *supra* note 376, at 2407-08.
[405] *See* OSTP Memorandum, *supra* note 8.

its own program. NOAA's program has received high marks and thus should offer a particularly good model for OMB.[406]

In addition, since OMB review does involve changes to agency rules, some mechanism should be provided to allow agency staff to dissent or file nonconcurrences on changes made to rules to which they contributed if they believe the changes are contrary to the scientific record. If, for example, an agency scientist was intimately involved in preparing a scientific analysis that then formed the basis for an agency rule, but in the course of OMB review, changes were made to this underlying analysis, the agency scientist should be allowed to file a dissent in the public record. Since agency scientists can apparently lodge dissents when changes are made within their own agency, their right to dissent should not end simply because the rule crosses agency boundaries.[407]

To remedy this gap OSTP, as part of its scientific integrity initiative, should enact a written policy that allows dissents and nonconcurrences by any staff member who was involved in an initial rule or regulatory project, at least when they believe the scientific record has been mischaracterized. At the dissenter's request, the dissent or nonconcurrence should be placed in the public record. This dissent would be allowed for changes not only made during intra-agency review, but for changes made to the agency's rule that originate outside the agency. The NRC's program offers a useful model for establishing this dissent and nonconcurrence process.[408]

OSTP should also include a resolution process for scientific disagreements raised by a dissenter, perhaps modeled on the NRC is differing professionals opinion program.[409] This additional procedure ensures that the agency's use of science is not only transparent but is also rigorous to the extent that scientific and technical disagreements are subjected to additional review and investigation. Without this mechanism, a dissent or nonconcurrence would only inform agency processes in cases when the agency itself chose to take the information seriously or was pressured to do so by those who noticed the dissent in the record.

Finally, OMB should ensure that any significant changes made to the scientific analysis supporting an agency's rule during the course of its review be subjected to the

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[406] See supra notes 319-324 and accompanying text. In particular, NOAA has developed a rigorous scientific misconduct program that can be used against NOAA employees by those within and outside the agency. NOAA has also created ambitious and enforceable codes of conduct to guide science-based decisionmaking with the agency. Finally, NOAA provides public tracking information on its program, including the status and nature of the misconduct challenges. *See id.*

[407] *See also* Section IV.B.3, *infra.*

[408] *See* Section III.B.2., *supra*.

[409] *See* OMB Final Information quality Peer Review Bulletin at 2, 3 (Dec. 2004), available at http://www.whitehouse.gov/sites/default/files/omb/memoranda/fy2005/m05-03.pdf. Influential scientific information means "scientific information the agency reasonably can determine will have or does have a clear and substantial impact on important public policies or private sector decisions." *Id.* at 11.

requirements for peer review set forth in OMB's own Peer Review bulletin.[410] This peer review of significant changes is particularly important to the extent that these changes are classified as deliberative process and would otherwise escape external scrutiny. Since it is difficult to determine the extent to which a change is "scientific" or based on a policy choice, moreover, OMB should err on the side of determining that any significant change made by it to an agency's science-based rule be subjected to this additional expert review.

OMB should establish scientific integrity policies for its own personnel that at least meet OSTP's minimum standards. In addition, when significant changes are made during the course of OMB's review of a highly-influential science-based rule, OMB should comply with its own Final Information Quality Bulletin for Peer Review and engage external peer review to evaluate the scientific reliability of the change(s).

OSTP should develop a government-wide dissent policy, modeled after the NRC's Collaborative Workplace Program, 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. This right should apply regardless of whether the change to the analysis originates in their own agency or another agency within the federal government (e.g., OMB). 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.

3. Identifying and Redressing External Constraints that Impede an Agency's Efforts to Improve the Rigor and Transparency of its Use of Science

Within the five programs studied, significant sources of slippage in the agencies' development of robust decision-making processes occurred through external impediments that arise from within the Executive Branch or Congress. It would be bad form indeed to suggest that the agencies' use of science should be improved when the agencies have been placed in decision-making structures that do not allow these improvements to be made. Yet without some formal, government-wide procedures for identifying and

[410] *See id.* at 37-40. While an agency enjoys discretion in determining how to conduct this review, OMB requires that some documented and rigorous form of peer review take place. Although OMB is silent on whether significant changes made to an agency's scientific analysis that occur wholly after peer review must be re-subjected to a second round of expert review, it seems implicit in OMB's basic directive that influential science that supports regulation must be subject to peer review. If the agency's scientific analysis changes in important ways for "influential" scientific rules, then presumably some earlier expert review does not grandfather in the subsequent scientific analyses and decisions. While conducting this peer review could be costly and time-consuming, OMB's failure to conduct this mandated peer review for the significant changes that occur as a result of its review puts it in direct violation of its own guidelines.

addressing these external constraints, agencies may find themselves blocked from making useful and reasonable improvements to their decision-making processes.

Several hard constraints on the scientific transparency and rigor of agency decision-making processes arise from laws themselves. In the FWS, unreasonably short congressional deadlines for a decision appear to be the primary cause of the FWS's truncated analysis process for species listing and critical habitat designations.[411] Recall that the FWS is required by statute to make a listing decision within a little over a year after receiving a petition.[412] The FWS staff reiterated that these timelines are so tight that they do not provide the FWS with sufficient time to utilize external peer review panels or engage experts more actively throughout their analytical process.[413] This short timeframe has also led the FWS to resort to collaborative staff-management authored proposed rules (without an initial scientific analysis) that are less than ideal for important science-policy decisions, as detailed infra.[414] Even the development of complete administrative records supporting listing decisions may be compromised as a result of the whirlwind timeframe that governs these decisions.[415]

Statutory constraints also undermine the ability of the agencies to share with the public the underlying research the agencies use to make a decision. In EPA's pesticide program, for example, Section 10(g) of FIFRA prevents public access to studies conducted by most pesticide manufacturers unless a person is granted clearance through a certification process.[416] This section was apparently passed by Congress to prevent competitors in other countries from benefiting from safety data produced by U.S. manufacturers as required by FIFRA.[417] Yet as detailed earlier, Section 10(g) impedes public access to the bulk of the scientific research the agency considers in its registration decisions. Specifically, section 10(g) requires that a person certify that he/she will not share the information with manufacturers in other countries in order to gain access to manufacturer-provided data. But even then, access to this critical information is limited insofar as: it is allowed only after a pesticide registration decision is made; pesticide manufacturers are notified of each person who views their information; and the information must be viewed at the agency's office.[418] EPA summarizes each of these

[411] See Section III.A.2.
[412] *See id.*
[413] Interview with FWS Staff, Endangered Species Program, Jan. 9, 2012. The FWS engages external peer review on the proposed rule simultaneously with public comment. This has caused it to occasionally revise its proposal and reopen comment. *See* Section III.A.2. A much more streamlined and efficient process would involve expert review followed by public comment, or even more ideally two stages of peer review that occur before and after public comment.
[414] *See id.*
[415] *See id*.
[416] 7 U.S.C. § 136h(g)(1). *See* Section III.A.1.b.
[417] *See, e.g.*, 95 vol3 1978 U.S.S.C.A.N. 1966 (discussing US manufacturers concerns that data would be used by foreign competitors who would be afforded a competitive advantage as a result).
[418] 7 U.S.C. § 136a(c)(2)(A). There are some exceptions, *id*. at 136h(d), but they appear to be unusual.

studies in data tables, but there is effectively no external oversight over this internal review of manufacturer data.[419]

In the programs examined in this study, the Paperwork Reduction Act (PRA) and Data Quality Act (DQA) were also implicated in imposing additional statutory impediments on the agencies' rigorous and transparent use of science for regulation. In the case of the PRA, EPA is currently required by OMB to clear each of its requests for data from manufacturers in its pesticide registration program through OMB.[420] This process can involve an additional six months of delay on each pesticide registration decision. The PRA clearance also raises a risk (as yet unrealized) that some of EPA's requests for data might ultimately be blocked by OMB.[421] If this occurs, EPA may lack data it believes is essential to conduct its pesticide assessment, and yet again the reasons for this data shortfall would be protected by deliberative process. Somewhat similarly, OMB enjoys general oversight of the agencies' compliance with the Data Quality Act.[422] There was some indication that at least in the IRIS program, OMB may be using DQA complaints as a way to regain control as the primary clearance authority over select IRIS assessments.[423] Thus a DQA complaint could trigger a shift in control over the agency's regulatory project from the agency to OMB, where again it may be protected as deliberative process.[424]

Finally, although information was difficult to locate for purposes of comparison, insufficient legislative appropriations to support an agency's science-based regulatory program can also impact the agency's ability to do its analyses rigorously and in a timely way. Resource limitations appear to be a significant external constraint on the FWS's listing process for example.[425] The FWS's small budget allows it to allocate roughly $250,000 to its analysis and deliberations dedicated to listing a single species and a total of $300,000 to $500,000 for a complete habitat designation and listing rule.[426] For purposes of comparison, the NRC allocates on average $4 million to its analysis of the renewal of a license for one nuclear power plant and this licensing process occurs over the course of nearly two years, in comparison to the one year afforded the FWS.[427] Although estimates of the costs of EPA's programs were not available,[428] informal

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[419] *See* Section III.A.1.b.
[420] *See id.*
[421] Interview with EPA Staff, Office of Pesticide Programs, August 5, 2011.
[422] *See* Curtis Copeland and Michael Simpson, The Information Quality Act: OMB's Guidance and Initial Implementation (Aug. 19, 2004), available at http://www.dtic.mil/cgi-bin/GetTRDoc?AD=ADA445489 (describing OMB's role in the DQA).
[423] *See, e.g.*, GAO, CHEMICAL ASSESSMENTS, *supra* note 146, at 24-26.
[424] At the very least and in the interim, deliberative process privileges should be presumptively disfavored for OMB's DQA oversight processes as well.
[425] Interview with FWS Staff, Endangered Species Program, Jan. 9, 2012.
[426] *Id*.
[427] *See* OIG, License Renewal Report, *supra* note 263, at 4.
[428] Estimates of the costs for the review of pesticide registrations may be available and the author is still tracking that figure down.

speculation by staff in the NAAQS program placed the cost of conducting one revision of an air quality standard closer to the NRC's budget than the FWS's allowance.[429] Whatever the case, it would be disingenuous to demand that an agency improve the integrity and transparency of its use of science if it is not provided funding adequate to do the work, at least in comparison to other agencies. Thus, the under-funding of agency scientific work is also an important external constraint that deserves exploration and potentially supportive advocacy by the OSTP.

Constraints arising purely within the Executive Branch further obstruct the agencies' effort to develop robust processes for their use of science. As just discussed, OMB clearance requirements imposed by Executive Order 12866 are currently implemented in a way that prevent the agencies from identifying in a clear and accessible way how the science and policy in their final decisions changed as compared with their earlier scientific analyses. Caps on the number of discretionary FACA committees within an agency, established by President Clinton under Executive Order 12838, also serve as a barrier to the agencies' effort to enlist external peer review of their regulatory work.[430] Both the EPA's IRIS and the FWS's programs generally use contractors to solicit external peer review in order to avoid these and other restrictions imposed on the agencies' use of FACA.[431] EPA officials in particular lament the FACA limitations for IRIS risk assessments. Since a FACA science advisory panel is more likely to provide the agency with a cohesive and comprehensive set of unified comments as compared with comment letters from individual expert reviewers, IRIS officials believe a FACA panel is the preferred option.[432] Caps on discretionary FACA committees, however, leave the agency with the only choice of employing independent reviewers, which one EPA staff member believes may tend to exacerbate the already unwieldy and protracted public and interagency comment processes.[433]

There are statutory and regulatory constraints (such as OMB's review which is protected as deliberative process) that limit the ability of the agencies to ensure that their decisions are scientifically robust and transparent in keeping with the President's Directive. OSTP and the

[429] Interview with EPA Staff, Office of Air Quality Planning and Standards, Jan. 17, 2012.
[430] *See* Executive Order 12838 and OMB Circular A-135 (requiring agencies to reduce the number of discretionary advisory committees by one-third). ACUS has recommended rescinding this cap on FACA committees. *See* ACUS Recommendations 2011-7 at 10, available at http://www.acus.gov/wp-content/uploads/downloads/2011/12/Recommendation-2011-7-Federal-Advisory-Committee-Act.pdf.
[431] Interview with FWS Staff, Endangered Species Program, Jan. 9, 2012; Interview with EPA Staff, National Center for Environmental Assessment, Feb. 3, 2012. This reluctance by agency to use FACA committees due to the approval and paperwork requirements is explored in Reeve Bull, The Federal Advisory Committee Act: Issues and Proposed Reforms, Sept. 12, 2011, available at http://www.acus.gov/wp-content/uploads/downloads/2011/09/COCG-Reeve-Bull-Draft-FACA-Report-9-12-11.pdf, at 47-49.
[432] Interview with EPA Staff, National Center for Environmental Assessment, Office of Research and Development, Feb. 3, 2012.
[433] *Id.*

agencies should identify these 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. Once information has 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 to OSTP's request for agency 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.

For example, agencies are encouraged to ensure peer review of their scientific analyses, yet the agencies currently encounter impediments to assembling external peer reviewers under Federal Advisory Committee Act. Caps that limit the number of discretionary FACA committees and other impediments to the use of FACA should be eliminated to enable agencies to use science advisory boards when they believe they are warranted. See Administrative Conference Recommendation 2011-7.

B. Best Practices

President Obama has called for "transparency in the [agency's] preparation, identification, and use of scientific and technological information in policymaking."[434] Although there is most definitely no "one size fits all" with respect to the incorporation of science into regulatory projects, there are basic steps – as just suggested in the President's memorandum – that are considered essential to robust scientific processes and that translate equally well to the agencies' use of science for regulation.

Drawing heavily from the innovations arising in the agencies themselves, this section proposes some presumptive best practices for robust and transparent decision-making process in the agencies' use of science. These best practices allow considerable flexibility and are developed in a way that primarily codifies existing agency practices. To the extent the best practice principles do impose new requirements, however, they should involve very little added time, resources, or paperwork for the agencies. Indeed, following the best practices might ultimately reduce the time and resources expended on science-intensive regulations since these steps are intended to make the agency's decision processes more streamlined and transparent. The best practices should also expedite an agency's existing processes by clarifying what good decision-processes entail. Since most agencies currently lack clear statements of their existing processes for incorporating science into regulation (*see infra* Section IV.B.8 for a recommendation addressing this

[434] *See id.*

omission), a basic set of guidelines will help draw out or even fine tune some of these unrecorded procedural details.

Each of these best practices draws its authority from three important, overlapping sources. First, each best practice is linked to directives in President Obama's and/or the OSTP's memoranda on scientific integrity. These White House goals are considered fundamental, at least in abstract terms, to good agency practice with respect to the incorporation of science into policy. Second, each of these best practices is being implemented in at least one of the agencies under study; thus they are capable of being put into practice and deemed important enough to be utilized in at least one science-intensive regulatory program. Finally, for each best practice there is evidence that some agencies are not currently reaching the goal.

Since unique features of an agency's decision-making can make certain best practices impracticable or even undesirable, these recommendations should be read as presumptive guidelines and not firm requirements. This flexibility is essential given how little is known about the agencies' use of science, coupled with the considerable variation between programs, a point evident even in the course of this study. A presumption also avoids the need to identify with precision the types of science-intensive regulations that are covered by best practices (e.g., only informal rulemakings) and those that are not.

1. Availability of a references list and the underlying references

One of the basic expectations for regulatory science is that the agency should identify all of the literature it consulted (including literature it ultimately rejected) in its scientific analysis. The agency should also ensure that this literature is, if at all possible, available to the public and peer reviewers.[435]

Accordingly, where agency time and resources permit, agencies should attempt to post not only the bibliography of the literature it consulted, but also the articles themselves, particularly the unpublished studies. To the extent that the agency is not able to post unpublished studies – due to statutory prohibitions like the one in FIFRA mentioned above – they should articulate these limitations. Moreover, to the extent that copyright protections prevent this posting, then agencies should seek permission to disseminate the work, and if this fails then the agency should again explain the reasons and provide the public with information on how to request the information directly from

[435] *See, e.g.*, *id*. at 1 ("Except for information that is properly restricted from disclosure . . . each agency should make available to the public the scientific or technological findings or conclusions considered or relied on it policy decisions"); Holdren Memorandum, *supra* note 8, at 2 (principle I.3. stressing "[o]pen communication among scientists", "the free flow of scientific and technological information" and directing agencies to "expand and promote access to scientific and technological information by making it available online in open formats."); see also Bipartisan Center report, *supra* note 3, at 41 (recommending, among other things, that "once an agency has opened a docket on a rule or guidance that will draw on scientific studies, it should make available on the Web a list of the studies it is reviewing and should regularly update the list").

the author. Ensuring that the underlying research is available is a basic component of scientific transparency and this applies with equal force to regulatory science.[436]

For the agency programs examined in this study, it appears that the agencies generally provide bibliographies and reference lists that support their regulatory projects. EPA's NAAQS program again provides the high water mark, reinforced through its extraordinary HERO literature base which provides public access to the underlying studies, or at least the abstracts as permitted by copyright law.[437] EPA, DOI, and NRC generally provide bibliographies for their rulemakings (this feature was not examined in detail at NRC), although in some cases the public or reviewers will have to go through extra steps to gain access.[438] Like EPA, NRC has produced a publicly accessible online library that provides the public with instant access to many of the NRC documents that support its science-intensive rules, including many unpublished studies and staff reports cited in its decision documents.[439]

Despite these positive developments, there do not appear to be formal policies or a universal commitment, even in the programs studied, to ensure that the supporting literature is identified and reasonably accessible to the public in all cases. A review of several proposed rules at the FWS, for example, revealed that not only the references, but the reference list itself had to be requested from (or perhaps viewed at) the field office. Since these studies are apparently already compiled for purposes of internal review,[440] it would seem relatively easy to make them publicly available through the internet. Indeed, one staff indicated that FWS is currently attempting to provide this kind of access.[441] Likewise, EPA often includes unpublished studies in its risk assessments; it too is attempting to develop a database for this research for at least its IRIS program.[442]

It could well be that all of the agencies will soon be developing extensive databases of the studies they use for regulation, such as posting bibliographies online with hyperlinks. Indeed, some of this is already being done.[443] Yet given the explicit prominence that the availability of underlying research plays both in basic science and in the President's directive, this type of literature accessibility should be considered a basic tenet for any rigorous regulatory program.

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[436] *See supra* notes 26-27 and accompanying text (discussing these values in basic science).
[437] *See* Section III.A.1.a.
[438] FWS does not include the bibliography in its regulatory analysis published in the Federal Register and it is only sometimes posted online in the regulatory docket. As a result, the public must request the reference list from the field office. *See* Section III.A.2, *supra*.
[439] *See* Section III.A.3.
[440] *See* Hall email, *supra* note 210, at 1 (describing this arrangement).
[441] Interview with FWS Staff Member, Field Office, Feb. 15, 2012.
[442] Interview with Staff, National Center for Environmental Assessment, Jan. 18, 2012.
[443] See, e.g., EPA, IRIS Toxicological Review for Hexachloroethane (Sept. 2011), available at http://www.epa.gov/iris/toxreviews/0167tr.pdf (providing a hyperlink in the reference list that allows the reader to click their way to each of the references cited).

In supporting its science-based regulatory decision, an agency should identify and make publicly available a list of the scientific literature it consulted, which ideally includes the literature it rejected as well as the literature it relied upon. This reference list should be posted online whenever possible.

When an agency relies on studies that are not published, it should post the studies on its website as soon as is practicable, subject to copyright and other legal restrictions. When this public transparency is not possible, these restrictions should be explained in the agency's individual analyses and possibly more generally in describing its regulatory program for the public.

2. Staff Authorship or at least Attribution is important for Agency Analyses

Providing authorship or at least attribution to the agency staff who prepares a technical analysis provides a means of accountability and well-deserved credit to government scientists.[444] Identification of the authors of an analysis also helps provide information regarding potential conflicts or biases of the scientists; identifies their disciplinary affiliations; and permits others to assess the extent to which the authors are both expert in the subject matter and retain some distance from having a personal or professional interest in the outcome of the analysis.[445]

Several management-level scientists at EPA confirmed the important role of authorship in their programs, particularly with respect to providing credit to talented agency staff.[446] Authorship also serves to afford agency staff a stake in the final product, thus sharpening debate, internal scrutiny, and the quality of the final product within the agency.[447] At the same time, these agency managers cautioned that since the reports were

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[444] Within science, authorship is fundamental to ensuring transparency, integrity, and accountability. Journals place significant weight on this authorship. *See supra* note 29 and accompanying text (discussing the critical role of authorship in science). While the development of scientific analyses used for regulation is different and may even include nonscientists on the analytical team, the underlying value of some basic authorship and attribution is essentially the same. Moreover, as discussed in the text, this basic credit is not only owed to the staff preparing the analysis but helps retain talented scientists in government. Both of these values are critically important in the President's scientific integrity initiative. *See* Holdren Memorandum, *supra* note 8, at 3 (principle IV noting that "[a]gencies should establish policies that promote and facilitate, as permitted by law, the professional development of Government scientists and engineers"); *see also* Obama Memorandum, *supra* note 7, at 1 (directing agencies to develop retention policies that attract talented scientists).

[445] *Id*.

[446] Interview with EPA Staff, National Center for Environmental Assessment, Jan. 18, 2012; Interview with EPA Staff, National Center for Environmental Assessment, Feb. 3, 2012; Interview with EPA Staff, Office of Pesticide Programs, August 5, 2011

[447] Interview with EPA Staff, National Center for Environmental Assessment, Office of Research and Development, Feb. 3, 2012; Interview with EPA Staff, Office of Pesticide Programs, August 5, 2011; Interview with EPA Staff, National Center for Environmental Assessment, Office of Research and Development, Jan. 18, 2012; Interview with EPA Staff, Office of Air Quality Planning and Standards, Jan. 17, 2012.

co-authored by interdisciplinary teams and subject to multiple levels of peer review and intra-agency review, the staff did not have the power to unilaterally veto revisions (much as an individual NAS or SAB panel member cannot control the content of each feature of the report).[448] Nor were individual authors within EPA actively encouraged to dissent or withdraw as authors when they did not agree with every feature of the resulting analysis.[449] Instead, authorship in these teams is consensual and parallels the approach to authorship taken by science advisory boards or NAS panels where authors are encouraged to agree, but remain free to dissent. Like a consensus report, the agency authors are intimately involved in producing the product; they agree in general terms with the substance of the report; and by contributing their name to the report they signal that they are comfortable with the process for producing the report and its general content.[450] In the unusual case where this consensus cannot be reached, however, agency staff can be removed from the acknowledgements or accreditations or can be changed from authors to contributors.[451] They can also, at least informally (see below), prepare a dissent for the report and the public record.[452]

At the FWS and NRC, there is no similar form of authorship or even meaningful attribution for scientific staff, and there is no reason to believe that these agencies are especially unique with regard to this issue. In the case of the FWS, one agency official suggested that there is generally insufficient time or resources to ensure that the staff reports are adequately reviewed, and thus the reports remain "works in progress" as they move through collaborative intra-agency review processes where they are constantly revised.[453] Making these reports public, agency officials suggest, could increase the resource and time drain on the agency and also place staff biologists in the bulls-eye for political attack and even interference.[454] At NRC, the justifications are less clear but could arise from a concern that authorship and attribution may actually increase incidents of retaliation and chill rigorous staff analysis; a management authored analysis protects staff in this way. More research is warranted on the agencies' reasons for not crediting staff with the scientific analyses, at least in an acknowledgements section. Concerns about resources could be addressed simply by ensuring that draft reports, when made public, are accompanied by internal review comments and marked as a draft. Alternatively, staff-authored drafts could be accompanied by a disclaimer – as they are for draft NAAQS reports – that the staff's analysis is a draft and does not necessarily

[448] Interview with EPA Staff, National Center for Environmental Assessment, Office of Research and Development, Feb. 3, 2012
[449] *Id*.
[450] *Id.*
[451] *Id.*
[452] Interview with EPA Staff, Office of Pesticide Programs, August 5, 2011.
[453] Interview with FWS Staff, Endangered Species Program, Jan. 9, 2012.
[454] Id.; Interview with FWS Staff Member, Field Office, Feb. 15, 2012.

represent the views of the agency, even after it has been internally peer reviewed by other agency staff.[455]

As an important and related point, the programs under study provide at least preliminary support for the observation that staff-authored analyses tend to be more evidence-focused, nuanced, and likely to concede limitations, gaps, and assumptions in the available evidence as compared to analyses that are heavily influenced, if not written by managers.[456] In at least one very well-documented controlled experiment in EPA's NAAQS program, the staff-authored policy assessment provided a much more complete and sophisticated discussion of the relevant scientific literature as compared with the more superficial, incomplete, and arguably ends-oriented, parallel analysis prepared by management.[457] Both EPA's Office of Research and Development and the CASAC noted the significant differences between the staff versus the management authored reports with regard to the robustness, quality, and transparency of the science-based analysis.[458] Though it is merely one example, this experiment suggests that science-integration may benefit from a two-step process that begins with a staff-authored scientific assessment followed by a management-drafted decision based on the evidence.[459] This experience at EPA is also fully consistent with the literature on conflicts-of-interest and the desirability of ensuring that researchers engaged in the analyses do not personally benefit from the results or otherwise have a clear end in mind in the course of developing the analysis.[460]

In sum and where possible, agency analyses should track the principles and norms of science. It thus follows that whenever practicable, scientific and technical assessments conducted by the agency should confer consensus-type authorship rights on the staff who prepares them. These staff authors should be intimately involved in determining what changes will be made to the analysis based on input from expert peers and other commenters. Where authorship is not possible, the staff who prepared the report should at least be given attribution.

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[455] *See* Section III.A.1.a., *supra* (discussing how the NAAQS analyses contain this disclaimer).
[456] At NRC and the FWS, the agencies produce more collaborative science-policy analyses that may originate with staff but are heavily layered with supervisors and manager comments such that the final draft scientific assessment effectively has no clear author but is a product of the agency program working together. There is apparently ongoing discussion in at least the FWS that a listing analysis might also benefit from greater development at the staff level, before extensive review occurs from management. Interview with FWS Staff Member, Field Office, Feb. 15, 2012. In this case the concerns are less about conflicts of interest emerging from the reviewing managers and arise more with respect to the fact that the time allotted for conducting the actual analysis is cut short by the great amount time allotted for multiple reviews by supervisors, all of which must be completed within a year. Yet placing more responsibility on staff might have additional benefits in this situation – such as accountability and providing scientific credit -- that make it even more worthwhile for the FWS to consider processes that place greater emphasis on staff-authored analyses, even if they consist of only the initial literature review.
[457] *See* Section III.A.1.a. (discussing this example in more detail).
[458] *Id.*
[459] *Id.*; Interview with EPA Staff, Office of Air Quality Planning and Standards, Jan. 17, 2012.
[460] *See supra* note 36 and accompanying text.

Agency 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. If authorship rights are not possible, attribution should be provided to individual agency staff for their contributions.

3. The Right to Dissent

Agencies should also develop policies to ensure that they encourage vigorous and diverse debate among agency scientists.[461] This goal of promoting both vigorous and diverse debate is made difficult by the realities of government service (e.g., shared mission and long tenure). Open debate may also be discouraged to the extent there are perceptions by staff that management wants a particular finding and will continue to request information until they "get the answer they are looking for."[462] Yet scientific integrity requires not only protecting skeptics within the agency's scientific staff, but nurturing an environment of robust and open debate and vigorous scrutiny of agency work products.[463]

The NRC's open and collaborative workplace policy offers the most comprehensive approach to address this challenge.[464] This program includes the open door policy, non-concurrence process, and differing professionals program. While these programs have not been given the resources that some might wish or that they necessarily deserve, they are now well-established within the agency. Through these programs, employees are encouraged to question and voice objections and are, as mentioned, given formal avenues to pursue their disagreements and are sometimes even awarded for doing so.[465] Whether these written, formal policies are internalized within the NRC, however, is difficult to determine. Some staff still report they fear retaliation for disagreeing with superiors.[466] On the other hand, surveys of job satisfaction at NRC are generally quite high.[467]

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[461] *See, e.g.*, Obama Memorandum, *supra* note 7, at 1 (directing that the agencies ensure "the highest level of integrity in all aspects of the executive branch's involvement with scientific and technological processes"); Holdren Memorandum, *supra* note 8, at 1 (principle I.1. directing agencies to develop policies that "[e]nsure a culture of scientific integrity. Scientific progress depends upon honest investigation, open discussion, refined understanding, and a firm commitment to evidence.").

[462] *Cf.* Patricia M. Wald, *Analysts and Policymakers: A Confusion of Roles?*, 17 STANFORD LAW & POLICY REVIEW 241 (2006) (describing this problem in the security arena).

[463] *See supra* notes 26 and accompanying text (underscoring the central role that vigorous scrutiny by diverse peers plays in science).

[464] *See* Section III.B.2., *supra*.

[465] *See id.*

[466] *See id.*

[467] *See* NRC News, "NRC Receives Top Rankings from Annual Survey," Sept. 22, 2011, available at http://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=2&ved=0CDUQFjAB&url=http%3A%2F%2Fpbadupws.nrc.gov%2Fdocs%2FML1126%2FML11265A309.pdf&ei=8lInT-

Both FWS and EPA interviewees stated that in practice they utilize an approach that parallels these formal processes in the NRC for permitting and even encouraging dissent and internal debate. Specifically, both agencies report that it is traditionally accepted that staff can file public memoranda dissenting on scientific findings.[468] There was at least one example of this practice in the FWS and in the EPA pesticide program.[469] The EPA and FWS also purport to nurture diverse, open, robust debate among scientists.[470] The FWS in particular suggests that this open and vigorous give-and-take between management and staff defines the scientific culture of the Service.[471] Moreover, the geographic dispersion of FWS's scientists across more than 50 staff and regional offices creates a spatial distance among the employees, particularly in relation to headquarters, which in the case of the FWS only seems to further ensure the diversity of views and the perception of a level playing field with headquarters in terms of scientific expertise and knowledge.[472]

The informal policies in the FWS and EPA do not appear to be documented, however, and may not be well known by employees. Given the informality of these dissent policies, moreover, it seems doubtful that employees will feel they can be assured that supervisors will not retaliate against them in some settings when they chose to dissent. It is also not clear whether an employee's dissent will always be placed in the public record, since supervisors could determine that these statements should be withheld as deliberative process. Additionally, incomplete guidelines and oversight with respect to how to create an administrative record supporting a decision, at least at the FWS, raise the possibility that some important documents, like staff dissents, could be dropped out of the record due to sheer inadvertence.[473]

While formal dissent policies, like those developed by NRC, may prove too cumbersome for all agencies, a simple written policy that explains the freedom of staff to publicly dissent and that sanctions retaliation against dissenters would provide enhanced scientific autonomy for agency staff.[474] Dissents should also be placed in the public record at the staff member's request. This right to dissent is particularly important when agencies do not provide authorship or contribution rights to scientists, and thus scientists

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uJG8PO2wXZzoXmAg&usg=AFQjCNFvL50u5xPjLXdopYqMhYwMc16WEw&sig2=JGIpo7HZhdEmEJuEdH3BEA (reporting on this high job satisfaction report).

[468] Interview with FWS Staff, Endangered Species Program, Jan. 26, 2012; Interview with EPA Staff, Office of Pesticide Programs, August 5, 2011.

[469] *Id.*

[470] Interview with FWS Staff, Endangered Species Program, Jan. 9, 2012; Interview with FWS Staff, Endangered Species Program, Jan. 26, 2012; Interview with EPA Staff, Office of Pesticide Programs, August 5, 2011.

[471] Interview with FWS Staff, Endangered Species Program, Jan. 9, 2012; *see also* Hall memo, *supra* note 196.

[472] Interview with FWS Staff, Endangered Species Program, Jan. 26, 2012.

[473] See Section IV.B.5., *infra* (discussing best practices for the development of administrative records).

[474] Agencies' scientific misconduct policies focus on intentional and reckless fabrication and thus do not even reach these good faith disagreements. *See* Section III.B.1., *supra*, and accompanying text.

cannot even withdraw their name as a contributor in order to express dissent. A formal dissent policy also ensures that expressions of disagreement cannot be hidden under deliberative protections claimed by a supervisor or other agency official.[475]

In developing a dissent policy, each agency should also ensure that changes to the analysis as a result of interagency review or consultations are included. For example, if an agency scientist contributes to a scientific analysis that is changed in the course of OMB review, he/she should be allowed to file a dissent on the public record just the same as if that change were suggested by officials within the scientist's own agency. Thus the dissent policy should make it clear that the right to dissent attaches to an analysis for which an agency staff member contributed, regardless of what governmental institution ultimately changed that analysis.

> **Agencies 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. Such dissenting staff members should be protected from reprisals. Any staff member's dissent or non-concurrence should be made part of the public record at the agency staff member's request.**

4. Ensuring Expert Peer Review of Science-Intensive Regulatory Products

Peer review is a cornerstone of the scientific process, and some level of expert review is similarly integral to ensure the vigorous scrutiny of agency work.[476] Both the President's directive and the Holdren memorandum on scientific integrity explicitly reference this critical role of expert peer review.[477] OMB's Peer Review Bulletin also underscores the value of expert review to the agency's use of science.[478]

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[475] Protecting employees from retaliation is an extremely important feature of such a policy. Given the size and scope of these various whistleblower issues, however, the details are left for a separate ACUS report or similar investigation. NRC's more formal program, by contrast, may offer a particularly helpful model for agencies that utilize a hierarchical management structure; in these management-heavy structures, scientific information may be at even greater risk of being dropped out or adjusted as it moves up the chain of command. In other settings, however, the formality of the program may be unnecessarily costly and could even undermine a culture of collegiality for agencies that purport to be more collaborative in their preparation of analyses, like FWS.

[476] *See supra* notes 26and 39 accompanying text.

[477] *See* Obama Memorandum, *supra* note 7, 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"); Holdren Memorandum, *supra* note 8, 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* BiPartisan Policy Center, *supra* note 3, at 17 (recommending that "[f]ederal agencies should use scientific advisory committees to the maximum extent possible to review the science behind regulatory policies"); National Performance Review, Sept. 1993, Improve Regulatory Science, at 61 (recommending the use of external advisory boards).

[478] *See* OMB's Peer Review Bulletin, *supra* note 409.

In the federal government, agencies have at their disposal multiple tools for engaging this expert peer review. These tools include: a) developing quality control processes, such as technical audits, for more routine agency decisions; b) developing formal or informal processes for intra-agency review; and c) utilizing external peer review by soliciting individualized reviews or assembling expert review panels. In some settings, peer review panels are even required by statute.[479]

This study reveals that some agencies utilize these peer review tools extensively and in ways that go well beyond the bare minimum requirements set forth by statute and OMB's guidelines. For example, while EPA is required to engage CASAC in the review of its proposed revision to an air quality standard, EPA is not required to have each of its staff reports reviewed multiple times by this science advisory body.[480] Similarly, EPA relies on external peer review as a critical step in its IRIS assessments, but there is no legal requirement that it solicit this external review for most of its assessments.[481] Even when pressed by very short statutory deadlines for decisions, the FWS incorporates external peer review into its listing and habitat designation decisions.[482] And it has persisted with this commitment to external peer review in the face of both congressional and stakeholder opposition.[483] Interviews with agency officials in all three agencies reinforce the high value they place on expert peer review for their regulatory work, particularly with respect to the value of external peer review.[484]

The agencies studied here fared very well in their commitment to expert peer review, but their records were not perfect. At least the NRC was criticized by its Inspector General for failing to develop validation and quality control processes for the information collected by agency staff in their review of permit renewals and amendments.[485] Indeed, it seems likely that if there are lapses with regard to peer review, they may occur in programs that involve more routinized licensing decisions. EPA's pesticide program, which does engage internal expert review of the agency's scientific projects, was also criticized by one anonymous scientist for not engaging external expert peer reviewers in the review of its risk assessments.[486] The merits of the agencies' choices will only become clearer once they are identified and explained.

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[479] *See* Section III.A.1.a. and A.3, *supra.*
[480] See 42 U.S.C. § 7409(d)(2).
[481] While some IRIS risk assessments are likely "influential" under OMB's peer review bulletin, it seems unlikely that all of them are. *See* OMB, Peer Review Bulletin, *supra* note 409. Yet EPA engages external peer review in all the IRIS assessments. *See* Section III.A.1.b., *supra*.
[482] *See* Section III.A.2., *supra*.
[483] *Id.*
[484] Interview with EPA Staff, Office of Air Quality Planning and Standards, Jan. 17, 2012; Interview with EPA Staff, National Center for Environmental Assessment, Jan. 18, 2012; Interview with EPA Staff, National Center for Environmental Assessment, Feb. 3, 2012; Interview with FWS Staff, Endangered Species Program, Jan. 9, 2012; Interview with NRC Staff, Oct. 26, 2011.
[485] *See* Section III.A.3., *supra*.
[486] *See* Section III.A.1.b., *supra*.

Although some form of expert peer review is considered fundamental in the agencies' use of science, the actual tools that the agencies utilize for any given science-based project defy generalization. With the single exception of OMB-prescribed expert peer review for "influential" scientific assessments[487] and scattered congressional mandates that require science advisory board review in narrow regulatory settings,[488] there also are few minimum requirements placed on agencies that limit or frame their ultimate choices in engaging this expert review. This flexibility seems wholly warranted given the many factors at play.[489] As discussed later, while agencies should explain why they select a particular approach to expert review in their decision-making process, beyond this explanation requirement, too many prescriptive requirements for expert peer review should be avoided, at least based on the current knowledge of these processes.

Conversely, however, restrictions that limit the agencies' use of external peer review should be eliminated. A prior recommendation discusses how caps on FACA committees and perhaps other features of the implementation of FACA may impede the ability of agencies to enlist external peer review.[490] These and any other barriers identified by the agencies and OSTP with respect to limiting agency peer review options should be removed or at least reduced to the extent possible.

Beyond removing barriers, a second recommendation is to establish as a best practice a simple expectation that agencies should, whenever practicable, utilize some type of expert review for science-based decision-making and should explain their peer review choices in individual programs when doing so will not impose a significant burden on the agency This expert peer review need not involve external review, but at a minimum should include some quality control by agency technical experts.

Consistent with President Obama's directive, an agency's scientific analysis should be reviewed by other experts or subject to some mechanism of quality control, even if this oversight occurs wholly inside the agency. 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.

5. Four Analytical Steps that Enhance the Transparency of the Agency's Policy Choices

One of the core problems in science-policy is the difficulty of identifying how the agency's policy decision has been informed by a robust assessment of the best available

[487] *See* OMB, Peer Review Bulletin, *supra* note 409, at 37-40.
[488] *See supra* note 479.
[489] *See* National Performance Review, *supra* note 477, at 59 (recommending flexibility in agencies ability to use a variety of different peer review methods for regulatory science).
[490] *See* Section IV.A.3., *supra*.

scientific evidence.[491] Administrators have often said "the science made me do it" when the opposite was in fact the case. Moreover, in some cases agencies have failed to develop robust scientific records to support decisions, and in rarer cases those records have been skillfully manipulated in ways that are invisible to non-experts and in some cases even to expert reviewers. The literature is filled with examples of this lack of transparency of the respective roles of science and policy in the agency's regulatory work.[492]

The antidote to these problems – in theory – is for the agency to present its analysis in a way that allows its choices, including the policy decisions in both the proposed and final rule, to be compared against an accessible statement of the scientific evidence, including the gaps, uncertainties and limitations of that evidence. Indeed, this is precisely what is required by the President's scientific integrity memorandum.[493] Yet bringing this theoretical ideal into practice has stymied the agencies and other commentators.

While the NAAQS process may not have the ultimate answer to this implementation challenge, it appears to have the best answer presently.[494] Key features of the NAAQS process that help draw out the relationship between policy and the underlying scientific information are: 1) the initial articulation of specific policy questions arising in a regulatory project that might be informed by science; 2) an assessment of the available evidence bearing on these questions; 3) application of the evidence to the policy questions at issue, with robust statements of all material uncertainties and assumptions; and 4) a report that identifies the various plausible policy alternatives based on the scientific record that is accessible to policymakers.

Clearly each of these steps cannot be done in an elaborate way for every science-intensive regulatory project, but most of these steps are already implicit in agency analyses. Thus, even if these discrete steps are collapsed into a single document, they will nevertheless offer an analytically useful way to begin to identify overarching policy questions and the important role that science plays in resolving them.

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[491] *See* Section I, *supra* (discussing this problem).

[492] *See*, *e.g.*, Doremus, *supra* note 6; Holly Doremus, *Scientific and Political Integrity in Environmental Policy*, 86 TEXAS LAW REVIEW 1601 (2008); Strauss, *supra* note 389; Wendy Wagner, *The Science Charade in Toxic Risk Regulation*, 95 COLUMBIA L. REV. 1613 (1995); *see also* OIG MacDonald Report, *supra* note 10.

[493] The Holdren Memorandum requires agencies to "communicate scientific and technological findings by including a clear explication of underlying [significant] assumptions; accurate contextualization of [significant] uncertainties; and a description of the probabilities associated with both optimistic and pessimistic projections, including best-case and worst-case scenarios where appropriate." Holdren Memorandum, *supra* note 8, at 2; *see also* Obama Memorandum, *supra* note 7, at 1 (directing agencies to "make available to the public the scientific or technological findings or conclusions considered or relied on in policy decisions.").

[494] *See* Section III.A.1.a, *supra*.

1. *Policy Questions.* Agencies should first identify the policy questions that can be informed by the scientific evidence. The NAAQS process dedicates an entire report to this stage of the process,[495] yet articulating the science-policy questions could be done with relatively little effort in an initial paragraph of an agency's report.[496] Ideally, agencies would also include these key questions in their requests soliciting relevant information from the general a public; a request that was made in every regulatory program under study.

2. *Assessment of the Evidence.* Agencies should then identify and evaluate the existing scientific evidence – mostly the literature – that bears on these policy questions. This step of summarizing and interpreting the literature lays the groundwork for the agency's next step – its choice and application of models and other assessment tools to inform the policy questions, often in a more focused and quantitative way. Since an evaluation of the literature is implicit in science-intensive regulatory work, separating out this step will not only be natural step in most cases, but will make the resulting analysis more transparent.[497]

3. *Application of the Evidence.* Agencies should then identify and justify their choice of models and other analytical tools (in some programs this is done generically at a program-wide level)[498] and then apply these application tools to the scientific evidence described in step 2. This application of model(s) to the evidence should highlight the policy-relevant choices involved in selecting among plausible models or using multiple models and should also identify the significant, policy-relevant assumptions adopted in applying the models themselves (e.g., the choice of algorithms for important variables, etc.). This application of the evidence to the policy question should also identify significant uncertainties that result from using these models, assessments, etc. EPA's NAAQS report again is considered to be particularly good at providing this kind of explication.[499]

4. *Bridge the Evidence to the Policy Questions.* The agency should then explain in ways that nonscientists can understand how this scientific analysis informs the core policy questions. This discussion should identify the significant

[495] *Id.*
[496] The FIFRA process, albeit inconsistently, also involves a planning stage that identifies the policy-relevant questions. Although they are presented in only a few paragraphs, these more focused questions nevertheless go a long way to help frame the resulting scientific analysis. *See* Section III.A.1.b., *supra*.
[497] Interview with EPA Staff, National Center for Environmental Assessment, Jan. 18, 2012; Interview with FWS Staff Member, Field Office, Feb. 15, 2012.
[498] *See* Section III.A.1.b., *supra* (describing this feature of FIFRA risk assessment models, which are reviewed by EPA's SAP).
[499] *See* NAS FORMALDEHYDE REPORT, *supra* note 2, at chapter 7.

choices that need to be resolved by policy considerations, as well as the range of plausible choices, before recommending a preferred course.[500]

In terms of best practices, the agencies under study generally did not disaggregate their analyses into these separate steps. For example, only in the case of NAAQS and to a lesser extent in FIFRA is an evaluation of the evidence and an assessment of the evidence separated in the agency's decision-making.[501] The FIFRA and NAAQS programs are also the only programs that consistently articulate specific policy questions that serve to focus the resulting scientific analysis.[502] Finally, only the NAAQS process provided a frank discussion of how the scientific information informs the pressing policy questions, at least in a way that is accessible to nonscientists.

Since each of these analytical steps is necessarily implicit in much of the work the agencies do, the recommendation below encourages the agencies to make these analytical steps explicit, particularly the first three steps since they should be easy to separate out for most agency analyses. The fourth step is arguably the most important, but it will likely require more agency resources since it involves an additional discussion that attempts to bridge policy and science. It also requires the agency to communicate this analysis to nonscientists, which is not a simple matter. In the meantime, the agencies are encouraged to study the NAAQS policy assessments for ideas on how this fourth step might be accomplished within their unique programs.[503]

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 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 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 how different plausible choices would change the resulting policy decision. The agency should also endeavor to follow the model of the NAAQS policy assessment in bridging science and policy, although this step will likely involve more effort and experimentation.

[500] In EPA's policy assessment, the staff explains the different scientifically plausible options available to the decision-maker and outlines the details of the scientific support (pro and con) for each option. CASAC is intimately involved in reviewing this science-policy synthesis to ensure that it is accurate in its representations of the underlying scientific assessments. *See* Section III.A.1.a., *supra*.
[501] See Sections III.A.1.a. and b., *supra*.
[502] *Id.*
[503] *See* Section III.A.1.a., *supra* (discussing these policy assessments and giving links to some recent policy assessments).

6. Transparent records that apply Deliberative Process protections sparingly

Both the Obama and Holdren memoranda direct agencies to make their underlying analyses and reasoning as transparent as possible, and this presumably includes an expectation that the agencies will share all stages of their work through comprehensive administrative records. As the President states: "If scientific and technological information is developed and used by the Federal Government, it should ordinarily be made available to the public."[504] As just discussed, because there is a range of interpretations of the scientific literature, alternative models, and often dozens of important judgments with regard to how to address remaining uncertainties, it is important for agencies to show their work to the greatest extent possible. Rulemaking records that are incomplete and neglect to show the agency's analytical process can obscure these important decisions. Indeed, if the decision-making processes studied here reveal anything – and this is exemplified most dramatically by the NAAQS process – it is that the series of documents and records that lead up to a final decision tell the story of the analysis. Recall that in both NAAQS and pesticide reviews, the pre-NPRM period involves multiple different analytical documents, notice and comment processes, and approximately four years of scientific discourse over the scientific information.[505] In such a decision process, the final decision document is simply the conclusion or ending. Without these earlier chapters, one is unlikely to be able to reconstruct the analysis that preceded it.

In meeting this goal of comprehensive administrative records, the agencies' practices were mixed. EPA's NAAQS process and NRC's informal rulemakings appear to involve the creation of relatively complete and open records, and at least NRC indicated that it utilizes deliberative process privileges only in exceptional cases involving privacy or security.[506] The administrative records in the other programs appeared to involve a less consistently open approach towards deliberative process and record creation. Despite its command that all interagency written comments be included in the record,[507] for example, EPA's IRIS risk assessments still involve lengthy phone calls and meetings with other affected agencies that do not appear to be recorded in the public record.[508] Particularly given the early point in the process when these communications occur, this deliberative input may lead to changes in the framing of the basic scientific assessment that are never explicated and remain invisible. EPA's

[504] Obama Memorandum, *supra* note 7, at 1; *see also* Holdren Memorandum, *supra* note 8, at 2 (directing agencies to ensure the "free flow of scientific and technological information" which includes "[o]pen communication among scientists . . . and the public").
[505] *See* Sections III.A.1.a. and b., *supra*.
[506] Statement of NRC Staff, Feb. 1, 2012.
[507] *See* Section III.A.1.c., *supra*.
[508] Interview with EPA Staff, National Center for Environmental Assessment, Feb. 3, 2012. It is not clear whether this decision to rely extensively on these deliberative discussions is a choice of OMB or EPA, although given the OMB's more vigorous application of the privilege to its communications, it seems more likely to be the former.

pesticide staff similarly concedes that phone calls originating from USDA to EPA are not included as part of the record.[509] The FWS also uses the deliberative process privilege to protect its record until the proposed rule is published, but even after that point one FWS staff member suggested that the FWS might still use the privilege in some cases to withhold some documents.[510]

Additionally, in the programs studied, the agencies' administrative records were not always compiled in ways that ensured that each important analytical step in the agency's decisionmaking was documented. FWS staff, for example, concedes that the record-compiling policies and practices at the Service are both dated and have become somewhat ad hoc.[511] As a result, each field office may create the record supporting a listing differently. One office might prepare the record diligently by compiling all drafts, carefully documenting the changes made at each step of the process and the reason for the change, and identifying substantive input between staff and management. In other offices the documents may be gathered late in the process, with the possibility that in this more haphazard creation of the administrative record, key documents will be missed, overlooked, or lost.[512]

An additional best practice principle for the agencies' integration of science into policy is thus to expect them to produce a comprehensive record that tracks their science-based decision-making for a given regulatory decision. This involves assembling draft reports, memoranda, and comments that document each significant step in the agency's analytical process. Providing this kind of open accounting of the agency's analytical process parallels a similar commitment to openness in science (i.e., that the underlying data should be made available) and indeed is even more critical in science-policy where there is more opportunity for hidden policy choices to influence an agency's analysis. Any gaps in this public documentation constitute weak links in the analytic chain and present the possibility that key decisions will be obscured from public view.

In the preparation of this comprehensive administrative record for science-intensive regulations, there should also be a strong presumption against deliberative process claims. To the extent that claiming deliberative process for the substance of interagency meetings is routine, for example, this tradition should be reversed and the privilege should be justified for each document before removing it from the public record. As Judge Patel recently reminded OMB in a case in which OMB asserted a similarly expansive deliberative process privilege claim: "It is the government's burden to set forth the exemption and justify withholding a document pursuant to that particular exemption. This is accomplished on a document by document basis by use of a 'Vaughn

[509] Interview with EPA Staff, Office of Pesticide Programs, August 5, 2011.
[510] Interview with FWS Staff Member, Field Office, Feb. 15, 2012.
[511] Interview with FWS Staff Member, Field Office, Feb. 15, 2012.
[512] *Id.*

index.'"[513] If instead OMB is allowed to claim deliberative process for all if its Presidential review duties, it "would effectively remove the OMB from the FOIA's reach. Without express statutory authority in this respect, this court is unwilling to provide the OMB with such a blanket waiver."[514]

To effectuate this best practice, agencies should develop written policies and regularized guidelines that instruct agency staff to place all important discussions on the record unless a very narrow set of circumstances is present that justifies an Executive Privilege.[515] Each significant analytical step, draft, and change should be included in this record. Every outside and interagency communication should be documented and described. Internal review comments should be made available, where possible. Again, while these complete record-keeping practices may not be necessary for all informal rules, this documentation is particularly important for science-intensive regulations.

Finally and ideally agencies should place their administrative records on the internet to permit easy public access. The FWS, as noted, does make its supporting record available at the time the proposed rule is published, but the record is apparently available only at one field office and is not available online.[516] In practice, then, public access to the FWS's administrative records supporting its listing and habitat designation decisions is limited. The other agencies studied generally posted their entire records and supporting documents on the web, either through regulations.gov or their own program's electronic library.

> **Agencies should resist applying deliberative process protections to documents and communications that influenced the development of science-based regulatory projects. To the extent agencies do invoke the deliberative process privilege, they should justify so doing with respect to each document that is withheld from the public. Draft science-policy analyses, such as draft papers, can be made public with the disclaimer that they do not necessarily represent the policy or scientific position of the agency. Agencies should**

[513] Center for Biological Diversity v. Office of Management & Budget, 546 F. Supp.2d 722, 729 (N.D. Cal. 2008) (emphasis added).
[514] *Id.*; *see also* NRDC v. U.S. DOD, 442 F.Supp.2 857, 861 (C.D. Cal. 2006) (requiring OMB and other agencies to provide "original justifications" for withholding documents under FOIA on a document-by-document basis).
[515] In 1980, the Administrative Conference recommended that advice an agency receives from other agencies or from the President and his/her advisers that pertains to matters of policy need not be placed in the public record, whereas advice related to factual matters should be memorialized therein. Administrative Conference Recommendation 80-6, *Intragovernmental Communications in Informal Rulemaking Proceedings*, 45 Fed. Reg. 86,407 (1980). The current report concludes that the distinction between fact-based and policy-based decisions is rarely clear in science-intensive rulemakings, *see* Section I, *supra*, and it therefore declines to use that distinction to determine whether agencies are justified in invoking the deliberative process privilege. Rather, it proposes that agencies assess each claim of deliberative process individually and invoke that privilege only in exceptional cases, such as those involving privacy or security.
[516] *See* Section III.A.2., *supra*.

prepare an administrative record that advances this transparency goal by ensuring that the documents, meetings, and other deliberations that resulted in potentially significant changes to scientific assumptions or interpretations are made part of the administrative record. These administrative records should be posted on the internet when possible.

7. Stopping Rules are Useful to Clarify the Point at which a Scientific Record and Debate are Closed

The notion that a scientific record is closed on new science or debate is antithetical to the scientific process, yet in policy settings this closure is essential if decisions are to be reached. In this study, these points of closure are loosely referred to as "stopping rules."[517] In the case of regulatory science, stopping rules are not based on science but instead are based on the agency's available resources, time and other policy considerations.

The need for "stopping rules" in regulatory policy arises in at least two different contexts. First, the agency must develop an explicit point at which it closes its consideration of new evidence. Without this type of stopping rule, each new study or discovery that arises in the course of the regulatory process could arguably throw the project back to the starting point, requiring the agency to conduct a re-analysis, reopen the comment period, etc. Second, the agency will generally find it necessary to close debate, even when important scientific issues have not been resolved.

Stopping rules are not only important to ensure that the agency stays on track to produce final decisions for science-intensive regulatory programs, but these rules are important to enhance the transparency of the decision-making process. Explicit stopping rules provide all participants, as well as agency staff, with clear policy direction on when scientific disagreements have come to a close. Without clear stopping rules, points of debate and new studies can even be used manipulatively, as well as in good faith, to throw the science-policy decision-making off course or run it through repeat circles of analysis and peer review, without any credible way of cutting off these iterative analyses and discussions.

With respect to emerging science, several agency programs – particularly the NAAQS and FWS's listing programs – have built-in stopping rules; both agencies face strict statutory deadlines that can and have been enforced by stakeholders in court.[518] Even in programs that lack these statutorily set stopping rules, some agencies have developed accommodations to meet the challenges posed by emerging science. In the

[517] The concept of stopping rules were introduced into the social studies of science literature by Sheila Jasanoff. *See supra* notes 41-42 and accompanying text for a discussion of stopping rules.

[518] *See* Sections III.A.1.a. and 2., *supra*. For example, the one year deadline for a decision under the ESA is so abbreviated that little new science or methodological breakthroughs are likely to emerge in the interim.

NAAQS program, EPA has reinforced its statutory deadline with an agency policy that once the integrated science assessment (EPA's analysis of the existing literature) has been peer reviewed, new science will not be considered until the next five year revision of a standard.[519] In IRIS assessments, EPA also attempts to limit itself to the scientific record created at the time a risk assessment is peer reviewed, although this appears to be a more informal convention.[520] In pesticide registration reviews, by contrast, new science is considered up to the point of the proposed decision.[521] The pesticide registration review process is new enough that there is not a lot of experience to determine whether earlier stopping rules are needed and whether this more open-ended approach could create the possibility of extended delays.[522] A best practice would suggest that agencies establish their stopping rules for emerging science ex ante and explicitly – for example determining that evidence arising after a critical analysis point will not be considered.

Setting stopping rules for when debate is closed is a much more difficult task for the agencies, particularly for programs that do not involve rigid statutory deadlines. Critical comments by peer reviewers and the public can identify multiple differences with the agencies' technical analysis. Each revision of the draft in response to comments may shrink the contested issues in need of elaboration or development, but the revisions can also open up new issues for yet another round of critical scrutiny and debate.[523] As a result, there is no clear point for when the rule is effectively good enough, and there is also no clear point for when an agency's response to a set of criticisms can be considered complete, particularly for heated scientific disagreements.[524]

Not surprisingly, most agency programs lack clear stopping rules that allow them to put an end to ongoing scientific debate, and this resulting ambiguity creates problems for the agencies. Without clear stopping rules, it is difficult for stakeholders to distinguish those situations in which the agency's decision to close debate is based on science or instead on practical realities. The lack of transparency in an agency's stopping rules may also explain some of the most vigorous criticisms of the quality and transparency of the agencies' science. For example, stakeholders from both the industry and public interest community interviewed for the study considered the most significant

[519] Interview with EPA Staff, Office of Air Quality Planning and Standards, Jan. 17, 2012. In some cases the agency may conduct a provisional scientific assessment near the end of the NAAQS review process that considers whether the new science would have materially changed its decision. EPA staff reports that these provisional science reports have never led to a finding that the new science would cause a material change in the standard. They credit this fact largely to the enormous scientific record that exists at the time of standard-setting and the resultant unlikelihood (but not impossibility) that a new study in fact will support a material change in the standard. Interview with EPA Staff, Office of Air Quality Planning and Standards, Jan. 17, 2012.
[520] Interview with EPA Staff, National Center for Environmental Assessment, Jan. 18, 2012.
[521] Interview with EPA Staff, Office of Pesticide Programs, Jan. 27, 2012;
[522] *Id*.
[523] *See also* Sheila Jasanoff, *Research Subpoenas and the Sociology of Knowledge*, 59 Law & Contemp. Probs. 95, 99-100 (Summer 1996) (discussing the "infinite regress" problem; basic methodological features of research are established on consensus but are susceptible to unraveling when under fierce attack).
[524] *Id*.

transparency problem in EPA's pesticide program to be the agency's insufficient and unjustified dismissal of some of their comments.[525] Yet this could easily be the result of confusion over the basis (stopping rules vs. science) for EPA's decision to close debate as it moves towards a decision. In IRIS, voluminous peer review comments from external reviewers, combined with a high level of intense stakeholder criticism, including from sister agencies, appear to contribute substantially both to the agency's excessive delays in preparing IRIS assessments and to the unwieldy nature of the resultant assessments that endeavor to respond to these numerous comments.[526] Again, the problem may be the lack of explicit stopping rules to end debate. Indeed, in IRIS it is possible that the EPA may not have the final say on setting stopping rules; instead closure is determined by OMB through intergovernmental arrangements that are not in the public domain.[527]

As a matter of best practices, agencies should endeavor to establish clear stopping rules for technically complicated regulatory decisions, particularly when they operate without judicially enforceable statutory deadlines.[528] Agencies should also be clear when they are closing debate simply because there is no clear resolution (e.g., setting a stopping rule on ongoing debate) versus when the agency instead believes there is a best scientific answer to a particular contested issue. This distinction will provide enhanced transparency on whether the agency is deciding based on policy or instead believes that as a scientific matter extended debate is not warranted.

In the NAAQS reviews, EPA has again been a pioneer in developing a different and potentially easier way to develop credible stopping rules for closing debate over unresolved scientific issues. Specifically, EPA relies on its science advisory board, CASAC, to effectively declare "closure" when it considers the EPA's responses to criticisms adequate.[529] This respected opinion of CASAC effectively puts a stop to disagreements and overrides criticisms and comments filed by stakeholders and the general public. Interestingly, moreover, while there were discussions of limiting CASAC's power to declare "closure" during the reform of the NAAQS process,[530] it

[525] *See* Section III.A.1.b, *supra*.
[526] Interview with EPA Staff, National Center for Environmental Assessment, Feb. 3, 2012.
[527] One of the major sources of frustration by EPA during OMB review is that OMB's "stopping rule" is an effective requirement that the agency make all of the requested corrections; until that point, the rule is not cleared for publication. One EPA staff relayed that "[b]oth OMB's minor and major comments are viewed as equal; all the changes need to be made." Interview with EPA Staff, National Center for Environmental Assessment, Jan. 18, 2012. *See also* GAO, Chemical Assessments, *supra* note 146, at Appendix III (identifying the important role that OMB has played in some IRIS assessments).
[528] Agencies are likely not to voluntarily promulgate binding rules that set reasonable deadlines for their projects and thus simulate statutory deadlines, but if they did set judicially enforceable deadlines on their regulatory projects through regulation this would also address the stopping rule challenge for agencies that lack statutorily required deadlines.
[529] *See* Section III.A.1.a., *supra*.
[530] This was based on a concern that this type of authority provided CASAC too much power and further delayed the proceedings, over time. Interview with EPA Staff, Office of Air Quality Planning and Standards, Jan. 17, 2012.

appears that the CASAC's closure role continues today.[531] EPA may have realized that it is in the agency's best interest to have an independent and trusted scientific arbitrator determine when the agency's response to criticisms and comments is sufficient.

In particularly controversial science-based projects, agencies should thus consider convening expert panels to assist them in setting stopping rules. Indeed, in weighing the advantages of external peer review, this attribute should be factored in as a benefit. External peer review likely works to facilitate closure only when the reviewers are convened as a panel, rather than individually, however. In the IRIS process, for example, the use of individual external peer review provides valuable scientific feedback, but because the reviewers don't confer, these individual peer review comments are as likely to expand the issues at play as narrow them. It is not unusual for individual reviewers to place emphasis on different issues or even conflict in their comments, for example.[532] In cases when advisory bodies are used, moreover, this external scientific review role should extend until the public comment period ends to ensure that the panel's deliberations consider the issues raised by stakeholders and facilitate closure. The importance and value of external peer review advisory boards with respect to stopping rules again reinforces one of the previous recommendations regarding eliminating unnecessary barriers to the agency's use of FACA for purposes of soliciting external peer review.

> **In regulatory settings, particularly in cases when agencies are not bound by judicially enforceable deadlines, the agencies should establish explicit stopping rules on regulatory projects, both with regard to when they will close their consideration of emerging research and when they chose 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.**

8. Providing a clear explanation of agency decision processes

In all programs studied, the flow charts and processes uses by agencies to incorporate science into their decisions had to be recreated from scattered documents and interviews. The processes remain particularly obscure for the FWS's listing and critical habitat designation decisions and to some extent for the NRC's regulatory process. Even for heavily revised programs like the IRIS process, which have been diagramed multiple times in the course of congressional investigations, GAO reviews, and critical commentary,[533] the agency's incorporation of science into the assessment process is

[531] Interview with EPA Staff, Office of Air Quality Planning and Standards, Jan. 17, 2012. See Section III.A.1.a., *supra*.
[532] Interview with EPA Staff, National Center for Environmental Assessment, Feb. 3, 2012. *See also* Section III.A.1.b., *supra*.
[533] *See, e.g.*, Center for Progressive Reform, Corrective Lenses for Iris, Sept.2010, available at http://www.progressivereform.org/articles/IRIS_1009.pdf.

generally not explicated at the level of detail that is useful for understanding whether all of the best practices outlined in this analysis have been followed.

To ensure that agencies provide an accessible, but detailed summary of their processes for incorporating science into specific regulatory programs, OSTP should require agencies to document and explain these processes as part of its scientific integrity initiative. This is consistent with the President's directive that "[t]he public must be able to trust the science and scientific process informing public policy decisions."[534] This explication of agency processes will guide staff and provide those outside the agency with an understanding of how science is being integrated into regulatory decisions. At the same time, it should not take agencies much time to comply with this directive since agencies are simply recording their existing, standard operating procedures.

An agency's explanations should include, where practicable, a description of how that agency conducted and reviewed staff analyses, the agency's use of deliberative process, choices made about stopping rules, the agency's use of expert peer review, the public accessibility of unpublished information that informed the report, etc. Ideally, the agency can follow the best practices offered here or a related best practice set of guidelines as a template to ensure all the relevant information is discussed.

Agencies should also be required to explain their processes. Particularly in the case of IRIS, EPA should be required to explain why interagency review occurs twice during the preparation of a risk assessment, for example, while public and expert review occurs only once. Indeed, given the fact that most of the participating agencies are stakeholders and engage out of a concern about compliance costs or potential liabilities, it seems fully appropriate for their engagement to be reserved to the single public comment period as is the case for interagency review in the other agency processes studied here.[535]

> **OSTP should require agencies to provide a detailed and accessible description of the process that they utilize for integrating science into their decisions for each of their science-intensive programs. This includes 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.**

9. Highlighting Agency Innovations

[534] Obama Memorandum, *supra* note 7, at 1.
[535] See data summary in Section III.C., *supra*.

In this study, the agencies did not publicize their innovations or successes. Yet as this study has revealed, many agencies have developed innovative mechanisms for ensuring transparency in their use of science, and they should advertise and disseminate these best practices for consideration by other agencies.

As part of its scientific integrity initiative, OSTP should advertise what the agencies are doing especially well with respect to the integration of science in regulation, particularly when their approaches might be useful to other agencies. In conducting this work, OSTP could borrow from ACUS's best practices project, which spotlights agency innovations, provides short summaries of these innovations, and offers a forum wherein agencies can describe their innovations.[536] Since these agency successes in the use of science are ground-tested and have been improved over time, they should be particularly instructive to other agencies.

OSTP or even the EPA Air Office should also produce a short, lessons-learned report based on the development of the NAAQS process. Since Section 109 of the Clean Air Act provides little room for discretion and policy judgment, the EPA's effort to identify uncertainties, assumptions, and choices in these scientific analyses is particularly instructive for other agency programs. It is also worth noting that every agency employee interviewed in the study who was not affiliated with the NAAQS process, with one exception, was unaware of the details of the NAAQS process, much less the content of these reports. Stakeholders who were familiar with the strong reputation of the NAAQS program were similarly unfamiliar with its details. The obscurity of the NAAQS process to those working on science-intensive regulations outside of the air pollution control arena is unfortunate and can be easily remedied with this type of publication.

Without an effort to learn from the success stories, other agencies may needlessly develop regulatory processes from scratch when there is a ready-made, time-worn approach already in use that provides a ready template for their efforts. Focusing on agency innovations also publicizes the agencies' successes and helps to counterbalance OIG, GAO reports, and congressional hearings that, by design, tend to focus almost exclusively on problems.

OSTP should identify and publicize the best practices developed by agencies for transparently incorporating science into their regulatory decisions. In doing this, OSTP could establish a forum – e.g., a website or workshops – through which agencies can share innovations in their integration of science into policy.

C. Future Questions for the Study of Regulatory Science

[536] See ACUS best practices at http://www.acus.gov/best-practices/

There are many issues regarding the agencies' use of science that will benefit from further research. Some of the issues that emerged from this study are described below:

Challenges to evaluating the reliability of data and studies submitted by applicants, particularly studies that are non-transparent (e.g., unpublished and/or publicly inaccessible)

A recurring theme in the study of the different agency programs, as well as in more general interviews, was a concern about how to ensure the reliability of scientific data and studies that are not published and/or publicly accessible. Coincidentally, much of this scientific information is submitted by applicants or regulated parties that generally have vested interests in the outcome of the research. In the case of pesticides, for example, FIFRA requires a member of the public to obtain Section 10(g) clearance before he/she can view the data or research submitted by pesticide manufacturers in support of their pesticide registration.[537] While a member of the public can typically gain this 10(g) access, it requires effort and is generally available only after a pesticide registration decision has been made.[538] Since the research and data submitted by pesticide manufacturers often comprise the majority of the studies available on a particular chemical, and since those studies can sometimes number in the hundreds for a single pesticide,[539] these barriers to public access to the underlying research that informs pesticide decisions are not a trivial problem.

Analogous problems arise in other agency programs. In natural resources law, for example, FWS consultations under section 7 of the ESA are required when an endangered species may be adversely affected by a federal action.[540] Yet the research that the FWS uses to make a determination of whether the federal project will put the species in jeopardy is a biological assessment conducted by the federal agency seeking to undertake the project.[541] Stakeholders and the FWS concede that the quality and comprehensiveness of these assessments are not always up to the FWS's standards.[542] Beyond the inherent conflicts involved in preparing the assessment, the applicant agency may not consider the assessments a high priority and may allocate resources accordingly.[543] Many of these preliminary assessments are not subject to notice and

[537] 7 U.S.C. § 136h(g)(1).
[538] *See* Section III.A.1.b., *supra*.
[539] Interview with FWS Staff, Endangered Species Program, Jan. 26, 2012. This could be empirically verified by counting the number of studies in the data tables for each pesticide listed in EPA's risk assessments, but it was beyond the scope of this study.
[540] 16 U.S.C. § 1536(a).
[541] Interview with former staff of Environmental Defense, Jan. 19. 2012; Interview with FWS Staff, Endangered Species Program, Jan. 26, 2012.
[542] Interview with FWS Staff, Endangered Species Program, Jan. 26, 2012.
[543] Similar quality problems can afflict Clean Water Act Section 404 applications that permit developers to place fill material in wetlands (technically to discharge a pollutant into waters of the United States). 33 U.S.C. § 1344. These applications are prepared by the developers, yet they provide much of the

comment, moreover, and the public may be only dimly aware that the processes are occurring, much less have the ability and knowledge to request these documents in order to review them.[544]

Similarly, in the re-licensing of nuclear reactors, NRC staff has been criticized for not verifying technical statements and assessments contained in an operator's application.[545] The NRC's OIG found that this verification work could have made a material difference in the safety evaluations of applications, at least in some cases.[546] Moreover, none of this underlying technical information was available to NRC personnel located off-site.[547] Stakeholders could also not independently verify whether the applicant-provided information was reliable.

While agencies acting on applicant-submitted information suggest that they review this information carefully,[548] the process remains nontransparent to the extent that outside parties cannot verify the reliability of this information independently. In most cases there is also no independent peer review of the information. Stakeholders are concerned that in these cases the agencies' decision-making processes will not provide sufficient supporting information to the public to allow for rigorous review.[549]

The ability of resource-strapped agencies to provide rigorous and transparent oversight of data submitted by applicants or regulated parties – without the benefit of external review by experts or even stakeholders or other members of the public – deserves further study. Some agency officials suggest that the agency dedicates considerable staff resources to ensuring the rigorous oversight of this incoming information, such as in pesticide registration reviews.[550] Yet the pressure to finalize decisions, even in the licensing context and particularly under statutory deadlines, may impair the ability of the agencies to undertake a number of iterative review steps with applicants in order to ensure that their studies are complete.[551] To the extent that there is

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information the Corps of Engineers use to determine whether the application should be granted. Similar quality problems can afflict Clean Water Act Section 404 applications that permit developers to place fill material in wetlands (technically to discharge a pollutant into waters of the United States. Interview with staff, PEER, Aug. 5, 2012.

[544] Interview with former staff of Environmental Defense, Jan. 19. 2012. The MMS' assessment of environmental impacts in the North Aleutian Basin was criticized by GAO fr classifying industry data as proprietary in ways that did not allow it to be shared more widely within the agency for purposes of analysis. GAO, Offshore Oil and Gas Development: Additional Guidance Would Help Strengthen the Minerals Management Service's Assessment of Environmental Impacts in the North Aleutian Basin, GAO-10-276, March 2010 (concluding that staff assessments are incomplete and vulnerable in part because of the lack of clear guidelines for preparing NEPA-required assessments of oil and gas development).

[545] *See* Section III.A.3., *supra*.

[546] *Id*.

[547] *Id*.

[548] Interview with EPA Staff, Office of Pesticide Programs, Jan. 27, 2012.

[549] Interview with staff, PEER, Aug. 5, 2012; Interview with former Environmental Defense employee, Jan. 19, 2012.

[550] Interview with EPA Staff, Office of Pesticide Programs, Jan. 27, 2012.

[551] *Id.*

no external oversight of these internal assessments of applicant-provided data and research, added procedural protections may be needed.[552]

The role of advisory groups and external peer reviewers

For some regulatory projects, Congress requires the agencies to empanel a science advisory board to review their work.[553] In a far larger number of regulatory projects, the agencies themselves determine that some form of expert peer review will be helpful, and they decide the form that peer review should take. In cases where agencies elect to use some form of external peer review, however, their decision-making processes are often unexplained. It is not clear, for example, when or why an agency decides that it should utilize external peer review. For instance, EPA and the FWS use external peer review for IRIS and listing decisions respectively, but EPA does not use external peer review for pesticide registration reviews. It is also not clear whether agencies always have the ability to empanel FACA panels in settings when those panels might be their preferred process for engaging external expert peer review, as compared with individual expert reviewers.[554]

Regardless of the analysis undergirding these choices, once the agency settles on the need for external peer review (or is required to use this expert review), the first and major challenge faced by the agency is the development of a credible process for selecting reviewers.[555] Determining when scientists have conflicts that exclude them from serving as an expert advisor is the most visible and perhaps the most difficult decision that an agency faces.[556] Yet there are also challenges associated with ensuring that the agency has the proper disciplinary mix of experts and that these experts are not skewed in favor of an interested party or otherwise cherry picked by the agency to support its decision. Existing federal guidance on these additional challenges, particularly under FACA, is slim.[557]

There are other challenges as well. For example, in regulatory areas that are highly specialized, the pool of experts may not be as large as the requisite size of the expert panel need to conduct the review.[558] Agency programs also appear to vary in the

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[552] For example, in situations like trade secret when the public and independent reviewers cannot access underlying studies or data, prophelactic processes – like mandating a classified peer review panel that audits the quality of the information or even periodic replication of the data or studies – seems justified, at least until it can be determined whether the information is of high quality.
[553] *See* Sections III.A.1.a. and 3., *supra*.
[554] *See* Section IV.A.3., *supra*.
[555] For statutorily created advisory bodies, Congress may place additional constraints on the agencies' selection process. See Sections III.A.1.a. and 3., *supra* (discussing these features in the creation of CASAC and NRC Advisory boards).
[556] *See* Bipartisan Policy Report, *supra* note 3, at chapter 2 (devoting much of its coverage of science advisory boards to these conflict challenges).
[557] *See, e.g.*, GAO, Federal Advisory Committees, Additional Guidance Could Help Agencies Better Ensure Independence and Balance (April 2004).
[558] Interview with EPA Staff, Office of General Counsel, Jan. 13, 2012.

point(s) in the process they decide to use expert review[559] and in how these advisors will be used, such as: commenting on agency products (e.g., EPA's IRIS)[560] versus actually advising the agency in a more iterative way as a collaborator (e.g., EPA's CASAC in the NAAQS)[561] versus actually suggesting projects and priorities (e.g., NRC's ACRS)).[562] There also appear to be significant differences in the amount of work expected of these advisors,[563] as well as the duration of the advisory committees, which range from standing committees to one-shot reviews.[564]

It is clear that there is no "one size fits all" to engaging external expert reviewers in the oversight of agency regulations, yet the reasons for much of this variation remain unclear. A study exploring these sources of variation would provide a solid foundation for a second study that then considers the ideal roles that advisory boards might offer to science-based regulation and how agencies might use external peer review more effectively.

Expert Elicitation

This study's foray into expert elicitation, thanks to the work of Roland Frye, highlights a developing and largely obscure area of science-policy that may become increasingly important over the next decade.[565] Expert elicitation is an approach that is even more complex than science advisory boards and even less well understood. Moreover, with the exception of Mr. Frye's research, there is little analysis of the existing use of expert elicitation in the agencies. Clearly, this area deserves further study.

Just as with science advisory boards, it is useful to understand the circumstances under which agencies decide to use expert elicitation for regulation. Researchers should also explore the primary challenges associated with the agency's use of expert elicitation, such as selection of the experts; transparency of the deliberations; and the agency's charge to the group.[566] Unlike advisory boards, moreover, there may be benefits to agencies, at least in the beginning of their use of expert elicitation, in employing several expert elicitation panels simultaneously or over time to obtain multiple predictions for the same question, as well as to develop additional mechanisms to help the agency ensure that its processes are credible.

Agency Outreach and Decision-making during the preNPRM stage

[559] Compare CASAC w/ NRC's ACRS, for example. See Sections III.A.1.a. and 3., *supra*.
[560] *See* Section III.A.1.c., *supra*.
[561] *See* Section III.A.1.a., *supra*.
[562] *See* Section III.A.3., *supra*.
[563] See *id* (identifying the commitment required of scientists to serve on advisory boards for NRC).
[564] Compare IRIS's use of expert peer reviewers with the role of CASAC in the NAAQS process. *See* Sections III.A.1.a. and c., *supra*.
[565] *See* Frye Paper at Appendix B
[566] *See id.*

This study highlights the efforts of certain agencies to provide transparency for their science-based decisions. These elaborate, iterative processes occur wholly before the proposed rule and notice and comment process. While formal notice and comment is not made superfluous by this extensive front-end work (particularly given the role of OMB review on the proposed and final rules), it seems probable that the 7+ iterative opportunities for public comment and peer review in the NAAQS process have a substantial impact on the content of EPA's draft proposed rule.

To the extent that administrative process remains focused on the notice and comment process as the major vehicle for soliciting public and stakeholder input, this study suggests that in at least some areas of science-based regulation, such a focus is missing most of the action. The processes employed by EPA and to some extent NRC indicate that a great deal of interaction with stakeholders occurs before the proposed rule stage. The differences between agencies in their approach to science-based decision-making during the preNPRM period also raise normative questions about regulatory process. It is possible, for example, that in more complex regulatory projects, additional formal stages of public and scientific input and dialog are needed on the agency's scientific assessments to provide a truly meaningful opportunity for public comment. The transparency afforded by the notice and comment period following a proposed rule, at least in some rulemaking settings, may not be sufficient. Understanding when these additional, preNPRM processes might be necessary for meaningful public review and exploring the form(s) that those processes could take thus deserves further study.

The privileged role of science

A theme that surfaced from a few interviewees[567] and was reinforced by critical commentary,[568] is a concern that the agencies may in some cases be almost too focused on scientific information, and that the scientific information becomes "privileged" at the expense of other vital information that should inform the agency's mission. For example, when asked what he thought the biggest problem was with EPA's science, one prominent interviewee stated that it was EPA's failure to take into account social science information, such as behavioral features that affect consumer behavior and hence cut to the core of EPA's mission of protecting public health.[569]

[567] Interview with Academic that was involved with EPA's Science Advisory Board, July 13, 2012; Interview with Staff, Pesticide Research Institute (a public interest organization), Aug. 1, 2011.
[568] *See, e.g.*, WILLIAM ASCHER, TODDI STEELMAN, AND ROBERT HEALY, KNOWLEDGE AND ENVIRONMENTAL POLICY: RE-IMAGINING THE BOUNDARIES OF SCIENCE AND POLITICS (2010) (arguing that science is unduly privileged in environmental law in the U.S. to the exclusion of other relevant and useful information).
[569] Interview with Academic that was involved with EPA's Science Advisory Board, July 13, 2012; *see also* Letter to Lisa Jackson, EPA from Deborah Swackhamer, Chair of EPA, Science Advisory Board, July, 8, 2012, 5-6 (discussing the important but neglected role of the social sciences in EPA's work).

Thus, another area for research is an examination of whether the agencies' high standards for oversight, review, and the creation of elaborate scientific databases might crowd out the development and use of other valuable types of information in certain regulatory settings. This exclusion of or inattention to other types of useful information could be due to an overly narrow framing of the kind of information that is relevant to the decision or an unnecessarily narrow framing of the agency's goal or mission.

Conclusion

The elephant in the room with respect to the agency's use of science, as quite a few interviewees volunteered, is the possibility or perhaps even the likelihood that after a five star, gold-plated, scientifically robust and transparent analysis is done on a given issue, the decision-maker will simply ignore the science. Regrettably, there is a record of precisely this outcome for scientific analyses that have been done by agencies, even in cases where the quality of the scientific analysis was considered high.[570]

It is beyond the scope of this study to determine when or whether policy considerations should ever trump scientific information, but when science is involved it is critical that the agencies' explanations and supporting record make it evident *when* these tradeoffs between science and other factors are being made by decisionmakers. The end-game for science-policy, under this view, is not to determine the outcome, but simply to make sure that the policy decisions can be assessed against the scientific record. This accountability should not be theoretical, either. Six feet of NAAQS criteria documents, standing alone, do not serve as a meaningful backdrop against which to assess the scientific rigor of a final policy decision. Scientific transparency means that agencies have provided an accessible means for sophisticated onlookers to identify discrepancies between the scientific record and the policy decisions being made on that record and to evaluate why those changes were made.

The recommendations advanced here are intended to advance this goal – namely to develop processes that ensure that agencies create scientific records that not only inform decision-making, but can be used to check or judge the quality of those decisions. These recommendations first attempt to remove the external barriers that agencies face in developing more rigorous and transparent processes. A review of five different

[570] *See, e.g.,* John M. Broder, "Obama Abandons a Stricter Limit on Air Pollution," The New York Times, Sept. 3, 2011 (describing President Obama's decision to reject a more stringent ozone standard despite strong scientific evidence, including CASAC endorsement) in its favor); Juliet Eilperin, "Proposed Standards for Air Quality Criticized," Washington Post, Dec. 21, 2005 (describing the Bush Administration's decision to reject a more stringent particulate standard despite strong scientific evidence, including CASAC endorsement, in its favor); Gardiner Harris, "Plan to Widen Availability of Morning-After Pill is Rejected," New York Times, Dec. 7, 2011 (overriding scientific advice, including from a science advisory panel) and deciding to require a prescription for the morning-after pill).

regulatory programs in three agencies reveals that there are some significant barriers, particularly with respect to the lack of transparency associated with OMB review.

The recommendations also suggest a list of best practices that agencies should consider in developing their decision processes that incorporate science into regulatory policy. These best practices not only identify key steps to ensuring rigor and transparency in the agencies' use of science, but identify innovations employed by other agencies that can be adapted to agency processes without a significant investment of resources or the need to develop new programs or hire more officials.

Finally, the recommendations call upon OSTP to help collect and generate important information on the agencies' use of science. This includes requiring agencies to describe their processes involving the use of science in more detail. OSTP should also create a forum for advertising agency innovations that can serve as best practices across government.

Regulatory science has been in the dark long enough. President Obama's integrity initiative provides the impetus not only for encouraging regulatory agencies to develop their own, improved integrity policies, but also for spurring oversight agencies like OSTP to seize the opportunity to collect critical information on agency processes that can be used more broadly to share successes and enlist outsiders in developing new and improved regulatory policies.