

SCIENCE IN REGULATION: A STUDY OF AGENCY DECISIONMAKING APPROACHES

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Feb. 18, 2013

This report was prepared for the consideration of the Administrative Conference of the United States. The views expressed are those of the author and do not necessarily reflect those of the members of the Conference or its committees.

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Executive Summary

This Executive summary sets out the focus of the study, the methods used, the general findings, and outlines recommendations.

Purpose and Focus of the Study

For the last three decades, federal agencies have been criticized for not being clear about the role that science played in their decision-making processes. In response to these criticisms, a number of efforts have been made by the Executive Branch and Congress to provide mechanisms that attempt to shore up the quality of the scientific process undergirding agency decision-making. Most recently, in 2009 President Obama issued a memorandum to the agencies directing that “To the extent permitted by law, there should be transparency in the preparation, identification, and use of scientific and technological information in policymaking.” At base, these initiatives demand heightened transparency of the agencies’ use of science, a demand that is central to ensuring the basic accountability of agency regulation.

This study examines the basic decision-making processes employed by agencies in science-intensive regulatory projects. Illuminating basic agency decision processes helps provide greater transparency about the agencies’ use of science since these processes reveal the points at which agencies look to external peer reviewers, the public, and other entities for critical feedback and advice. The elucidation of agency decision-making processes – essentially re-creating the agencies’ underlying flow charts for how they integrate science into regulation -- also provides information on how the agencies assemble and assess the available technical evidence relevant to a decision, how the agencies integrate that evidence into a larger policy decision, and how they explain their work to the larger public and scientific community. Indeed, precisely because the line between science and policy is blurred, it is critically important that the underlying decision-processes themselves be both analytically robust and transparent. It is no coincidence, in fact, that many of the worst examples of politicized science have occurred in settings where agency decision processes lacked both transparency and rigor.

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Methods

This study of the agency's integration of science into regulation examines the processes used by three agencies (namely the Environmental Protection Agency, the Fish and Wildlife Service, and the Nuclear Regulatory Commission) in five different regulatory programs. Some of these regulatory programs are regarded as exemplary while others are viewed as problematic; the diversity in the programs thus offers a rich basis for understanding how agencies integrate science into their decision-making processes. Moreover, while the programs reviewed in this study are not comprehensive and do not cover the full spectrum of possible agency approaches, the breadth of programs reviewed is sufficiently broad to offer a preliminary glimpse of some of the various challenges and creative adjustments that agencies have made in their integration of science into regulation.

Findings

The study concludes that the agencies have made considerable strides in ensuring the rigor and transparency of their integration of science into regulation. For example, some agencies explain how policy and science intersect in their regulatory projects in sophisticated, yet accessible ways. Likewise, some agencies have established 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. Some agencies have also established integrity policies that allow their staff to raise scientific differences with supervisors through various informal and formal mechanisms. Finally, a number of 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.

In addition to identifying these positive practices, a series of recommendations are developed for four separate areas of agency processes. First, the study recommends that innovative practices for incorporating science into the regulatory process be shared and that best practices be established. The study finds that while some agencies are innovative in their use of science, little of this innovation is recorded or shared with other agencies. In addition to recommending that information about innovative practices be systematically collated and disseminated, the report also identifies a number of "best practices" for integrating science into regulation as well as a number of other innovative approaches that deserve further study and experimentation. In identifying these best practices, the report also underscores that because there is such a wide variation in regulatory projects, a one-size fits-all approach to the integration of science in regulation is ill-advised.

Second, the study exposes a number of external constraints on agency decision-making processes that limit the ability of the agencies to improve their decision processes in keeping with the President's scientific integrity initiative. A second set of recommendations suggests that these various external constraints should be tracked more vigorously to identify their impact on agency science-intensive projects and ultimately reformed, if needed.

Third, because agencies necessarily must rely on scientific research produced by regulated parties to support in a number of health and environmental program, the study recommends that this privately produced research be subjected to the same types of requirements imposed on research published in scientific journals and on research produced with federal monies. At present this research is not subject to a vigorous oversight processes.

Finally, the investigation highlights the need for additional study of regulatory science in the future. The agencies' use of external peer reviewers, for example, is vital to ensuring that the agencies' integration of science into policy is both rigorous and transparent, yet very little is understood about this feature of agency decision-making. Indeed, just in this study alone, external peer reviewers were employed by the agencies in very different roles (e.g., collaborative and iterative versus providing a one-shot technical evaluation of a decision), were utilized at different points in the decision-making (e.g., early, continuous, or at the end), and in different ways (e.g., individual reviewers versus panels). Without some appreciation of the breadth or variety of the use of external peer reviewers, it is difficult to identify the most effective process moving forward. The agencies' variable use of external peer reviewers as well as other topics are recommended for future study in the final section of the report.

Specific Recommendations

Specific recommendations emerging from the research in the report are provided below.

I. Capitalizing on Agency Successes

A. Sharing Information

1. Agencies should provide the public with an 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.

2. OSTP, a standing NAS Committee, or some other body should take responsibility for identifying and publicizing the innovations developed by agencies for transparently incorporating science into their regulatory decisions.

B. Best Practices

3. In supporting its science-based regulatory decision, an agency should identify and make publicly available a list of the scientific literature it consulted, including even the literature it rejected when it is material to the scientific analysis, 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.

4. Consistent with President Obama's directive, agencies should be encouraged, not impeded, from having their scientific analyses reviewed by other experts, even if this oversight occurs wholly inside the agency. Any limitations on an agency's ability to have scientific work reviewed by scientific experts should be actively discouraged. Additionally and when possible, agencies should endeavor to explain how they ensured the rigorous review of their scientific products for each regulatory project.
5. 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 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.

C. Innovations that Should be Considered by Agencies but that are Currently too Novel to be regarded as Best Practices

6. All significant science-policy choices made by an agency in reaching a decision should be identified and explained in clear and understandable terms. In order to provide this heightened level of transparency, agencies should consider following an analytical process that: a) identifies the policy-relevant questions that can be informed by science; b) identifies in advance a study design, such as criteria for weighting individual studies, as well as identifying other *a priori* analytical choices, like stopping rules; c) provides a synthesis of the available evidence and relevant literature guided by this study design; and d) identify other significant assumptions, choices of analytical techniques, and remaining uncertainties and how different plausible choices might change the resulting policy decision. If possible, the agency should also follow the model of the NAAQS policy assessment in bridging science and policy in a final report, although this final step will likely involve more effort and experimentation.

Making these analytical steps explicit may not be practicable in some science-policy decisions and may not be practicable in other regulatory settings. This recommendation simply encourages agencies to consider this staged approach in their processes. Ultimately, with experience, this analytical approach may develop into a best practice. Until then, agencies are strongly encouraged to consider this analytical approach in conducting their work.

7. In regulatory settings, particularly in cases when agencies are not bound by judicially enforceable deadlines, the agencies should be encouraged to 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 currently unresolvable scientific debate in order to reach a decision. External peer review bodies may be particularly useful to agencies in establishing scientifically credible points at which debate should cease.
8. For science-intensive rules, an agency should identify specific types of future research projects that will advance understanding on the regulatory issue. This identification of research questions and priorities should influence the agency's research agenda as well as provide a benchmark for measuring regulatory progress. While agencies may need to experiment with when and how they incorporate "research checkpoints" into their regulatory analysis, the most fruitful time may occur at the point the record is closed, as determined by stopping rules.
9. Agency staff plays an important role in producing the agency's analyses. When practicable and appropriate, agency managers should consider providing staff

with some form of consensual authorship right or attribution for reports or analyses to which they contribute in a significant way. All staff authors who contributed in a significant way to a technical or scientific report should be acknowledged, including economists, lawyers, and other nonscientists. In a similar vein, reviewers and other contributors should also be identified by name and general contribution.

10. Agencies should encourage vigorous debate among agency scientists that may include developing written policies that allow agency staff to dissent or express their non-concurrence on a technical analysis to which they contributed. In cases where written dissents are permitted, agency managers should take seriously a staff member's request to place a dissent or non-concurrence into the public record. Dissenting employees should also be allowed and encouraged to publish these dissenting positions in the peer reviewed literature, provided that confidential governmental deliberations are not compromised. In all cases and regardless of the public availability of these discussions, dissenting staff members should be protected from reprisals.

II. External Constraints and Influences on Science-Based Regulation

A. External Constraints

11. There are statutory and regulatory constraints that limit the ability of the agencies to ensure that their decisions are scientifically robust and transparent in keeping with the President's Directive. The 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 and OSTP or other centralized agencies can take responsibility for collecting information and proposing government-wide recommendations.

B. OIRA Review

12. Under Section 2(a) and 6(a) of Executive Order 12866, the agencies are responsible for interpreting and complying with Section 6(a). The agencies' compliance under Section 6(a) should include at the very least:
 - 1) documentation of the major changes made at the suggestion or recommendation of OIRA at any point in the lifecycle of the regulation as required by Section 6(a)(3)(E)(iii) and 6(a)(3)(F). If there are no major changes, then the agency should provide a statement to that effect;
 - 2) an identification of all substantive changes made between the draft submitted to OIRA for review and the action subsequently announced in

compliance with Section 6(a)(3)(F)(ii). This includes but is not limited to a red-lined version of the document undergoing OIRA review;

3) for both #1 and 2, the agencies should provide a “complete, clear, and simple” identification and explanation of each major change in “plain, understandable language” for the public. Explication of these major changes should be accessible to the public – through for example a cover memorandum --- and not buried in hundreds of pages of red-lined documents. Although the Executive Order technically requires this accessible explication of all changes (and not simply the major changes) made at the suggestion of OIRA, a disclosure of the major changes is considerably less burdensome and appears consistent with the thrust of the Executive Order;

4) a library of all significant, substantive documents exchanged between OIRA and the agency throughout the life cycle of the regulatory action to ensure that the agency is in full compliance with Section 6(a)(3)(E)(ii) and (iii).

5) centralized public access to the information specified above to ensure practical, as opposed to merely theoretical, compliance with the general requirements of Section 6(a)(3)(E) and (F). Both reginfo.gov and regulations.gov should link to or provide the public with document libraries that enable simple access to and searching of documents required under Section 6.

Agencies should apply these same requirements of Section 6(a)(3)(E), as interpreted above, to all significant science-intensive regulatory actions, including agency guidances and other standards and policies, whether or not they are published in the Federal Register, as well as to all significant, supporting studies and projects that inform science-intensive agency rules, guidances, policies and related products. The requirements should also apply to all rules that are withdrawn, whether ORIA has reviewed them or not.

C. Changes made at the Suggestion of other Agencies and White House Offices

13. The agency should disclose material changes made at the suggestion or recommendation of White House offices or other agencies, consistent with Section 6(a)(3)(E)(iii), when doing so does not impair the deliberative processes.

III. Enhancing the Transparency of Research produced by Regulated Parties

14. Agencies should require conflict disclosures on all future research submitted to inform an agency’s licensing, regulatory, or other decision-making process -- whether published and unpublished. This conflict of interest disclosure should be similar to the conflict of interest disclosure required by the biomedical journals. See See ICJME Standards. The regulatory conflict of interest disclosure should

also, where possible, identify whether a sponsor reserved the right to participate in the design of the research; the collection of data; the interpretation of data; the writing or disseminating the report, or any other material features of the research. Finally, “[a]gencies and scientific advisory committees should be extremely skeptical of a scientific study unless they are sure that the principal investigator(s) (as opposed to the sponsor or funder) had ultimate control over the design and publication of the study.”*

15. “Studies used in the formulation of regulation should be subject to data access requirements equivalent to those under the Data Access Act (Shelby Amendment) and its implementing circular (OMB Circular A-110) regardless of who funded the study. If a study is used by an agency to inform the development of a regulation, then the same kinds of information about that study should be available upon request, regardless of whether the study was funded by the federal government, industry, or some other entity.”**
16. “Confidential Business Information (CBI) claims can . . . make it difficult for the interested public to evaluate studies that contribute to regulatory policy.”*** Agencies that provide CBI protections for studies or data that inform regulation should ensure that the CBI claims are justified. Given the strong incentives to regulated parties for overclaiming CBI protection and the resultant costs from this overclaiming to public health protection and research, it is important that the agencies’ CBI programs not provide a safe haven for unjustified suppression of relevant regulatory research. To that end and as a first step, the agencies should review their CBI programs to ensure that there is rigorous oversight of CBI and related trade secret claims on health and environmental research. Agencies should, where possible, penalize those CBI claims that, upon review, appear unjustified.

* Recommendation copied verbatim from BiPartisan Policy Center, Improving the Use of Science in Regulatory Policy 42 (Aug. 2009).

** *Id.* at 43.

*** *Id.*

IV. Specific Issues Recommended for Further Research

17. There are a number of topics recommended for research. They include:

- The role(s) of advisory groups and external peer reviewers
- Challenges to evaluating the reliability of data and studies submitted by applicants, particularly studies that are unpublished and/or otherwise publicly inaccessible
- The role of expert elicitation
- Agency outreach and decision-making during the pre-NPRM Stage
- The privileged role of science in regulation

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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 Sciences¹ and the Bipartisan Policy Center.² The agencies' failure to explain their work is one of the most common bases for remands.³ It is also tied to more fundamental concerns about how a lack of scientific transparency in the agencies can fuel the politicization of science.⁴

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

¹ 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].

² 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).

³ Nearly forty percent of the vacatur 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.”)

⁴ 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).

possibility that existing administrative processes are not adequate to police the quality and transparency of agency science.⁵ 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.”⁶ This 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 . . . ”⁷.

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.⁸

⁵ 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* note365.

⁶ 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>.

⁷ 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>.

⁸ 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.

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. The well-known NRC and Carnegie Commission reports that provide the foundation for much of our understanding of regulatory science focused primarily on other types of challenges, such as the transparency of risk assessments.⁹ Understanding the basic flow charts or processes by which agencies integrate science is thus largely unexplored territory.¹⁰ 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.

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 misconduct¹¹ 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,¹² 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.¹³ Even

⁹ See, e.g., NRC reports cited in *supra* note 1; see also CARNEGIE COMMISSION, RISK AND THE ENVIRONMENT: IMPROVING REGULATORY DECISION MAKING (June 1993); CARNEGIE COMMISSION, A SCIENCE AND TECHNOLOGY AGENDA FOR THE NATION: RECOMMENDATIONS FOR THE PRESIDENT AND CONGRESS (December 1992).

¹⁰ Unfortunately, because an exploration of the decision-making process or flow chart for integrating science into regulation has been largely ignored, there also is no readily accessible theoretical or normative framework that can serve as a foundation for this study. Instead, the basic norms of science – largely extracted from the philosophy, sociology and history of science – serve as general guideposts for assessing agency flow charts for integrating science into their decisions. See *infra* Sections III.A. and B.4.

¹¹ 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]; see also *infra* note 222 (providing an overview of the MacDonald scandal).

¹² See, e.g., NAS, FORMALDEHYDE REPORT, *supra* note 1.

¹³ See OIG MacDonald Report, *supra* note 11, at pg. 2 of cover letter. [All signals (*see, see, e.g., etc.*) should be italicized. There are many cases where they are not. Please review all footnotes and ensure that all signals are italicized.]

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.¹⁴ 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.¹⁵ 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 played by policy judgments is in fact central to ensuring the accountability of science-intensive regulations.¹⁶ 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 over the course of its decision process may even provide the courts with a record that reduces the risk of judicial challenge.

¹⁴ Interview with EPA Staff, National Center for Environmental Assessment, Office of Research and Development, Feb. 3, 2012.

¹⁵ Cf. Jamie Conrad, comments on draft ACUS Outline on Science in the Administrative Process project, Dec. 5, 2011 (raising this concern).

¹⁶ Interestingly, although it seems well settled that transparency is fundamental to ensuring the rigorous incorporation of science into policy, there has been little effort to consider this transparency from the standpoint of the integration of science over the life cycle of a rule. Yet in some ways this chronological view of science informing the decision is more illuminating than an agency's (often post hoc) explanation of what it selected as a default juncture at various points in the process. Somewhat similarly, the role of various governmental scientists and other actors as authors in a report as largely escaped notice in the larger regulatory science literature. See Section IV.A.3. *infra*.

As discussed in more detail below, a focus on the chronology of the decisionmaking process (or flow chart) reveals that the agency that initiates a science-based rule is not the only party in control of how science is integrated. Potentially significant constraints on 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) can arise from outside the agencies. 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 forces outside their control. 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."¹⁷ 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.¹⁸

¹⁷ 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).

¹⁸ *Id.*

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.¹⁹

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.²⁰ 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 evidence in a way that gives the endangered species the benefit of the doubt.²¹ By contrast, in its regulatory assessment of a pesticide registration, the EPA is required to

¹⁹ Exacerbating these challenges for the scientific analyst is ensuring that these assumptions and related are communicated successfully to the decisionmakers and other attentive (nonscientific) public. As one EPA manager noted, “with the complexity of scientific information ever increasing, limited time on the calendar for policymakers to be briefed, and ‘junk science’ (a buzzword to discredit scientific information, among other disparaging characterizations such as claims of bias), it is difficult for even the best communicators among scientists to effectively share what may be nuanced interpretations of available data and associated uncertainties.” Email from undisclosed EPA manager, March 5, 2012.

²⁰ 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>.

²¹ 16 U.S.C. § 1533(b).

balance the benefits of a pesticide against its costs to human health and environment.²² 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).²³

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 ²⁴ 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 ²⁵ assumptions must be factored into an exposure model.	Reasonable spray drift assumptions should be factored into an exposure model.
How should the species' range	The species' range should be	Population models need to

²² EPA must ensure that the pesticide does not present "unreasonable adverse effects on the environment." 7 U.S.C. § 136a(a).

²³ These differences are drawn largely from Statement of Task to the NAS Committee, *supra* note 20; 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.

²⁴ 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.

²⁵ 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.

be determined?	measured by assuming the most expansive range.	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.²⁶

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.²⁷ 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 answers, and thus calls for generic risk assessment guidelines may be misplaced if not mistaken.²⁸

²⁶ See, e.g., NAS, RISK ASSESSMENT, *supra* note 1, at 29-33.

²⁷ See, e.g., Interview with FWS Staff, Endangered Species Program, Jan. 26, 2012; Interview with EPA Staff, Office of Pesticide Programs, August 5, 2011.

²⁸ But see Nicholas Bagley & Richard L. Revesz, *Centralized Oversight of the Regulatory State*, 106 COLUMIA L. REV. 1260, 1320-24 (2006) (recommending the centralization of risk assessment guidelines).

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.²⁹ Over time, sectors within science, particularly editors of biomedical journals, have also insisted that the underlying data be shared;³⁰ the researchers’ affiliations and biases be openly disclosed;³¹ and that authorship be certified to ensure that an author has the right to make all final decisions on a manuscript, which

²⁹ See, e.g., HELEN E. LONGINO, SCIENCE AS SOCIAL KNOWLEDGE 80 (1990); Philip Kitcher, *Patterns of Scientific Controversies*, in PETER MACHAMER, MARCELLO PERA, & ARISTIDES BALTAZ, 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).

³⁰ 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).

³¹ See, e.g., SHELDON KRIMSKY, 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).

also serves as an endorsement by the scientist that the research findings and statement of methods are correct.³²

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 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.

³² 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>.

The task 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.³³ 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.³⁴ 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.³⁵ 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.

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.

³³ The Regulation Advisory Committee recommended a narrower study as opposed to reconnaissance research.

³⁴ See *infra* Section IV.C. (recommending this topic for further study).

³⁵ 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.

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 Administration, it was selected as the best candidate for studying agency processes in the general area of environmental and public health protection.³⁶ The second agency – the Fish and Wildlife Service (FWS) of the Department of the Interior – protects certain natural resources, including endangered

³⁶ 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.

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).³⁷ 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 (NAAQS), which are conducted through large, informal (only in the APA sense) 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

³⁷ 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.

program selected for study – the EPA’s Integrated Risk Information System (IRIS) – produces reference values and cancer potency estimates 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 narrower in scope 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 hazard and dose-response assessments.³⁸ These EPA programs also offer an in-depth view of science-based decisions at three different points in the administrative process spectrum (e.g., 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.

³⁸ The NRC refers to four stages of risk assessment, and IRIS captures only the first two stages: hazard ID and dose-response. Various EPA program offices will then apply exposure scenarios depending on the regulatory issue at hand to develop standards or related risk estimates.

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 identifying the overarching values and assumptions that influenced the technical decision-making (as discussed above with pesticides and endangered species); 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 underlying policy questions were and how the framing of the questions themselves affected the integration of scientific evidence for the issue at hand.³⁹ 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.⁴⁰ 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.⁴¹ 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,

³⁹ See *supra* note 29 (citing sources); see also *infra* note 452 and accompanying text (identifying these same principles in President Obama’s Memorandum on Scientific Integrity).

⁴⁰ See, e.g., SHELDON KRIMKSY, SCIENCE IN THE PRIVATE INTEREST 125-40 (2003).

⁴¹ See, e.g., Bipartisan Policy Center, *supra* note 2, at 15 (2009) (recommending that “[t]he Administration needs to devise regulatory processes that, in as many situations as possible, could help clarify for both officials and the general public which aspects of disputes are truly about scientific results and which concern policy”).

provides a clearer record against which subsequent policy considerations can then be judged.⁴²

3. *Skepticism:* Skepticism from a diverse set of experts is vital to robust science and also improves the transparency of the analysis.⁴³ 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.⁴⁴ 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 for purposes of reaching a decision. Since scientific questions will never be resolved completely, a decision subjected to stopping rules will be revisited again later, through an adaptive process that considers the new evidence and adjusts the original rule or decision as necessary.⁴⁵ While stopping rules can be amended, decision

⁴² *Id.* (recommending that “the Administration should require that a section of the Federal Register notice 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”).

⁴³ Longino, *Science as Social Knowledge*, *supra* note 29, at 80.

⁴⁴ See *supra* note 29.

⁴⁵ 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).

theory suggests that it is best that they be established in advance of a process, with an opportunity to make exceptions later.⁴⁶

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 and other policy considerations, such as equitable impacts, irreversible effects, statutory requirements, etc.: 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.⁴⁷ This information was supplemented by over a dozen interviews with various stakeholders;⁴⁸ a search of a few individual rules to provide samples of the

⁴⁶ 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).

⁴⁷ Several academics who have worked with or researched the agencies’ use of science were also interviewed.

⁴⁸ 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.

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.

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.

Stakeholders interviewed from industry included: the American Chemistry Council, and the Center for Regulatory Effectiveness, and Exponent.

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 review at regular, five-year intervals the standards, as well as the supporting scientific assessment criteria, for six criteria or general pollutants that EPA has identified under Section 108 of the Act.⁴⁹ 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.⁵⁰ First, Congress required that a primary NAAQS standard be set at a level that is "requisite to protect the public health" with "an adequate margin of safety."⁵¹ The Supreme Court has confirmed that this mandate allows EPA to consider only scientific and not economic factors in setting the standards for these criteria pollutants.⁵² Second, Congress required extensive involvement in the standard-setting exercise 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."⁵³ By statute, this panel

⁴⁹ 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. Interview with EPA Staff, National Center for Environmental Assessment, Office of Research and Development, Jan. 18, 2012.

⁵⁰ 42 U.S.C. § 7409(d)(1).

⁵¹ *Id.* at § 7409(b)(1).

⁵² *Id.* at § 7409(b)(1); *see* Whitman v. American Trucking Associations, Inc., 531 U.S. 457 (2001).

⁵³ *Id.* at § 7409(d)(2)(A)-(B).

is authorized to make recommendations to the Administrator on possible revisions, as well as to review EPA’s scientific assessments. In practice, the panel tends to focus its role on reviewing EPA’s various scientific and policy documents, although the panel can make recommendations independent from these documents.⁵⁴ In response, EPA created the Clean Air Scientific 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 decision to revise or retain a NAAQS must undergo a public notice and comment period.⁵⁵

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 labeled as impenetrable.⁵⁶

EPA’s challenges in conducting NAAQS reviews are made still more daunting because the literature that EPA must consider during a review period is substantial. A single NAAQS review can involve the analysis of thousands of studies.⁵⁷ 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 2006.⁵⁸ The EPA staff recommendations from that initiative have now been largely implemented,⁵⁹ as illustrated in the figure below.⁶⁰

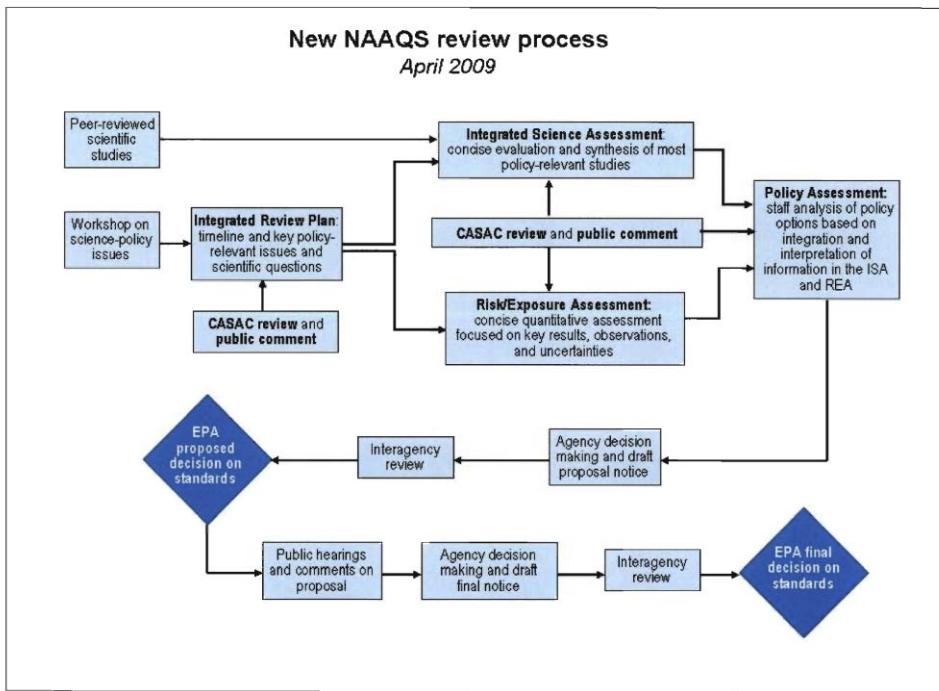
⁵⁴ *Id.*

⁵⁵ *Id.* at § 7409(b)(1), referencing (a)(1)(A).

⁵⁶ 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.

⁵⁷ 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.

⁵⁸ 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). Interestingly, some of this enhanced transparency, at least initially, was also expected to result from transferring responsibility from EPA staff to the political management for producing key reports, particularly the policy assessment. As discussed below, this particular tact did not ultimately work; many observers believed improved the scientific rigor or transparency of the document suffered and authorship was returned to EPA staff. Interestingly, some of this enhanced transparency, at least initially, was also expected to result from transferring responsibility from EPA staff to the political management for producing key reports, particularly the policy assessment. As discussed below, this particular tact did not ultimately work; many observers believed improved the scientific rigor or transparency of the document suffered and authorship was returned to EPA staff.

⁵⁹ 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 58, 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>.

⁶⁰ 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 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.⁶¹ The workshop focuses specifically on scientific discoveries and related developments occurring over the past five years that should inform EPA’s review of the 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.⁶²

The planning report is integral to enhancing transparency of the NAAQS review.⁶³ By framing the relevant science-policy questions, the planning report provides a focus for the remaining four years of EPA’s analysis.⁶⁴

⁶¹ See EPA, Generic NAAQS Review Process, March 2007, available at http://www.epa.gov/ttnnaaqs/pdfs/peacock_4_17_07_attachment2.pdf.

⁶² EPA, NAAQS Review, *supra* note 58, at 24.

⁶³ *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).

⁶⁴ 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}, PM₁₀, PM_{10-2.5}, or alternative PM indicators that might be considered?

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.⁶⁵

Generally, staff in the National Center for Environmental Assessment in the EPA's Office of Research and Development, supplemented by contracts with academics for specific topics, identify and evaluate thousands of studies published since the prior NAAQS review and then draft individual chapters of an ISA. The EPA staff interprets and integrates the scientific evidence to draw key conclusions and the basis for the conclusions. There are multiple points of review (at least three) from intra-agency reviewers, CASAC and the public before the ISA is considered final.⁶⁶ While the resulting ISAs are hailed as vastly more focused and concise than their predecessor (criteria) documents, they still are quite long and technical, and EPA has included, with CASAC encouragement, an Executive Summary in recent ISAs to aid communication of the findings to policymakers and stakeholders. In at least some cases these reports are more than 1000 pages in length, not counting the appendices.⁶⁷

3. Risk/Exposure Assessment Report

Based on its analysis of the scientific evidence in the ISA, staff in the EPA's Office of Air Quality Planning and Standards then prepares a separate risk assessment report that uses this evidence to model and 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

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- 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.

⁶⁵ In stark contrast to EPA's earlier version of this assessment in previous NAAQS processes (i.e., the infamous "criteria document"), the new and improved integrated scientific assessment is 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. While the ISA and the "criteria" document overlap significantly in content, the other two reports were not contained in the criteria document, by and large, and hence go beyond the information that EPA provided in earlier approaches.

⁶⁶ 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/ttnnaqs/standards/pm/data/2008_03_final_integrated_review_plan.pdf.

⁶⁷ 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>.

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.⁶⁸ 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.⁶⁹

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.⁷⁰

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), as well as alternative welfare protection scenarios and secondary standards, that are supported by the evidence and risk assessments. The policy analysis also provides a discussion of remaining questions and key uncertainties and identifies priorities for further data collection.⁷¹

The policy assessment is typically reviewed by internal EPA staff, the public and by CASAC twice to ensure it is faithful to the scientific assessments and that important scientific information is not lost in translation.⁷² 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.⁷³

5. Inter-agency Review

⁶⁸ See, e.g., EPA, Planning report for Integrated Assessment, *supra* note 66, at 41 (describing this goal of the risk assessment).

⁶⁹ See, e.g., *id.* at 54.

⁷⁰ 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/ttnnaqs/standards/pm/data/20110419pmpafinal.pdf>.

⁷¹ See Appendix C for an excerpt from a policy assessment report.

⁷² For a very brief summary of CASAC input, see *id.* at 2-100 through 2-101 (summarizing CASAC advice).

⁷³ 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](http://yosemite.epa.gov/sab/sabproduct.nsf/CCF9F4C0500C500F8525779D0073C593/$File/EPA-CASAC-10-015-unsigned.pdf).

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 apparently receives comments, both written and oral, on its proposal.

According to EPA staff, the oral communications are protected by the deliberative process privilege and are not made public, although interagency comments received in writing may be posted in the rulemaking docket after the rule is signed.⁷⁴ The idea behind this deliberative process exception to the Freedom of Information Act (FOIA) is to allow the free and uninhibited exchange of ideas and positions within government and thus it is a discretionary claim.⁷⁵ Nevertheless, OMB currently appears to apply the deliberative process exemption liberally.⁷⁶ In the course of this review,⁷⁷ OMB not only offers comments and suggestions on the EPA's rule, but some EPA staff members maintain that OMB determines the point at which a proposed or final rule responds adequately to all of the comments and can exert significant influence over the content of the rule.⁷⁸

6. *The Final Rulemaking Process*

EPA generally hires a contractor to summarize the public comments, which are collected in a Background Information Document ("BID") document. EPA staff then

⁷⁴ Interview with EPA Staff, Office of Air Quality Planning and Standards, Jan. 17, 2012. As discussed *infra* Section III.A.4., in some cases an email exchange between EPA and other agency, most commonly OIRA, is posted but the attachment that contains comments or edits is not posted. It is not clear whether EPA would claim that this information is protected by the deliberative process privilege in a request under the Freedom of Information Act.

⁷⁵ 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).

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).

⁷⁶ 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 484-485 and accompanying text.

⁷⁷ See *infra* Section =.

⁷⁸ 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. See also Section III.A.4., *infra*.

determine which comments warrant changes and which comments warrant discussion in the preamble of the final rule.⁷⁹ EPA staff also report that, after the notice and comment period has concluded, OMB reviews the draft final rule, just as it did the draft proposed rule. Again, OMB review may result in changes to the substance of the final rule.⁸⁰

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.

1. Attribution and authorship

One important feature of the NAAQS process is EPA’s reliance on staff to author or in the case of the ISA, co-author with external experts, 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.⁸¹ 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.)⁸² 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.⁸³

The team of staff authors is also listed by name in the acknowledgement section of the final report. This detailed acknowledgement section links each EPA staff to his/her specific contributions to individual chapters. 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). Although there is dim recollection of this withdrawal occurring at least once, the fact that staff are allowed to withdraw their names provide an indicia of authorship on the supporting NAAQS reports.

⁷⁹ *Id.*

⁸⁰ See Section III.A.4., *infra*.

⁸¹ Interview with EPA Staff, Office of Air Quality Planning and Standards, Jan. 17, 2012.

⁸² Interview with EPA Staff, National Center for Environmental Assessment, Office of Research and Development, Jan. 18, 2012.

⁸³ 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.

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.⁸⁴ The public can access at least summaries of these documents, as well as the full citations.⁸⁵ Providing this type of fingertip access to the enormous library of research that supports the NAAQS allows for more rigorous review of EPA's scientific work by those inside the agency, CASAC, and stakeholders.⁸⁶

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.⁸⁷ As one interviewee stated, "It is a process that delivers a credible standard."⁸⁸ 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."⁸⁹ 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.⁹⁰

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.⁹¹ 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.

⁸⁴ Interview with EPA Staff, National Center for Environmental Assessment, Office of Research and Development, Jan. 18, 2012.

⁸⁵ See the Health and Environmental Research Online (HERO) Database, last updated on February 8, 2012, available at <http://hero.epa.gov/>.

⁸⁶ Interview with EPA Staff, National Center for Environmental Assessment, Office of Research and Development, Jan. 18, 2012.

⁸⁷ See also Interview with Staff of American Chemistry Council, July 29, 2011.

⁸⁸ Interview with EPA Staff, Office of Air and Radiation, July 26, 2011.

⁸⁹ Interview with EPA Staff, Office of Air Quality Planning and Standards, Jan. 17, 2012.

⁹⁰ See NAS, FORMALDEHYDE REPORT, *supra* note 1, at 120-121.

⁹¹ See EPA, NAAQS Review, *supra* note 58, at 22 (see figure)

A second, innovative feature of the NAAQS process is the iterative involvement of the CASAC, which is itself a prominent science advisory body.⁹² 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.⁹³ CASAC also plays an important role in determining when a revised report has adequately responded to comments, as elaborated below.⁹⁴

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"⁹⁵ that allow it to put an end to debate and close the record with regard to new scientific discoveries.⁹⁶ 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.⁹⁷ While this "closure" role was criticized by some EPA staff members and temporarily suspended, in at least one recent case it appears that CASAC still continues to identify when it believes that a report is nearly complete and can be finalized and when yet another review is necessary.⁹⁸ 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.

⁹² 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).

⁹³ CASAC, last updated on February 8, 2012, available at

<http://yosemite.epa.gov/sab/sabpeople.nsf/WebCommittees/CASAC>.

⁹⁴ Interview with EPA Staff, Office of Air Quality Planning and Standards, Jan. 17, 2012.

⁹⁵ For a discussion of "stopping rules" see *supra* notes 45-46 and accompanying text.

⁹⁶ 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. Specifically, EPA will consider new studies up until the second ISA. After that point, all new evidence will be bracketed and reserved for the next five year NAAQS review. *Id.*

⁹⁷ *Id.*

⁹⁸ 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](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).

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.⁹⁹

Fifth, the current NAAQS reports provide attribution to named staff through a detailed acknowledgements section. The acknowledgement section identifies their specific contributions to the report and, if staff members disagree with the contents of the report they can ask that they not be acknowledged.¹⁰⁰ There was a sense among agency 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.¹⁰¹

Sixth and finally, during the throes of its evolution, the NAAQS process shed some light on the tradeoffs between scientific staff and political management in preparing technical documents. One of these revelations occurred when EPA placed responsibility for editing/finalizing the policy assessment with political rather than EPA staff. While staff helped draft the policy assessment, ultimate editing and decision-making authority was reserved for political management and the assessment was published as an Advance Notice of Proposed Rulemaking, thus also requiring OIRA clearance.¹⁰² The resulting policy assessment, prepared under the supervision of political management and reflecting management's views, was harshly criticized by both EPA's Office of Research Development and by CASAC as compared to the prior staff- authored reports of the same type.¹⁰³ CASAC in particular noted that this management-supervised 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.¹⁰⁴ In response to this

⁹⁹ 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; Interview with EPA Staff, National Center for Environmental Assessment, Office of Research and Development, Jan. 18, 2012.

¹⁰⁰ Exchange with EPA Staff, National Center for Environmental Assessment, Office of Research and Development, March 11, 2012.

¹⁰¹ 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.

¹⁰² Since the assessment was published as an Advanced Notice of Proposed Rulemaking, it required OMB-clearance. See EPA, Advanced Notice of Proposed Rulemaking: National Ambient Air Quality Standards for Lead, 72 Fed. Reg. 71488 (2007).

¹⁰³ Interview with EPA Staff, Office of Air Quality Planning and Standards, Jan. 17, 2012.

¹⁰⁴ 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

controversy, Administrator Jackson ultimately determined that the policy assessment should reflect the views of EPA staff, not political management.¹⁰⁵ Employees and CASAC report a high level of satisfaction with the change.¹⁰⁶ At least in this case, the staff-authored report provided a more robust, nuanced, and complete statement of the scientific information as it informs policy in comparison to a report that was within the ultimate control of EPA's political management.

In sum, there are a number of features of the NAAQS process that appear both innovative and promising for science-policy analysis.¹⁰⁷ While extrapolating from this expensive,¹⁰⁸ time-consuming,¹⁰⁹ and science-intensive NAAQS process to more mundane science-based regulatory projects is difficult, the process still appears to serve 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.¹¹⁰ Since its authorizing statute now requires EPA to review over 1000 pesticides every fifteen years,¹¹¹ the process EPA

agency is currently considering" and providing substantial details in the remainder of the letter regarding these concerns).

¹⁰⁵ See Jackson memorandum, May 21, 2009, *supra* note 59.

¹⁰⁶ 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.

¹⁰⁷ 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 1.

¹⁰⁸ 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.

¹⁰⁹ 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.

¹¹⁰ 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.

¹¹¹ EPA, "Registration Review Highlights", available at http://www.epa.gov/opprrd1/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

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."¹¹²

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.¹¹³ In contrast to the NAAQS process, however, EPA does not engage external peer reviewers for individual pesticide registrations except in highly unusual cases.

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.

¹¹² 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/oppfeed1/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. (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.

¹¹³ 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

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.¹¹⁴

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.¹¹⁵ The Summary Document also identifies in specific terms the data EPA needs to complete its assessment.¹¹⁶

2. The Data Call-in. EPA regulations establish the test protocols and risk assessment models it will use to evaluate each pesticide registration.¹¹⁷ Since it is not uncommon for some of the information needed to complete these assessments to be missing, EPA issues

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*.

¹¹⁴ The registration review process assesses the risks of pesticides already registered and in use. Perhaps because of this, the process is designed like an informal rulemaking process, without adversarial hearings but instead relying on notice and comment at several distinct points in the process. See generally 40 C.F.R. §§ 155.40-58 (setting out the pesticide registration review process).

¹¹⁵ 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/opprrd1/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 Acephate, available at* <http://www.regulations.gov/#!documentDetail;D=EPA-HQ-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.*

¹¹⁶ For a general description of the Summary Report see EPA's overview of the re-registration steps at http://www.epa.gov/opprrd1/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.

¹¹⁷ 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.

a “data call-in” to the manufacturers that requires them to conduct this additional testing to fill the gaps.¹¹⁸

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 the Science Advisory Panel (SAP), which is an external EPA science advisory group established by statute that EPA can use to review particularly important pesticide-related decisions,¹¹⁹ or an equivalent peer review body (e.g., the NAS).¹²⁰ 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.¹²¹ 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.¹²²

¹¹⁸ 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.

¹¹⁹ 25(d) of FIFRA, 7 U.S.C. § 136w(d).

¹²⁰ Interview with EPA Staff, Office of Pesticide Programs, Jan. 27, 2012.

¹²¹ 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>.

¹²² 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

4. Proposed Decision on Registration. The pesticide team uses the risk assessment to draft a proposed decision with regard to registration of the pesticide.¹²³ 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.¹²⁴ This proposed decision is also subject to notice and comment. OMB is not involved in reviewing these proposed rules, presumably because they are licensing decisions.

5. The Final Decision. EPA ultimately issues a final decision that responds to the information received through notice and comment.¹²⁵ 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.¹²⁶ Like the proposed rule, the final rule does not require interagency clearance or OMB review.

assessment. Chlorpyrifos Preliminary Human Health Risk Assessment, *supra* note 118, 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.

¹²³ 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.

¹²⁴ 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.*

¹²⁵ See 40 C.F.R. § 155.58.

¹²⁶ Interview with EPA Staff, Office of Pesticide Programs, Jan. 27, 2012.

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.¹²⁷ Because EPA staff members serve as authors, they both gain credit and bear responsibility for the quality of the analysis presented in the document.¹²⁸

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.¹²⁹ 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.¹³⁰

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.¹³¹ While the literature cannot be accessed through an internet database, as is the case with the HERO database used in NAAQS, EPA provides complete citations where possible.¹³² EPA also prepares web pages for each pesticide¹³³ and a "readers' guide" to the docket to walk the reader through the various key decisions and stages of the registration review process.¹³⁴

¹²⁷ See, e.g., Chlorpyrifos Preliminary Human Health Risk Assessment, *supra* note 118, at 1.

¹²⁸ Interview with EPA Staff, Office of Pesticide Programs, Jan. 27, 2012.

¹²⁹ *Id.*

¹³⁰ 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.

¹³¹ See Chlorpyrifos Preliminary Human Health Risk Assessment, *supra* note 118, at 102-110.

¹³² See, e.g., *id.*

¹³³ See http://www.epa.gov/opprrd1/registration_review/chlorpyrifos/index.htm for information on this pesticide, including the summary document and all other reports and decisions.

¹³⁴ See, e.g., Readers Guide for Acephate, March 18, 2009, docket number EPA-HQ-OPP-2008-0915-0002, available on regulations.gov.

EPA does not make the manufacturers' safety testing 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 limits general public access to the data to ensure that the safety and related test data are not released to pesticide manufacturers in other countries.¹³⁵ (The justification and continued necessity of this requirement is not developed here except to note that questions have been raised about its benefits, particularly in light of the costs to transparency with respect to basic toxicity and related information regarding registered pesticides). 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."¹³⁶ 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."¹³⁷ Most problematic, the information cannot be accessed until after a registration decision.¹³⁸ Because it is partly classified information under FIFRA (there is public access, but it is limited), the data must also be viewed in EPA offices.¹³⁹

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.¹⁴⁰ These summary tables provide outsiders with at least some window into the nature of the scientific information supporting a decision.

3. External Peer Review

EPA does not routinely seek external peer review of its individual pesticide registration decisions or supporting risk assessments.¹⁴¹ Instead, the opportunity for

¹³⁵ 7 USC § 136h(g)(1).

¹³⁶ 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>.

¹³⁷ 7 U.S.C. § 136h(g)(2).

¹³⁸ 7 U.S.C. § 136a(c)(2)(A).

¹³⁹ *Id.* at § 136h(g)(2).

¹⁴⁰ Interview with EPA Staff, Office of General Counsel, Jan. 13, 2012.

¹⁴¹ 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

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.¹⁴²

EPA does consult its standing Science Advisory Panel (SAP) for particularly difficult scientific questions, including registration cases, as in the reregistration of atrazine.¹⁴³ Generally, though, these consultations with SAP over registration reviews are the exception; indeed EPA staff could only recall one case where the SAP was involved in a conventional pesticide registration review since the 1996 amendments to the program. 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.¹⁴⁴

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, according to EPA staff, has been 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.¹⁴⁵

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.¹⁴⁶ 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.¹⁴⁷ 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

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.*

¹⁴² Interview with EPA Staff, Office of General Counsel, Jan. 13, 2012.

¹⁴³ Interview with EPA Staff, Office of General Counsel, Jan. 13, 2012. This consultation is iterative and is still ongoing. See Atrazine Evaluation Process, available at http://www.epa.gov/opp00001/reregistration/atrazine/atrazine_update.htm. More generally, EPA calls upon the SAP for consultation rather regularly. 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. For more general information about the SAP, see <http://www.epa.gov/scipoly/sap/basic.htm>.

¹⁴⁴ Interview with EPA Staff, Office of Pesticide Programs, August 5, 2011.

¹⁴⁵ Interview with EPA Staff, Office of Pesticide Programs, August 5, 2011. The reason for this is not altogether clear, although it appears to be a relic of the "Tozzi rule" that OIRA would refrain from being involved in reviewing licensing decisions, which presumably sweep in these registration reviews that look more like informal rules than adjudications.

¹⁴⁶ *Id.*; Interview with EPA Staff, Office of Pesticide Programs, August 5, 2011.

¹⁴⁷ Interview with EPA Staff, Office of General Counsel, Jan. 13, 2012.

Service) if there is a possibility that a pesticide may adversely affect endangered or threatened species.¹⁴⁸ This consultation step has been fraught with difficulty and delay and has sparked lawsuits and congressional oversight hearings.¹⁴⁹

5. Transparency

Stakeholders were generally satisfied with the transparency of EPA's pesticide assessments.¹⁵⁰ 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 reference doses for inhalation and ingestion for human

¹⁴⁸ 16 U.S.C. § 1536.

¹⁴⁹ 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 20-27 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.

¹⁵⁰ 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.

exposure to hundreds of chemicals.¹⁵¹ The assessments are not binding regulations, yet they can be 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, which in turn can lead to enforceable and costly emissions reductions from industry.¹⁵² Thus, while there is no statutory mandate under which EPA prepares these assessments (and thus no mandated time frames or procedural or substantive directions), there is nevertheless 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 (roughly analogous to what lay persons call safe) dose for inhalation and ingestion for over 500 chemicals through a risk assessment.¹⁵³ The end goal for this reference 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, divided by uncertainty factors to reflect extrapolation from animal data to humans, interindividual differences in response to exposure to a pollutant, etc.¹⁵⁴ 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).¹⁵⁵ 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.¹⁵⁶ First, EPA’s progress in producing assessments has been very slow, averaging between six to eight years per assessment.¹⁵⁷ In fact, in 2009 GAO listed the IRIS program as one of the areas of high risk inside government for waste and

¹⁵¹ EPA, “Integrated Risk Information System: What is IRIS,” available at http://www.epa.gov/IRIS/help_ques.htm#whatiris.

¹⁵² GAO, CHEMICAL ASSESSMENTS: CHALLENGES REMAIN WITH EPA’S INTEGRATED RISK INFORMATION SYSTEM 6 (Dec. 2011).

¹⁵³ More specifically, EPA is only assessing hazard and dose-response assessment and not exposure assessment and risk characterization, and does not attempt to develop risk management information.

¹⁵⁴ See, e.g., EPA, “Integrated Risk Information System: What is IRIS,” available at http://www.epa.gov/IRIS/help_ques.htm#whatiris.

¹⁵⁵ Interview with EPA Staff, Office of General Counsel, Jan. 13, 2012.

¹⁵⁶ 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>.

¹⁵⁷ Several stakeholders have criticized these delays, as has GAO in a series of reports. See, e.g., GAO, CHEMICAL ASSESSMENTS, *supra* note 152, at 2-4 (summarizing this critical review), available at <http://www.gao.gov/assets/130/122677.pdf>.

mismanagement.¹⁵⁸ Second, IRIS assessments are subjected to two separate rounds of interagency review, with the scientific assessment sandwiched between these interagency stakeholder discussions.¹⁵⁹ 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.¹⁶⁰

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.¹⁶¹ 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.¹⁶²

¹⁵⁸ See GAO, HIGH-RISK SERIES: AN UPDATE, GAO-09-271 (Jan. 22, 2009).

¹⁵⁹ 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 152, at Appendix III (describing on a chemical-by-chemical basis the role of agencies like OMB and DOD on EPA's assessments).

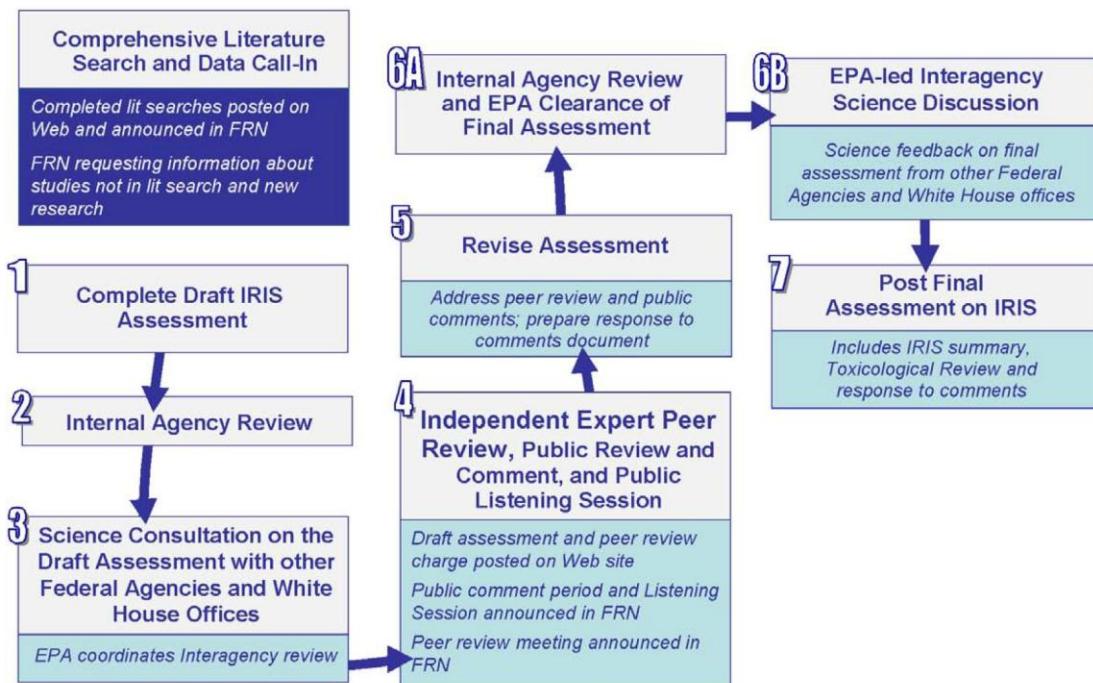
¹⁶⁰ See GAO, LOW PRODUCTIVITY, *supra* note 159, at 56-58 (describing and criticizing OMB's role in IRIS assessments).

¹⁶¹ 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 152, 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.

¹⁶² See, e.g., *id.*

Assessment Development Process for New IRIS



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.¹⁶³ 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.¹⁶⁴

¹⁶³ 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.

¹⁶⁴ 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.

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 hazard and dose-response assessment that can include development of a reference dose and reference concentration for non-cancer effects, and a weight of evidence classification and potency estimates for cancer effects. . 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.¹⁶⁵ 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,¹⁶⁶ which includes not only written comments placed on the record but other discussions by phone and meetings that are not on the record.¹⁶⁷ EPA sets deadlines for these comments, and the entire review is scheduled to last no more than 45 days.¹⁶⁸ 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).¹⁶⁹
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

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 152. EPA has not yet implemented this step, but suggests it will. One can imagine both advantages and disadvantages to this advanced notice.

¹⁶⁵ 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>.

¹⁶⁶ 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 159, at 56-58.

¹⁶⁷ 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.

¹⁶⁸ *Id.*

¹⁶⁹ *Id.*

to interagency review. Written comments by other agencies, including OMB, are again incorporated into the public record.¹⁷⁰

6. *Final Assessment.* Based on these comments, EPA revises its draft assessment and posts a final assessment.¹⁷¹

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.¹⁷² 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.¹⁷³ 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, 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.¹⁷⁴ 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.¹⁷⁵

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

¹⁷⁰ *Id.*

¹⁷¹ *Id.*

¹⁷² See EPA, Toxicological Review of Dichloromethane (Methylene Chloride), Nov. 2011, at <http://www.epa.gov/iris/toxreviews/0070tr.pdf>.

¹⁷³ *See id.*

¹⁷⁴ See NAS, FORMALDEHYDE REPORT, *supra* note 1, at chapter 7.

¹⁷⁵ *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 161, 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 152, at 44 (Letter from Paul Anastas, Assistant Administrator of EPA to GAO, Nov. 22, 2011).

the National Academies.”¹⁷⁶ The GAO report was skeptical of EPA’s ability to complete assessments within two years, however.¹⁷⁷ Indeed, much of the GAO report documented continued delays in EPA’s assessment that nearly doubled the time originally allocated to the projects.¹⁷⁸ GAO also indicated that EPA may be experiencing delays and turf battles with OMB over the interagency review process, including the Data Quality Act.¹⁷⁹

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 in accord with the EPA’s IRIS guidelines.¹⁸⁰ The form of the external peer review depends on the nature and extent of scientific evidence and the level of controversy.¹⁸¹ 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 chemicals/year);¹⁸² 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).¹⁸³ 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.¹⁸⁴ The peer review contractor sets up and manages this external peer review when it is not conducted by EPA’s SAB or the NAS.¹⁸⁵

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 external

¹⁷⁶ See, e.g., *id.* at 22.

¹⁷⁷ 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 152, at 27-28.

¹⁷⁸ See, e.g., *id.* at 8

¹⁷⁹ Apparently, several Data Quality Act correction requests have been filed on draft IRIS assessments. See generally Rena Steinzor et al., Corrective Lenses for IRIS (Oct. 2010), available at http://www.progressivereform.org/articles/IRIS_1009.pdf.

¹⁸⁰ See IRIS Flowcharts at Appendix E. Note that for IRIS assessments, there will always be external peer review. Presumably this ensures complete compliance with OMB’s peer review guidelines since even potentially nonsignificant agency decisions will be subjected to external peer review.

¹⁸¹ The Chemical Manager in consultation with the NCEA Director and other career managers determines which level of peer review is needed and prepares a publicly available peer review plan. See, e.g., NCEA Policy Report, *supra* note 163, at 5-6.

¹⁸² Interview with EPA Staff, National Center for Environmental Assessment, Office of Research and Development, Feb. 3, 2012.

¹⁸³ See, e.g., GAO, CHEMICAL ASSESSMENTS, *supra* note 152, at 8.

¹⁸⁴ See, e.g., *id.* at 5-6 and 7-10.

¹⁸⁵ 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.

reviewers selected by an EPA contractor.¹⁸⁶ Since the comments come from individual scientists who have not conferred (this process of independent review is used in the majority of cases where compliance with FACA appears too onerous), EPA finds that responding to the comments can be quite challenging.¹⁸⁷ 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 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.¹⁸⁸ 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 consensus peer review process and 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 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.”¹⁸⁹

3. Interagency Review

EPA staff report that interagency review remains a significant feature of the IRIS process.¹⁹⁰ 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

¹⁸⁶ 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.

¹⁸⁷ Interview with EPA Staff, National Center for Environmental Assessment, Office of Research and Development, Feb. 3, 2012.

¹⁸⁸ Interview with EPA Staff, National Center for Environmental Assessment, Office of Research and Development, Feb. 3, 2012.

¹⁸⁹ Interview with EPA Staff, National Center for Environmental Assessment, Office of Research and Development, Feb. 3, 2012.

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

as a form of expert peer review.¹⁹¹ 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.¹⁹²

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.¹⁹³ 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.¹⁹⁴

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 list.¹⁹⁵ 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.¹⁹⁶

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.¹⁹⁷

¹⁹¹ Although some health agencies were initially involved in interagency discussions, they have largely dropped out of the process. *Id.*

¹⁹² Interview with EPA Staff, National Center for Environmental Assessment, Office of Research and Development, Feb. 3, 2012.

¹⁹³ Cf., GAO, CHEMICAL ASSESSMENTS, *supra* note 152, at 19 (NASA requested OMB to hold an interagency workgroup to discuss EPA’s short comment deadlines).

¹⁹⁴ Interview with EPA Staff, National Center for Environmental Assessment, Office of Research and Development, Feb. 3, 2012. .

¹⁹⁵ See, e.g., EPA, “IRIS Agenda and Literature Searches,” available at http://cfpub.epa.gov/ncea/iris_drafts/recordisplay.cfm?deid=187215.

¹⁹⁶ See, e.g., EPA, “IRIS Progress Report 2011,” Aug., 2011, at 6, available at <http://www.epa.gov/iris/pdfs/irisprogressreport2011.pdf>.

¹⁹⁷ 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).

Attribution and authorship rights are considered a basic feature of the IRIS assessment process.¹⁹⁸ 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.¹⁹⁹

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,²⁰⁰ 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.²⁰¹

The approach to science-policy decision-making used by the FWS to list species and critical habitat under the Endangered Species Act²⁰² 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

¹⁹⁸ Interview with EPA Staff, National Center for Environmental Assessment, Office of Research and Development, Feb. 3, 2012.

¹⁹⁹ Interview with EPA Staff, National Center for Environmental Assessment, Office of Research and Development, Feb. 3, 2012.

²⁰⁰ 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.

²⁰¹ 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 11. The discussions of transparency problems in the listing and habitat designation decisions thus seem to carry over to these other areas.

²⁰² 16 U.S.C. § 1533.

a field staff office.²⁰³ 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.²⁰⁴

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.²⁰⁵ If based “solely on the basis of the best scientific and commercial data available,”²⁰⁶ 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.²⁰⁷

In making this determination, FWS is statutorily required to consider five factors, any of which can trigger listing.²⁰⁸ Much like the NAAQS determinations, the FWS is prohibited from considering economic impacts in listing species.²⁰⁹ The designation of critical habitat, however, must take economic and related considerations into account as required by statute.²¹⁰

²⁰³ See Attribution subsection on FWS, *infra*.

²⁰⁴ 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.

²⁰⁵ The split jurisdiction is based on the different expertise of the staff. The FWS has jurisdiction over freshwater and land animals. NMFS has jurisdiction over marine and anadromous animals. See, e.g., <http://www.nmfs.noaa.gov/pr/laws/esa/> (describing this jurisdictional split).

²⁰⁶ 16 U.S.C. § 1533(b)(1)(A).

²⁰⁷ *Id.* at § 1532(6).

²⁰⁸ *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.*

²⁰⁹ *Id.* at § 1533(b)(1)(A).

²¹⁰ *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”).

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.²¹¹ 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.”²¹² The FWS’s decision typically involves a relatively extensive scientific analysis that relies largely on evidence submitted by a petitioner.²¹³ 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.²¹⁴
- 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 decision the FWS then has twelve months (by statute) to issue a proposed finding with regard to whether a listing is warranted.²¹⁵ 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.²¹⁶ This analysis in the proposed rule is conducted by staff and management working together.

²¹¹ 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.

²¹² 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).

²¹³ 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.

²¹⁴ 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.

²¹⁵ 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>.

²¹⁶ 16 U.S.C. § 1533(b)(1)(A).

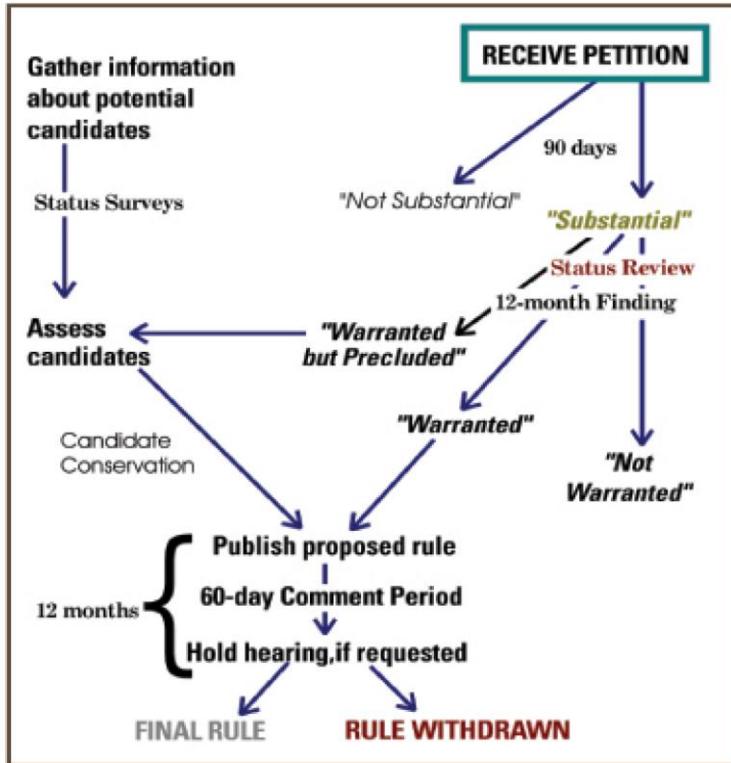
If the FWS concludes that listing is warranted,²¹⁷ then its decision takes the form of a proposed rule upon which it solicits public comment. As described below, with the help of a contractor, the FWS also solicits external, independent peer review on its proposal. In the same proposed rule, the FWS is required by statute to propose the designated critical habitat for the species.²¹⁸ Although the listing proposal does not require OMB review, the critical habitat designation must be cleared by OMB.²¹⁹

- 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.

²¹⁷ 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 213 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.

²¹⁸ 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.*

²¹⁹ Interview with FWS Staff, Endangered Species Program, Jan. 9, 2012.



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.²²⁰ The proposed rule and accompanying technical documents that comprise the

²²⁰ 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 11, 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.²²¹

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 investigate 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.²²² 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).²²³ 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.²²⁴

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.²²⁵ A FWS staff

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. [Perhaps this could form the basis of a recommendation to FWS? Perhaps they should formally embrace this policy.] 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.

²²¹ Interview with FWS Staff, Endangered Species Program, Jan. 9, 2012.

²²² 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 11, 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 11, summary letter at 2, available at http://www.lb9.uscourts.gov/webcites/10documents/HomeBuilders_conflict.pdf

²²³ OIG MacDonald Report, *supra* note 11, at 130.

²²⁴ *Id.*

²²⁵ No documents, except for a possible bibliography and two critical habitat reports, required under NEPA and Executive Order 12866, are posted online. [It is not quite clear how Executive Order 12,866 requires this. Please elaborate.] One of the two critical habitat reports is a supporting environmental assessment

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.²²⁶ 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.²²⁷ 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.²²⁸ 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.²²⁹

2. External Peer Review

The FWS voluntarily solicits independent peer review relating to its proposed listing decision from at least three independent specialists.²³⁰ 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.²³¹

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.²³² 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

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 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.

²²⁶ Interview with FWS Staff Member, Field Office, Feb. 15, 2012.

²²⁷ *Id.*

²²⁸ *Id.*

²²⁹ *Id.*

²³⁰ See, e.g., Joy Nichopoulos, *The Endangered Species Listing Program*, 24 ENDANGERED SPECIES BULLETIN, Nov./Dec. 1999, at 5, 9.

²³¹ *Id.* at 9.

²³² 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.

desired outcome.²³³ 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 listing process, and tax the limited resources of staff.²³⁴ According to FWS officials, however, peer review has been helpful and provides a robust check on the FWS's scientific and technical analyses.²³⁵ This peer review can occasionally alter the FWS's analysis in substantive ways.²³⁶

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.²³⁷ 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.²³⁸

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.²³⁹ 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.²⁴⁰

²³³ Interview with FWS Staff, Endangered Species Program, Jan. 9, 2012. [Can we cite to something other than an interview for this point? Couldn't we cite to the legislative record or some other source to document this criticism?]

²³⁴ See STANFORD ENVIRONMENTAL LAW SOCIETY, *supra* note 217, at 53 (reporting on this).

²³⁵ Interview with FWS Staff, Endangered Species Program, Jan. 9, 2012.

²³⁶ *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).

²³⁷ Interview with FWS Staff, Endangered Species Program, Jan. 9, 2012.

²³⁸ *Id.*; Interview with FWS Staff Member, Field Office, Feb. 15, 2012.

²³⁹ *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).

²⁴⁰ 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 232, 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.").

In the bibliographies that were available online,²⁴¹ only some of the cited literature was published. Other references included unpublished studies and internal memoranda. Presumably these documents would also need to be requested from the field office that serves as the designated contact point for listings.²⁴²

5. The Role of OMB and Interagency Review

As discussed, OMB does not review listing decisions,²⁴³ but decisions regarding critical habitat designations do require OMB clearance.²⁴⁴ As with OMB's review of EPA's proposed rules, the internal deliberations are considered deliberative process and are therefore privileged, although the changes that result from formal review are required by Executive Order 12866 to be disclosed to the public.²⁴⁵ 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 the 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), the NRC is governed by a five member board of Commissioners appointed by the President for five year, staggered terms. No more than three of the Commissioners may be affiliated with the same political party.²⁴⁶ As a consequence, the NRC is a bipartisan body. The internal politics and external mechanisms of pressure at the NRC are thus different than at an Executive Branch agency.

²⁴¹ See, e.g., Reference List for the Chupadera Springsnail, Document ID FWS-R2-ES-2011-0042, available at regulations.gov.

²⁴² 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 220, 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.

²⁴³ Interview with FWS Staff, Endangered Species Program, Jan. 9, 2012. Officials in FWS were not sure why OMB refrains from reviewing species listing decisions.

²⁴⁴ *Id.*

²⁴⁵ See *infra* Section III.A.4.

²⁴⁶ See Energy Reorganization Act of 1974, Sec. 201.

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, the NRC regulatory issues often concern technical issues and modeling assumptions that require considerable engineering expertise.²⁴⁷ 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.²⁴⁸

Finally, NRC's statutory mandates generally do not impose many deadline-forcing requirements on NRC. Consequently, the 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 the 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 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.²⁴⁹ 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.²⁵⁰

The NRC's actual process or flowchart for undertaking its technically-based, informal rulemakings is not explicated in the NRC fact sheets, on the NRC's webpage, or even in technical documents or directives (at least that the author could find). Like the other agency programs studied in this report, the NRC's process for promulgating

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

²⁴⁸ *Id.*

²⁴⁹ 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).

²⁵⁰ 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 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.²⁵¹ While the process outlined below for technical rulemakings may not describe all the 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.²⁵² 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.²⁵³
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.²⁵⁴ 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)²⁵⁵ that offer analysis and sometimes

²⁵¹ 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>.

²⁵² Interview with NRC Staff, Nov. 2011. A more extensive discussion of the role of the ACRS appears below in section III.a.3.c.

²⁵³ Interview with NRC Staff, Office of General Counsel, Nov. 15, 2011.

²⁵⁴ 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).

²⁵⁵ 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.²⁵⁶ 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 not exceed ten pages.²⁵⁷ SECY papers now are relatively short and to the point, although the technical rulemakings often include multiple attachments.²⁵⁸ In some cases, documents are also included in the record that either precede or follow issuance of the SECY papers.²⁵⁹

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.”²⁶⁰ This draft Statement of Consideration is deliberative and the Commission therefore does not, at least initially, make it available to the public.²⁶¹ The proposed rule and its accompanying Statement of Consideration are circulated internally to the Office of General Counsel (OGC) for legal concurrence.²⁶² 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.²⁶³
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 Act²⁶⁴ and in determining whether an NRC

²⁵⁶ Interview with NRC Staff, Office of General Counsel, Nov. 15, 2011. For samples, *see supra* note 251. *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>.

²⁵⁷ Interview with NRC Staff, Office of General Counsel, Nov. 15, 2011.

²⁵⁸ *Id.*

²⁵⁹ *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;rpp=10;so=ASC;sb=postedDate;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>.

²⁶⁰ Interview with NRC Staff, Nov. 2011.

²⁶¹ *Id.*

²⁶² *Id.*

²⁶³ 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/>.

²⁶⁴ 44 U.S.C. § 3501, et seq.

- regulation constitutes a “major rule” under the definition section of the Congressional Review Act.²⁶⁵
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.²⁶⁶

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.²⁶⁷ In virtually all cases, except when the papers expose personnel, proprietary information, or security

²⁶⁵ 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.

²⁶⁶ Interview with NRC Staff, Nov. 2011.

²⁶⁷ 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-commission&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.²⁶⁸ Outsiders interested in the NRC's policies can thus track the scientific assumptions and use of the technical literature in virtually all of the NRC's 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

The 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.²⁶⁹ 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 the NRC staff, generally available in this docket or on ADAMS.²⁷⁰

b. Overview of the 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

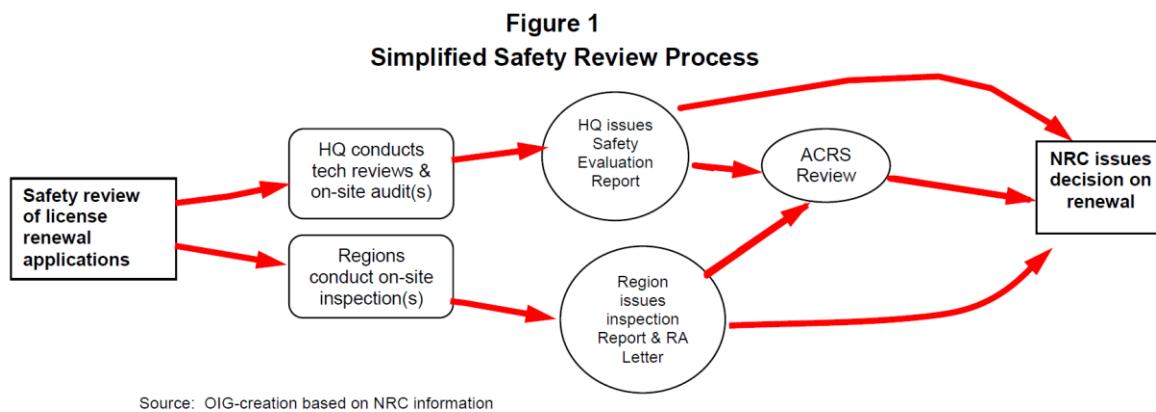
²⁶⁸ U.S. NRC, Commission Papers (SECY), last updated on January 9, 2012, available at <http://www.nrc.gov/reading-rm/doc-collections/commission/secys/>. The NRC website also provides an accessible portal to these SECY papers. *Id.* See also Statement of NRC Staff, Feb. 1, 2012.

²⁶⁹ 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/>.

²⁷⁰ 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.²⁷¹

The 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, the NRC can extend this license for an additional twenty-years if it believes the plant can continue to be operated safely.²⁷² The NRC has developed technical directions for reviewing these license renewal applications.²⁷³ The NRC's flow chart for this decision-making process is provided below.²⁷⁴



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.²⁷⁵ 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,²⁷⁶ 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.²⁷⁷ 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

²⁷¹ 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.

²⁷² 10 C.F.R. Part 54.

²⁷³ See OIG, Audit of NRC's License Renewal Program, Sept. 6, 2007, at 1 (summarizing these regulations).

²⁷⁴ *Id.* at 3.

²⁷⁵ 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.

²⁷⁶ An explicit methodology was also found lacking for the post-renewal inspection process. *See id.* at 29.

²⁷⁷ In addition, less than three percent of the passages contained detailed information to support the conclusions. *Id.* at 46-47.

NRC's safety evaluations.²⁷⁸ The OIG also found that inspectors and auditors were prohibited from removing operator documents on-site, which made it more difficult for them to conduct the analysis and write the report.²⁷⁹ 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.²⁸⁰

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.²⁸¹ 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.²⁸² 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.²⁸³ 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

²⁷⁸ *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 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.

²⁷⁹ *Id.* at 14-17

²⁸⁰ *Id.*

²⁸¹ 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.

²⁸² 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.

²⁸³ 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.

public or even those within the agency could oversee the licensing decisions when the 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 the NRC's 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 work²⁸⁴ suggests that they are a critical feature of the decision-making structure, at least for science-intensive issues.²⁸⁵

In some rulemaking settings and in virtually all license decisions, peer review by one of the two expert advisory groups is required by statute.²⁸⁶ In other cases, the 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)²⁸⁷ 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 the NRC on licensing, with particular attention to nuclear reactor safety.²⁸⁸ The NRC by rule has

²⁸⁴ 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.

²⁸⁵ See Roland Frye, The United States Nuclear Regulatory Commission's Use of Scientific and Technical Advisory Committees, Dec. 2011, at Appendix B.

²⁸⁶ 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. [Have you checked with Rollie on how frequently this type of additional peer review occurs?] 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.

²⁸⁷ 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.*

²⁸⁸ 42 U.S.C. § 2039. For fuller discussion of the creation and history of this advisory committee, see Frye, *supra* note 285, at 3-5.

charged ACRS with a number of responsibilities.²⁸⁹ Among these responsibilities is the mandatory 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.²⁹⁰ The NRC staff typically provides a written response to each of the advisory committee's comments, although historically this was not always the case.²⁹¹ 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 the NRC staff, there have been some vigorous disagreements.²⁹² In several cases, in fact, the NRC staff did not agree with or accept ACRS' recommendations.²⁹³ Interviewees report, however, that ACRS has never disagreed with staff with regard to the granting of a license or construction permit.²⁹⁴

Beyond its formal role in reviewing staff rules, technical documents, and licenses, the ACRS also reports to the Commission at least annually.²⁹⁵ The ACRS may also, on its own initiative, "conduct reviews of specific generic matters or nuclear facility safety-related items."²⁹⁶ It may even recommend that the Commission initiate a rulemaking – a formal recommendation that requires a response from the Commission in 90 days.²⁹⁷ ACRS's scope of powers thus appears quite expansive and may be broader than EPA's CASAC.

²⁸⁹ 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 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).

²⁹⁰ 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.*

²⁹¹ *Id.*

²⁹² See Frye, *supra* note 285, at 6-7.

²⁹³ 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.

²⁹⁴ Interview with NRC Staff, Oct. 26, 2011.

²⁹⁵ 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 285, at 7.

²⁹⁶ 10 C.F.R. § 1.13.

²⁹⁷ *Id.* at § 2.809. It is not clear whether or how often this occurs. Such recommendations must be posted on the NRC website, but in a quick search there did not appear to be a central repository for such postings.

The second advisory committee, ACMUI,²⁹⁸ plays an important but narrower role in the NRC decision-making as compared with ACRS. ACMUI was created an NRC regulation²⁹⁹ and reports to staff as needed on medical questions that are referred to it.³⁰⁰ The Commission may also request advice and expert opinions from this body.³⁰¹ The ACMUI receives informational copies of all proposed regulations under its purview,³⁰² 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 the NRC staff disagree on key issues.³⁰³

Since the 1980's, the NRC has also employed expert elicitation to develop expert recommendations on particularly difficult technical issues.³⁰⁴ 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.³⁰⁵ Roland Frye has prepared a memo providing a detailed analysis of that program, which is included in Appendix B.

4. Review by the Office of Management and Budget

Some science-intensive rules not only pass through the levels of agency staff and political management, but are subjected to review by the Office of Information and Regulatory Affairs. Under Executive Order 12866, only regulations with the most significant implications are selected out of the agencies' larger set of rules and formally reviewed,³⁰⁶ but when this review occurs, the literature indicates that the underlying changes associated with OIRA may be material and yet can be difficult to assess.³⁰⁷

²⁹⁸ 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 285, at 10.

²⁹⁹ 10 C.F.R. § 1.19(a).

³⁰⁰ Interview with NRC Staff, Office of General Counsel, Nov. 15, 2011; Interview with NRC Staff, Oct. 26, 2011.

³⁰¹ *Id.*

³⁰² Interview with NRC Staff, Office of General Counsel, Nov. 15, 2011.

³⁰³ *See* Frye, *supra* note 285, at 11-12.

³⁰⁴ Roland Frye, Use of Expert Elicitation at the Nuclear Regulatory Commission, Feb. 16, 2012, included as Appendix B.

³⁰⁵ 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 304, at 1).

³⁰⁶ See Exec. Order No. 12,866 §§ 3(f), 58 Fed. Reg. 51,735, 51,742 (Oct. 4, 1993). As Section 3(f) makes clear, OMB's review attaches to numerous regulatory projects, and economically significant rules constitute only a fraction of the rules undergoing OMB review.

³⁰⁷ As the GAO observed in their 2003 study, "the OIRA regulatory review process is not well understood or documented, and the effect that OIRA's reviews have on individual rules is not always easy to determine." GAO, OMB's Role in Review of Agencies' Draft Rules and the Transparency of Those Reviews, Sept. 2003, at 110.

Since this study examines the processes the agencies use to develop science-based rules and assesses the transparency of each step in a rule’s development, changes made to science-intensive rules that occur as a result of OIRA review cannot be ignored. If substantive changes are being made to science-intensive rules as a result of OIRA review and if those changes are not identified, then a potentially important step in the development of science-intensive rules may not be accessible to the general public or to scientists who review the rule. [Note that there are other ways that OIRA’s responsibilities may allow it to alter the substance of science-intensive rules. For example, under the Paperwork Reduction Act, OIRA must review and ultimately approve agency requests for information from private parties, including scientific and technical information.³⁰⁸ Even though this clearance role provides OIRA with the ability to influence the substance of science-intensive projects, for example by affecting the types of information an agency can request in the development of its rule, these additional OIRA responsibilities are not examined here since they fall outside the scope of this study – namely the examination of agencies’ decision-making processes.]

Executive Order 12866 imposes specific disclosures requirements on the agencies with respect to OIRA’s review, yet despite these requirements a number of interviewees and the literature more generally – including two studies by the GAO – highlight the lack of transparency of OIRA-induced changes to science-intensive rules.³⁰⁹ In order to gain more empirical purchase on the agencies’ disclosure of OIRA-inspired changes, the only two subsets of rules in this study subjected to formal OIRA review – the EPA’s NAAQS rules and FWS’s ESA habitat designations (sixteen rules in total) -- were examined to assess compliance with the transparency requirements of Section 6(a)(E).³¹⁰

a. The Transparency of the Changes made during OIRA’s Review

Although in theory the agencies might claim the deliberative process privilege with regard to the disclosure of the results of OIRA’s review of agency rules, President Clinton imposed several transparency requirements on the agencies under Executive Order 12866 that override these claims. Specifically, under Executive Order 12866 the agency originating a rule is required to “[i]dentify for the public, in a complete, clear, and simple manner, the substantive changes between the draft submitted to OMB for review and the action subsequently announced” and also to “[i]dentify for the public those changes in the regulatory action that were made at the suggestion or recommendation of

³⁰⁸ This role is discussed above, for example, in OIRA’s review and clearance of EPA’s requests for information from pesticide manufacturers under the Paperwork Reduction Act. *See supra* Section III.A.1.b.

³⁰⁹ See the remainder of this Section for support for this statement (Section III.A.4., *infra*).

³¹⁰ The Nuclear Regulatory Commission is an independent agency and is not (yet) subject to the review requirements of Executive Order 12866. As discussed, the FWS’ listing of endangered species has historically been exempt from OMB review under the Executive Order, as have pesticide approvals under FIFRA. *See supra* Section III.A. Finally, since IRIS assessments are not rulemakings, they also are not technically covered by Executive Order 12866.

OMB.”³¹¹ OMB for its part must “make available to the public *all* documents exchanged between OMB and the agency during the review.”³¹² All of this information must be “provided to the public . . . in plain, understandable language.”³¹³

OMB and the agencies appear to interpret these Executive Order transparency requirements narrowly, in a way that generally limits the transparency of the changes made at the suggestion of OIRA.³¹⁴ Specifically, for at least some of the rules examined here, the changes made during OIRA review were difficult to identify and impossible to understand. This lack of disclosure appears in direct conflict with Section 6 of the Executive Order and President Obama’s memorandum directing agencies to maximize the transparency of their regulatory activities.

1. Documents Exchanged between OIRA and the Agencies

Executive Order 12866 requires that after a rule is published or an agency announces that it will not move forward with a regulation, “OIRA [must] make available to the public all documents exchanged between OIRA and the agency during the review by OIRA under this section.”³¹⁵ However, OMB reads the documentation requirements of section 6(b) to apply only to documents exchanged between the agency and the branch levels of OMB.³¹⁶ All staff exchanges are treated by OMB as exempt from the reach of this requirement. No justification could be found for this interpretation of the Executive Order, and at least the GAO has been critical of it.³¹⁷ No documents underlying OIRA’s review of the rules in this study – other than return letters -- were posted on OIRA’s website or otherwise made publicly available by OIRA. The absence of documents is consistent with OIRA’s narrow interpretation of its responsibilities.

³¹¹ Exec. Order No. 12,866 §§ 6(a)(3)(E)(ii)–(iii)

³¹² Specifically, the EO states: “After the regulatory action has been published in the Federal Register or otherwise issued to the public, or after the agency has announced its decision not to publish or issue the regulatory action, OMB shall make available to the public all documents exchanged between OMB and the agency during the review by OMB under this section.” *Id.* at § 6(b)(3).

³¹³ *Id.* at § 6(a)(F).

³¹⁴ See *infra* Sections III.A.4.a.1-3.; see generally GAO 2003, *supra* note 307, at 119 (“the difficulties that we experienced during this review clearly demonstrated that OIR A’s reviews are not always transparent to the public.”).

³¹⁵ Section 6(b)(4)(D) of Executive Order 12866.

³¹⁶ See, e.g., GAO, IMPROVEMENTS NEEDED TO MONITORING AND EVALUATION OF RULES DEVELOPMENT AS WELL AS TO THE TRANSPARENCY OF OMB REGULATORY REVIEWS at 32, n.40 (April 2009) (reporting that “[a]ccording to OMB representatives, the requirement to make available “all documents exchanged between OMB and the agency” issuing the regulation only applies to exchanges made by OMB staff at the branch chief level and above, not documents exchanged between OMB desk officers and staff in regulatory agencies.”); see also GAO 2003, *supra* note 307, at 57 (reporting on the OIRA document policies that read 6(b) in a limited fashion). This express statement could not be located on OMB’s site or in its various memos, however.

³¹⁷ See *id.*

(i) Identification of all Substantive Changes occurring during OIRA's Review

Section 6(a)(3)(E)(ii) of the Executive Order requires the agency originating the regulatory action to “[i]dentify for the public, in a complete, clear, and simple manner, the substantive changes between the draft submitted to OIRA for review and the action subsequently announced.” For both the NAAQS and ESA rules, the agencies’ compliance with the Executive Order requirements consisted, at best, of posting a red-lined version of the rule produced during OIRA’s formal review. This documentation was incomplete across the rules in the study, however; for one out of every three rules, there was no red-lined document available, and for one proposed and final rule (lead) there was no documentation of the rule prior to OIRA review.³¹⁸

Even when the agencies did provide red-lined documents of changes occurring during OIRA’s formal review, however, this documentation did not “[i]dentify for the public, in a complete, clear, and simple manner” and in “plain, understandable language” “the substantive changes” made during OIRA’s formal review as required by Section 6(a)(3)(E)(ii) and (F). In each of these red-lined documents, substantive changes occurring during OIRA review were not separated out of the dozens of grammatical, formatting, and purely editorial and stylistic changes. Instead the changes that appear likely to be substantive were discovered only by reading through each page of the red-lined documents that often run several hundreds of pages long.³¹⁹ The GAO noted similar compliance lapses by other agencies in its 2009 study.³²⁰

In addition, locating the red-lined documents was far from “simple” as required by the Executive Order.³²¹ While OMB’s Reginfo.gov contains a detailed search engine that pulls up information on each rule that is or has undergone OIRA review, this database does not post or link to the red-lined documents.³²² In this study, the red-lined documents for the EPA and FWS rules had to be located on a rule-by-rule basis by

³¹⁸ Red-lined documents were not available for: The Canadian Lynx critical habitat final rule; the Primary NAAQS review for Lead (proposed and final); the Primary NAAQS review for Nitrogen Dioxide (proposed and final). For three of these five rules, the pre-OMB draft rule was available, however. The level of compliance was thus higher here than observed by GAO in 2009; they report that 62% of the agencies documented at least some features of OMB’s formal review. GAO 2009, *supra* note 316, at 13.

³¹⁹ The reader can view the red-lined documents located for the NAAQS rules and habitat designation rules canvassed in this study at [/wewagner/upload_for_acus](#). The “re-created” red-lined for the proposed and final primary NAAQS nitrogen dioxide review is available at [/wewagner/nitrogen_dioxide_change_docs](#).

³²⁰ GAO observed a wide range of agency compliance with Section 6, ranging from no compliance to detailed memoranda that detailed OIRA changes. *Id.* It appears that the majority of agencies adopt something like the approach here, which is simply posting a single red-lined copy of the draft rule as a result of OMB review. *Id.*

³²¹ Section 6(a)(3)(E)(ii). GAO encountered the same difficulties in its 2009 study. See GAO 2009, *supra* note 316, at 34.

³²² See <http://www.reginfo.gov/public/do/eoAdvancedSearchMain>

running searches for the documents in the agency's individual rulemaking dockets.³²³ This search was further complicated by the fact that the name that the EPA assigns to these red-lined document is not regularized;³²⁴ in some cases the red-lined document is located only after opening dozens of posted documents that contain OMB or Office of Management and Budget in the title of a rulemaking docket, which in turn can contain hundreds of entries.³²⁵ In the case of the FWS, the search is still more complicated since the FWS did not maintain online dockets for habitat designations under the Endangered Species Act. Instead, one must call the FWS field office that originated those rules during office hours (this office phone number is listed at the end of the published rule in the Federal Register).³²⁶ The Field Office personnel then attempt to identify the appropriate documents and provide them electronically or by mail.

In sum, the evidence of agency compliance with Section 6(a)(3)(E)(ii)'s requirement to identify the substantive changes occurring during OIRA's formal review generally consists, at best, of the posting of a redlined version of the changes that occurred during formal OIRA review in a rulemaking docket. Once found, this document does not identify the substantive changes made by OIRA nor explain them; one must read the hundreds of pages of red-lined to pull out changes that might be important.

(ii) The Identification of changes made at the Suggestion or Recommendation of OIRA

Executive Order 12866 also requires the agency originating a regulatory action to “[i]dentify for the public those changes in the regulatory action that were made at the suggestion or recommendation of OIRA.”³²⁷ yet the agencies did not provide this documentation for any of the rules in this study. Again, this suggests EPA and the FWS are not in compliance with the Executive Order 6(a)(3)(E) requirements for at least some rules. The fact that the red-lined documents reveal hundreds of changes raise the likelihood that OIRA suggested at least some of them during its formal review. Yet there was no effort by the EPA or the FWS to identify which of these redlined changes were

³²³ The dockets were searched for “OMB” and “Office of Management and Budget.” Searches for “OIRA” and “Office of Information and Regulatory Affairs” typically produced no documents. OMB uses a RIN number to identify rules; agencies use docket numbers. To track down the agency’s identification of changes resulting from OMB review, one must locate the agency’s docket number by entering the unified regulatory agenda using the RIN number. In cases where the docket number is still not provided, further tracking and linking to find the agency’s docket is necessary.

³²⁴ Again, GAO encountered the same difficulties in its 2009 study. See GAO 2009, *supra* note 316, at 34 (describing the differences in agency labeling practices).

³²⁵ See the OIRA-EPA exchanges for each of the NAAQS rules in the data compiled for this study at [/wewagner/Document Inventory of OMB review](#).

³²⁶ The docket index was only available for the rule that was undergoing litigation and it seemed from the discussions with several field offices that the preparation of a docket index might be the exception rather than the rule.

³²⁷ Section 6(a)(3)(E)(iii) of Executive Order 12866.

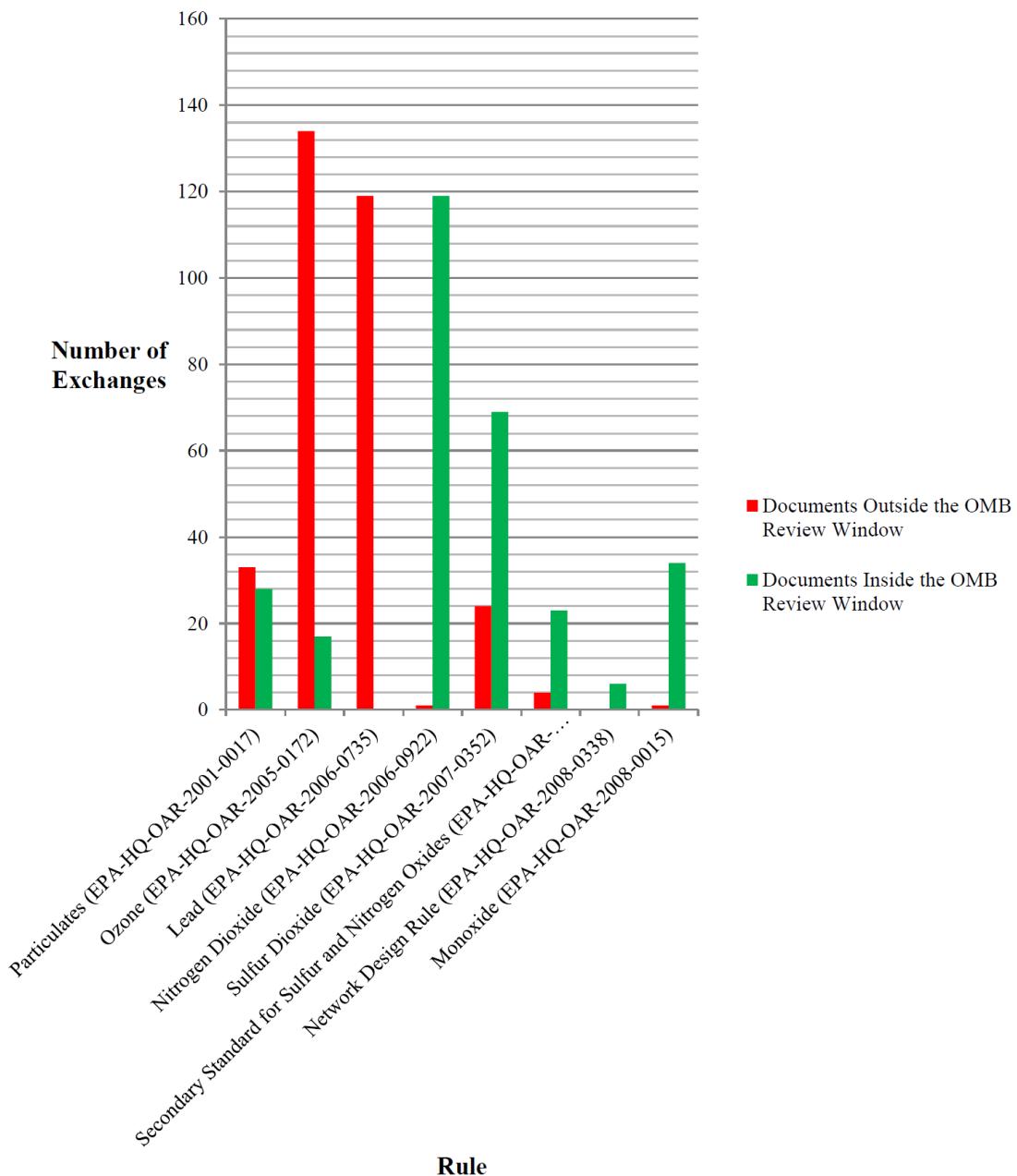
made “at the suggestion or recommendation of OIRA” as opposed to other agencies or the originating agencies themselves.

An agency might maintain that all changes made in a red-lined version that documents the changes made during OIRA’s review were also changes “made at the suggestion or recommendation of OIRA.” But even if that were true with respect to the changes made during OIRA’s formal review, it misses the changes made at the suggestion of OIRA that were made outside this short timeframe. To get a sense of OIRA’s review, I assembled all available documentation of OIRA’s exchanges cataloged in the EPA NAAQS and FWS habitat designation dockets. Although OIRA does not make the correspondence between its staff and the agency publicly available, the agencies do docket some of this written information consistent with their responsibilities under Section 6(a)(3)(E).³²⁸ The figure below provides a summary of these docketed agency-OIRA communications for the NAQQS rules canvassed in this study.³²⁹ As this figure indicates, the docketed exchanges vary a great deal from rule to rule, but for some rules, relatively extensive exchanges occurred between the agency and OMB outside the formal review period.³³⁰

³²⁸ EPA did create a site dedicated to tracking rules through the rulemaking process, including those going through OMB review. <http://yosemite.epa.gov/opei/RuleGate.nsf/> In a search of the archived rules, however, very little and perhaps none of the information collected in this study on OMB review of NAAQS rules was available. That is not a criticism of the site; only an acknowledgement that the site is not complete.

³²⁹ The excel lists for each of the rules in this study where dockets were available is provided at [/wewagner/Document Inventory of OMB review](#).

³³⁰ See *id.*; see also Appendix G.



In the NAAQS rules in particular, nearly half of the communications between OIRA and EPA occurred outside the formal window of OMB review. In the lead primary NAAQS review all of the nearly 120 docketed exchanges between OIRA and EPA occurred outside the very short (1 day) OIRA formal review window.³³¹ (Readers can access each of the documents by following the hyperlinks to the documents detailed in the footnote.)³³² See also Appendix H. Yet precisely because many exchanges occurred

³³¹ See Docket EPA-HQ-OAR-2006-0735 at [/wewagner/Document Inventory of OMB review](#)

³³² To view the individual documents, go to [/wewagner/Document Inventory of OMB review](#) and click a docket number. This will list the OIRA-EPA exchanges, along with some details. In the last column, there

outside the formal review window, the ability of the public to assess the actual changes to a rule “made at the suggestion or recommendation of OIRA” as required by Section 3(a)(3)(E)(iii) is effectively impossible. At best, one can piece together scattered docketed email exchanges between OMB and the agency to identify potential changes, and then compare those potential changes against the published rule.³³³ Even then, the agency dockets are incomplete. Some docket exchanges consist only of the short cover emails, and omit the attachment that contain the substantive comments and suggested edits. In its report, GAO similarly noted extensive OMB engagement with agency rules outside of the formal review process that were not accounted for by agencies in compliance with the Executive Order.³³⁴

In sum, while Section 6(a)(3)(E)(iii) requires the agencies to “[i]dentify for the public those changes in the regulatory action that were made at the suggestion or recommendation of OMB,” the EPA and FWS did not identify these changes for any of the rules in this study.³³⁵ While it is possible that this simply means that there were no changes in any of the rules, the red-lined documents and other documents posted, particularly by EPA, belie that possibility. Indeed, given the likelihood that no identification of changes will be interpreted by the public as signifying that OIRA offered no changes, agencies should either provide the identification of changes for each rule or indicate that there were no changes made at the suggestion or recommendation of OIRA.

It is not clear why the agencies did not provide this identification of changes as required by Executive Order. One partial explanation for this noncompliance is the possibility that the agencies read a cryptic 1993 OMB directive to suggest that Section 6(a)(3)(E)(iii) should be read as a subset of Section 6(a)(3)(E)(ii).³³⁶ Yet even in this statement, the agencies are still directed by OMB to identify the changes “made at the

is a hyperlink to the original document which is posted at regulations.gov. In the long term, I hope to gather more detailed information about the nature of these exchanges, both in substance and in relation to formal review. At this point, however, the reader must assess for themselves the nature of these various communications.

³³³ GAO 2003, *supra* note 307, at 111 (reaching a similar conclusion).

³³⁴ *Id.* at 5.

³³⁵ The same finding appears to be drawn from the GAO study, which found very few agencies able to attribute the changes to OMB. *See, e.g., id.* at 111.

³³⁶ *See, e.g.,* Memorandum to Executive Heads and Departments from Leon Panetta, Oct. 12, 1993, at 9, available at

http://www.whitehouse.gov/sites/default/files/omb/assets/inforeg/eo12866_implementation_guidance.pdf.

The 1993 memorandum provides only this one sentence guidance on Section 6(a)(3)(E):

In addition, after the regulatory action has been published in the Federal Register or otherwise issued to the public, each agency is to identify for the public, in a complete, clear, and simple manner, the substantive changes that it made to the regulatory action between the time the draft was submitted to OIRA for review and the action was subsequently publicly announced, indicating those changes that were made at the suggestion or recommendation of OIRA (Sec. 6(a) (3)(E) (ii) & (iii)).

See also GAO 2003 Study, *supra* note 307, at 56-57, 95 (discussing difficulty with OMB’s apparent legal interpretation).

suggestion or recommendation of OIRA.”³³⁷ OIRA’s interpretation could also be read to require the agencies to identify changes “made at the suggestion or recommendation of OMB,” be limited only to formal OIRA review, but again OIRA’s interpretation does not go that far.³³⁸ Regardless, since the agencies, not OIRA, are tasked with responsibility for meeting the requirements of Section 6(a) of the Executive Order,³³⁹ OMB’s interpretation – even if it did preclude agency compliance with (E)(iii) which it does not – will not insulate the agencies from their important disclosure requirements. Indeed, the responsibility to identify changes resulting from OIRA review was likely placed on the agencies precisely in order to provide an independent check on this review.

Equally problematic in terms of the agency’s compliance with Section (E)(iii), OIRA review can sometimes result in the suspension or even termination of rules; yet beyond the fact that a rule is withdrawn (identified on OIRA’s website), there is no record of what happened during this suspension period or what OIRA suggestions led to the withdrawal or suspension of the proposed rule. The GAO raised concerns about this as well and issued recommendations for heightened transparency about rule withdrawals. As just one example, from a rule in this study - the primary NAAQS for nitrogen dioxide - EPA initiated a review process with OIRA in January 2009, but withdrew the proposed rule two weeks later without public explanation.³⁴⁰ It took EPA another four months to

³³⁷ *Id.*

³³⁸ OMB directs agencies to identify changes made between the “time the draft was submitted to OIRA for review” and when the regulatory action was subsequently publicly announced, which could include both formal reviews and more informal reviews occurring outside the formal review period. In any event, reading the (E)(iii) disclosures as limited to only the formal review period is not a reasonable reading of the Executive Order and hence, by extension, it is not a reasonable reading of OMB’s passage either.

Collapsing Sections (ii) and (iii) of the Executive Order together to require disclosure of changes occurring only during formal review conflicts with basic rules of legal interpretation that afford each section an independent meaning; moreover, subsection (iii) refers to an identification of all “changes [made] in the regulatory action,” while subsection (ii) refers only to “substantive changes” made “between the draft submitted to OIRA for review and the action subsequently announced.” Collapsing the two sections to preclude an identification of changes occurring outside the formal review is also inconsistent with the structure and intent of Section 6, which seeks to provide basic transparency of the results of OIRA review, as well as with the President Obama’s memorandum on transparency. Finally and perhaps most important, to limit disclosures of OIRA-induced changes only to the formal review period risks missing most, if not all, of the changes made at the suggestion of OIRA, in at least some rules. Perhaps in 1993 when OIRA issued this statement, its influence was limited to the formal review period. Twenty years later, it is clear – on OIRA’s own admission -- that many changes made to rules at the suggestion or recommendation of OIRA occur outside the formal review period and the interpretation makes disclosure badly incomplete.

See, e.g., GAO 2003, *supra* note 307, at 36-37 and 113-114.

³³⁹ See Section 2(a) and Section 6(a) of the Executive Order. Section 2(a) for example directs that: “Because Federal agencies are the repositories of significant substantive expertise and experience, they are responsible for developing regulations and assuring that the regulations are consistent with applicable law, the President’s priorities, and the principles set forth in this Executive order.” Section 6(a), entitled “Agency Responsibilities” reinforces that compliance is the responsibility of the agencies.

³⁴⁰ See <http://www.reginfo.gov/public/do/eoDetails?rrid=116780> (the record of EPA’s withdrawal of the proposed rule after a two week period at OMB). A review of the more than 400 documents in the EPA’s docket did not reveal any documents that explained the reason for withdraw or even the fact that the initial draft had been submitted. To this extent, the EPA is arguably in violation of Section 6(a)(3)(E)(i) to the

return to OIRA with a new proposed rule.³⁴¹ Yet there are no docketed exchanges regarding this brief unconcluded OMB review that explain what transpired or how or whether OMB suggested or recommended changes that influenced EPA's subsequent draft proposed rule.³⁴² While it is possible that the initial submission to OIRA and subsequent withdrawal did not lead to any changes to the rule made at the suggestion or recommendation of OIRA, this seems unlikely. Several agency officials interviewed for this study also suggested that OIRA is becoming increasingly active in pre-review in an effort to avoid these withdrawals; OIRA simply urges the agency not to send a rule for OIRA review so that a public record of withdrawal is not created. The potential significance of these types of informal or non-formal review exchanges was further underscored by a recent Washington Post article that reported an apparent request by OMB that EPA hold a publicly important rule and not submit it to OMB for review.³⁴³

To the extent that these pre-review activities and withdrawals ultimately lead to changes "at the suggestion or recommendation of OMB," they should be disclosed and explained by the agency. Additionally and in order to remain faithful to the spirit of the President's memorandum on transparency, the agencies should document these changes even if the regulatory action is never published. Otherwise these withdrawals and holds provide a major loophole in ensuring the basic transparency of OIRA review as promised by Section 6(a) of E.O. 12866.

(iii) No Enforcement of Agency or OMB Compliance

Across the rules investigated here, there was no centralized effort to ensure agency compliance with Section 6(a)(3)(E) nor were sanctions levied against noncomplying agencies. OMB concedes that it does not monitor the agencies'

extent that it doesn't provide the draft that it submitted to OMB at the initiation of this, ultimately withdrawn rule.

³⁴¹ See <http://www.reginfo.gov/public/do/eoDetails?rid=11715> (the record of EPA's second submission of the proposed rule to OMB). The draft submitted and then withdrawn in January 2009 could not be located on EPA's docket. To the extent that changes were made to that proposal as a result of OIRA's suggestions, they do not appear to be provided in the public record.

³⁴² Since this discovery of the withdrawal was accidental, this type of concluded review may be a far more frequent occurrence. A search of EPA rules that have been withdrawn over time yielded a list of 162 rules since 1981. (To replicate this search, go to <http://www.reginfo.gov/public/do/eoAdvancedSearchMain>. Select EPA as the main agency and "withdrawn" as the "concluded action". Also click "concluded reviews" rather than the default of pending reviews (located on the right column of the search terms). GAO also indicated concern about withdrawn rules and the lack of documentation of OMB's influence in the process. *See, e.g.*, GAO 2003, *supra* note 307, at 7.

³⁴³ Juliet Eilperin, Obama administration slows environmental rules as it weighs political cost, Feb. 12, 2012, Washington Post, available at http://www.washingtonpost.com/national/health-science/obama-administration-weighs-political-cost-of-environmental-rules/2012/02/07/gIQAvJzx8Q_story.html. An effort to locate documentation of these discussions was not successful, however. The docket on the Tier III rules was empty. [EPA-HQ-OAR-2011-0135](#) . (See <http://www.epa.gov/rfa/tier3.html> for the discussion of the rule and the docket number).

compliance with Section 6(a)(3)(E) of the Executive Order;³⁴⁴ OMB also does not reference or link to the agency's redlined document in its own database, reginfo.gov, to make it easier for the public to evaluate agency compliance. Similarly, within the agencies there did not appear to be a coordinated system to ensure compliance with section 6(a)(3)(E) or even to issue agency-wide interpretations and directions for what this section requires.

b. Scientific Significance of the Changes that result from Formal OIRA Review³⁴⁵

A number of interviewees maintained that OMB did make changes to the scientific and technical characterizations of some of EPA rules (and the NAAQS rules in particular),³⁴⁶ but evidence of this influence was not provided and thus the nature and significance of these changes was controverted. To gain a preliminary assessment of the nature of changes made during OIRA's formal review, I coded all non-editorial changes³⁴⁷ in each of the available red-lined documents for the rules canvassed in this study based on whether the changes appeared technical or non-technical.³⁴⁸ Technical changes are those that involved alterations to technical discussions in the preamble or rule, such as qualifying scientific discussions, adding scientific or technical citations, revising the numbers in tables, and recommending different substantive standards altogether that would seem to benefit from further scientific review and discussion. Non-technical changes may be significant, but they concern legal issues, economic issues, or other types of changes that do not affect the characterization of the scientific record or make technical or scientific changes to the rule or its preamble. For example, the following red-lined excerpt – which occurred to EPA's rule during OIRA review -- would be counted as a technical change since it involves changes to the enforceable rule that occurred during OMB review.

³⁴⁴ GAO 2009, *supra* note 316, at 32.

³⁴⁵ As discussed above, there is no way to identify the changes made at the suggestion of OIRA throughout the rulemaking record.

³⁴⁶ See, e.g., infra notes 590-591 and accompanying text.

³⁴⁷ See Appendix G for further definitions of this term.

³⁴⁸ See Appendix G. A proposed rule might record thousands of changes in the red-lined reviewing pane, but less than one-hundred of these changes appear non-editorial and are thus coded as either technical or non-technical. The coded changes then constitute only a fraction of the changes made during OMB review. Note that the methods used here are different from those employed by GAO in its 2003 and 2009 study in which GAO categories the cumulative changes made by OIRA to a rule on a spectrum ranging from significant to nonexistent. See, e.g., GAO 2003, *supra* note 307, at 29-30.

An Excerpt of the Redlined Changes Occurring during OIRA's Formal Review of EPA's Proposed Rule for the Sulfur Dioxide NAAQS³⁴⁹

5. Calculation Procedures for the 1-hour Primary SO₂ NAAQS.

(a) Procedure for identifying annual 99th percentile values. When the data for a particular site and year meet the data completeness requirements in section 3(b), or if one of the conditions of section 3(c) is met, or if the Administrator exercises the discretionary authority in section 3(d), identification of annual 99th percentile value is accomplished as follows.

(i) The annual 99th percentile value for a year is the higher of the two values resulting from the following two procedures.

(1) Procedure 1. For the year, determine will be based on the number of days with at least 75 percent of the hourly values reported.

(A*i*) For the year, from only the days with at least 75 percent of the hourly values reported, select from each day the maximum highest hourly value.

(B*i*) Sort all these the valid daily maximum hourly values from a particular site and year by descending value. (For example: (x[1], x[2], x[3], * * *, x[n]). In this case, x[1] is the largest number and x[n] is the smallest value.) The 99th percentile is determined from this sorted series of daily values which is ordered from the highest to the lowest number. Using the left column of Table 1, determine the appropriate range (i.e., row) for the annual number of days with valid data for year y (c_{n,y}). The corresponding "n" value in the right column identifies the rank of the annual 99th percentile value in the descending sorted list of daily site values for year y. Thus, P_{0.99,y}= the nth largest value.

(2) Procedure 2. For the year, determine the number of days with at least one hourly value reported.

(A) For the year, from all the days with at least one hourly value reported, select from each day the maximum hourly value.

(B) Sort all these daily maximum values from a particular site and year by descending value. (For example: (x[1], x[2], x[3], * * *, x[n]). In this case, x[1] is the largest number and x[n] is the smallest value.) The 99th percentile is determined from this sorted series of daily values which is ordered from the highest to the lowest number. Using the left column of Table 1, determine the appropriate range (i.e., row) for the annual number of days with valid data for year y (c_{n,y}). The corresponding "n" value in the right column identifies the rank of the annual 99th percentile value in the descending sorted list of daily site values for year y. Thus, P_{0.99,y}= the nth largest value.

(b) The 1-hour primary standard design value for a site is mean of the three annual 99th percentile values, rounded according to the conventions in section 4.

A review of the available red-lined documents for the NAAQS reviews revealed that in most rules the majority of the non-editorial changes were technical in nature. See Table below. The changes made to FWS rules, by contrast, were about equally divided between technical and more substantive (often legalistic) changes and were, overall, fewer in number.³⁵⁰

³⁴⁹ Red-lined of the Proposed NAAQS Standard for Sulfur Dioxide at pages 244-46, Docket id EPA-HQ-OAR-2007-0352-1347, available at regulations.gov.

³⁵⁰ See Appendix G .

<u>Title</u>	<u>Proposed/Final</u>	<u># Non-editorial Changes</u>	<u>#/% of non-editorial Changes that were technical</u>
Secondary	Proposed	44	35 (80%)
Secondary	Final	21	13 (62%)
Lead			
Monitoring	Proposed	24	15 (62%)
Ozone	Proposed	12	6 (50%)
Network			
Design	Proposed	5	0 (0%)
Sulfur Dioxide	Proposed	49	42 (86%)
Sulfur Dioxide	Final	16	10 (62%)
Monoxide	Proposed	26	13 (50%)
Monoxide	Final	14	10 (72%)

While it was not possible without considerably more expert assistance and detective work to determine the significance of most of these various technical changes, for more than half of the NAAQS rules examined in this study, the science-based rules did change during OIRA's review in ways that affect the enforceable requirements of the regulation.³⁵¹ For example, the required number of ambient monitors to measure both carbon monoxide and nitrogen dioxide concentrations in the ambient air³⁵² were reduced by about twenty percent during OIRA's review (since EPA did not identify the changes made at OIRA's suggestion, it is not possible to determine whether the change was actually made at the suggestion of OIRA).³⁵³ During OIRA review, EPA changed the rule for the secondary standard for the oxides of nitrogen and sulfur to adopt the primary standard (EPA had initially declined to set a secondary standard) (the same qualification applies to this change).³⁵⁴ At OIRA's recommendation, EPA also loosened the secondary

³⁵¹ In its 2009 report, the GAO identified about 30% of the rules it reviewed as involving significant changes that "revised the scope, impact, or costs and benefits of the rules". GAO 2009, *supra* note 316, at 5.

³⁵² For the WORD-generated track change document that highlights this change in the nitrogen dioxide rule, see the final red-lined rule posted at [/wewagner/nitrogen dioxide change docs](#). For the change in the carbon monoxide final rule, go to pages 100- 101 of the red-lined final rule for carbon monoxide, which is listed as EPA-HQ-OAR-2008-0015-0200A track final rule and is posted at [/wewagner/upload for acus](#).

³⁵³ If the reduced number of monitors falls comfortably within some range agreed upon by the scientists, meteorologists and statisticians, and has no scientific costs or downsides, then these changes may not intersect with scientific issues. If however there are technical implications of a reduced number of required ambient monitors, then these changes do occur at the intersection of science and policy.

³⁵⁴ EPA apparently preferred to provide no secondary standards; during OMB review the primary standard was inserted.

standard for ozone (this change was not located through examination of the red-lined documents but instead is reported in the literature, which is why OIRA’s role is clearer).³⁵⁵ OIRA’s influence could not be identified in the lead proposed and final rules, but the number of substantive documented exchanges (N=119) occurring between OIRA and EPA give an outsider the impression that OIRA’s influence on the lead rule may have been significant.³⁵⁶ See also Appendix H and hyperlinked documents in the footnote. Finally, OMB returned two of the NAAQS rules regarding ozone NAAQS in 2011 due primarily to concerns about the implementation of the NAAQS rule on the economy, where the rules remain to this day.³⁵⁷

Since the red-lined documents provide only the changes occurring during formal OIRA review, moreover, they miss all of the changes made at the suggestion or recommendation of OIRA occurring at other points in the regulatory life cycle. A review of some of the scattered documents included in EPA’s NAAQS rulemaking dockets reveal that these pre-formal review exchanges also involve disagreements about interpretation of scientific evidence. See Appendices F and H. While the examples in NAAQS documents are necessarily incomplete, they do indicate that OIRA is not reluctant to get “deep” in the science, as various interviewees suggested.³⁵⁸

A few complementary studies also find that OIRA involved in technical and scientific features of the agencies’ regulatory actions. In their detailed study of OIRA involvement in EPA’s IRIS profiles during the Bush Administration, for example, the Majority Staff of the House Subcommittee on Investigations and Oversight concluded that OIRA played a central role in “challenging the science being done at regulatory agencies.”³⁵⁹ “[T]he Subcommittee has ample documentation showing that OIRA’s staff scientists did far more than merely coordinate and facilitate science discussions across agencies. OIRA’s staff scientists directly challenged the science put forward by EPA IRIS staff in very detailed peer review-type comments.”³⁶⁰

The Majority Staff include in their report extensive documentation of communications between OIRA and the agencies that provide numerous examples of

³⁵⁵ See, e.g., Robert Percival, *Who’s in Charge? Does the President Have Directive Authority over Agency Regulatory Decisions?*, 79 Fordham Law Review 2487, 2520-21 (2011); Juliet Eilperin, Ozone Rules Weakened at Bush’s Behest, Washington Post, March 14, 2008, at A1., available at <http://www.washingtonpost.com/wp-dyn/content/article/2008/03/13/AR2008031304175.html>

³⁵⁶ See the documents posted in EPA’s docket, cited at *supra* note 331

³⁵⁷ See Ozone return letter which put an end to the Network Design rule and the Ozone primary NAAQS review, available at http://www.whitehouse.gov/sites/default/files/ozone_national_ambient_air_quality_standards_letter.pdf

³⁵⁸ See *infra* note 591.

³⁵⁹ Majority Staff of the Subcommittee on Investigations and Oversight, Nipping IRIS in the Bud: Suppression of Environmental Science by the Bush Administration’s Office of Management and Budget at 2 (June 11, 2009), available at http://www.ucsusa.org/assets/documents/scientific_integrity/miller-iris-report-june-09.pdf.

³⁶⁰ *Id.* at 5.

substantive editorial change(s) by OIRA to EPA's characterization of the science. As just one representative example, OIRA staff inserted the following bold passage to EPA's summary of the scientific literature in an IRIS profile:

this may imply that different activities may expose different age groups more than others, or that some PBDE congeners may accumulate differently with age, **however the sample size here is very small and firm conclusions cannot be made.**³⁶¹

This type of editorial insert is similar to a number of the technical changes identified in the NAAQS red-lined documents examined in this study; the technical edits frequently qualify the characterization of the relevant literature in ways that alter the weight or credibility to be attached to them.³⁶² In GAO's 2003 study there are similar references to substantive, technical changes by OIRA to EPA rules. For example, OIRA suggested adding the qualification that EPA was adopting "plausible but highly uncertain assumptions" to EPA's preamble;³⁶³ in another rule, GAO identified how OIRA successfully convinced EPA to remove manganese from the list of hazardous constituents in its final rule.³⁶⁴

c. Implications

The risk that science-intensive rules can be changed in ways that are at odds with public understanding or the scientific record are heightened when the rulemaking process includes opportunities for agency officials to change the rules without public disclosure or expert review. While the most salient example of this type of manipulation in recent years did not involve OIRA or the White House, but instead involved actions by a high level DOI appointee, Julie MacDonald,³⁶⁵ a close examination of the McDonald experience and other examples in which science has been politicized reveal a set of circumstances – often present during OIRA review -- that seem to make rules particularly susceptible to these behind-the-scenes manipulations. Specifically, in most if not all cases of politicization of science, the process governing the integration of science into regulation tends to involve: 1) a regulatory decision that involves high stakes; 2) high-level interventions or related pressures occurring at a point in the decision process where

³⁶¹ See *id.* at 7. Excerpted from interagency documents provided in full at Appendix A.

³⁶² See Red-lined Drafts of Proposed and Final NAAQS and Habitat Designation rules at [/wewagner/upload](#) for acus

³⁶³ GAO 2003, *supra* note 307, at 79.

³⁶⁴ See *id.* at 9.

³⁶⁵ During her tenure, MacDonald managed to alter the scientific record supporting species listing and habitat designations through a variety of techniques. The result in a number of cases was alterations in the agency's rules. While MacDonald's actions may have been motivated by a policy agenda, the changes she made were to the characterization of the scientific evidence. *See, e.g.*, Office of Inspector General, U.S. Department of Interior, "The Endangered Species Act and the Conflict between Science and Policy" (2008). This type of political meddling into the scientific record to alter decisions on policy grounds is only one of many examples of the politicization of science by government officials. *See, e.g.*, Holly Doremus, *Scientific and Political Integrity in Environmental Policy*, 86 TEXAS LAW REVIEW 1601 (2008)

there is limited to no transparency regarding the changes, and 3) the absence of rigorous scientific oversight or peer review of the changes, including changes to the characterization or use of the relevant science.³⁶⁶

Experience thus reveals significant risks associated with decision-making processes that allow last-minute, high level changes to an agency's characterization of scientific or technical evidence, especially where these changes are not recorded, justified, or subjected to scientific or technical review. Section 6(a) attempts to counter some of these risks through its direction to the agencies to document the changes made as a result of OIRA's review, both formal and informal. Yet compliance with Section 6(a) by the agencies in the rules studied here was incomplete. While the preliminary study of NAAQS and ESA rules conducted here illuminates some features of OMB review in need of further study, it also highlights areas worthy of preliminary recommendations by ACUS.

First and as mentioned above, EPA and FWS, for the rules studied here, did not identify or explain the "changes made at the suggestion or recommendation of OIRA" as required by Section 6(a)(3)(E)(iii) of Executive Order 12866. For some rules, numerous exchanges occurred between OMB and EPA both inside and outside of the formal review process and yet none of the resultant changes made at the suggestion of OIRA to its regulatory actions were identified by the EPA. The 2009 GAO study similarly concludes from interviews of OIRA officials that changes, particularly during informal review, can be significant and yet are undisclosed.³⁶⁷

³⁶⁶ See, e.g., *id.* at 1640 (concluding that "[t]he single biggest contributor to the lack of political integrity in this Administration's environmental-policy decisions is the absence of barriers between political appointees who view their mission as the single-minded advancement of the President's policy agenda and career employees charged with providing scientific advice or analysis."). Julie MacDonald, for example, edited decisions in ways that were largely invisible to outsiders and that often occurred at the "eleventh hour." See, e.g., OIG Report, *supra* note 365, at 1 and 16. MacDonald also had conflicts of interest on some of the decisions that were unknown to others and influenced her decisions. *See id.* at 3. One of the case studies elaborates on these features that are particularly likely to lead to the politicization of science. In one case:

The [FWS] rule drafted by the field biologists represented the views and recommendations of the biologists, and as the rule for the CHD traveled through the region, fairly few edits were made to the recommendations of the biologists. However, once the rule was forwarded to Washington, D.C., [a FWS biologist] said the rule underwent significant editing [by MacDonald].

Id. at 21. In another example, "Macdonald . . . changed the text of the final rule the day before it was completed." *Id.* at 33. In yet another "MacDonald recommended numerous edits to the gulf sturgeon rule that were different than what the FWS recommended" and directed changes to be made "despite concerns expressed by region biologists and solicitors that the record did not support" them. *Id.* at 56.

³⁶⁷ GAO 2003, *supra* note 307, at 95 (observing that in some of the rules reviewed, "OIRA suggested significant changes prior to formal submission of the rule to OIRA). *See also id.* at 113 (concluding that "restricting the transparency requirements in Executive Order 12866 only to a brief period of formal review seems antithetical to the intent of those requirements."); *id.* at 114 ("it is not clear who OIRA believes that the executive order's transparency requirements should not cover the part of the review period when the most important changes can occur.").

Second, even with respect to the agency’s responsibility for identifying the changes occurring during OIRA’s formal review, compliance by the agency proposing the rule is incomplete on several levels. For about one-third of the NAAQS and ESA rules, there was no explication of the substantive changes that occurred during OIRA formal review. In addition, for the remaining rules, the agency’s red-lined version of the proposed or final rule did not “[i]dentify for the public, *in a complete, clear, and simple manner, the substantive changes* between the draft submitted to OIRA for review and the action subsequently announced” as required by subsection (E)(ii) (emphasis added). These red-lined documents were also very difficult to locate within the larger, individual rulemaking dockets and not provided in a “simple” manner.

More complete agency compliance with the requirements of Section 6(a)(3)(E) for science-intensive rules would help abate the risk that these rules can be changed in ways that escape not only understanding by the public, but by scientists familiar with the technical details of the rule. Recommendations in the final section identify how this transparency of these changes can be increased in the future.

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.³⁶⁸ 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.³⁶⁹ 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 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.³⁷⁰

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.³⁷¹ According to one former

³⁶⁸ See, e.g., *supra* note 5; 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.

³⁶⁹ See, e.g., Doremus, *supra* note 5; OIG MacDonald Report, *supra* note 11.

³⁷⁰ See *infra* Section IV.B.3.

³⁷¹ 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,

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.³⁷² 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.³⁷³ While the current guidelines are still developing and thus are inevitably incomplete, they constitute a solid foundation for future integrity programs. Regardless, the purpose of this report is to provide only a brief synopsis of these emerging programs without a detailed critique of their details.

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 policies. Recall that President Obama requested OSTP to develop a government-wide program to enhance the scientific integrity of agency work, and Director Holdren’s subsequent memorandum set the parameters for that program.³⁷⁴ 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.³⁷⁵ DOI is currently working on a communications policy in response to the

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.

³⁷² Interview with former OSTP employee, Jan. 23, 2012.

³⁷³ See generally OSTP, Scientific Integrity Policies Submitted to OSTP, available at <http://www.whitehouse.gov/blog/2011/08/11/scientific-integrity-policies-submitted-ostp>.

³⁷⁴ See *supra* notes 6-7 and accompanying text.

³⁷⁵ 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 about paralysis and/or extended delays in which the DOI would operate with absolutely no integrity guidelines in place. *Id.*

scientific integrity initiative and has plans to address a succession of other issues over time.³⁷⁶

The goal of DOI's current integrity policy, which is focused primarily on policing misconduct and establishing codes of conduct, 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.³⁷⁷ 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.³⁷⁸

In its initial scientific integrity policy, DOI has established a relatively elaborate scientific misconduct process.³⁷⁹ Under the policy, DOI staff and outside parties can make allegations of scientific misconduct against a staff or official within DOI.³⁸⁰ 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.³⁸¹ While the definition of misconduct is relatively narrow and includes only intentional or reckless “fabrication, falsification, or plagiarism” in scientific activities,³⁸² 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.”³⁸³

DOI’s process involves the initial submittal of a non-anonymous allegation of misconduct by anyone, including persons outside the agency.³⁸⁴ If the allegation is determined to be credible, then an inquiry will be conducted.³⁸⁵ If it is ultimately

³⁷⁶ *Id.*

³⁷⁷ *Id.*

³⁷⁸ *Id.*

³⁷⁹ 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); *see also supra* note 222.

³⁸⁰ DOI Scientific Integrity Guidelines, *supra* note 379.

³⁸¹ 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.

³⁸² DOI Scientific Integrity Guidelines, *supra* note 379, 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).

³⁸³ *Id.*

³⁸⁴ *Id.* at 3.8A(1).

³⁸⁵ 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

determined that intentional or reckless misconduct occurred, then sanctions – spanning the range from termination to reprimand – may be issued.³⁸⁶ As mentioned, DOI’s integrity policy also offers codes of conduct and principles to guide staff behavior, although these objectives appear difficult to enforce, in part because of their ambiguous definitions.³⁸⁷

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.³⁸⁸ 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.³⁸⁹ DOI admits that its first policy has a limited range in

³⁸⁶ 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.

³⁸⁷ 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 379, 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.

³⁸⁸ 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.*

³⁸⁹ 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 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

addressing problems of scientific integrity.³⁹⁰ 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.³⁹¹

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.³⁹² Although NOAA is not within the three agencies under study here, because its guidelines build heavily on DOI's guidelines, because the National Marine Fisheries Service within NOAA is also responsible for the protection of endangered species, and finally because NOAA is viewed by public interest groups as considerably more effective, they are discussed briefly in closing.³⁹³ NOAA's policy, like DOI's, establishes a scientific misconduct program,³⁹⁴ but NOAA ultimately departs from DOI's policy in several important ways. First, NOAA commits to an annual, public reporting of misconduct allegations and

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.

³⁹⁰ 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.

³⁹¹ Interview with Department of Interior Staff, Aug. 29, 2011.

³⁹² 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.

³⁹³ 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.

³⁹⁴ 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.

proceedings occurring within the agency.³⁹⁵ This addresses 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 easier to enforce because of their specificity and because the code of conduct is explicitly referenced as enforceable.³⁹⁶ 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.³⁹⁷

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 developed under President Clinton).³⁹⁸ 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 complete³⁹⁹ and the Health and Human Services (HHS) Office of Research Integrity site refers to EPA’s program as a finalized program.⁴⁰⁰

³⁹⁵ 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 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.

³⁹⁶ 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 394. 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 394.

³⁹⁷ *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”).

³⁹⁸ Apparently, neither NOAA nor 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.

³⁹⁹ EPA Scientific Misconduct Policy, available at <http://ori.hhs.gov/sites/default/files/epapolicy.pdf>.

⁴⁰⁰ 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,

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.⁴⁰¹ It is worth noting that there are relatively few accounts of overt suppression and scientific manipulation at EPA,⁴⁰² at least as compared with DOI's travails.⁴⁰³ 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 Staff⁴⁰⁴

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.⁴⁰⁵ The policies include opportunities for the airing and resolution of internal disagreements through informal and formal channels.⁴⁰⁶ As elaborated below,

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.

⁴⁰¹ 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 399, 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.

⁴⁰² EPA staff was apparently prevented from conducting an assessment of the adverse consequences of coal ash [when did this take place?], 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.

⁴⁰³ 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.

⁴⁰⁴ This section benefitted significantly from comments and research assistance provided by Roland Frye.

⁴⁰⁵ 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.

⁴⁰⁶ 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. [Can we cite this directive?] It suggests clearance is needed to discuss NRC work, but

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.⁴⁰⁷

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.⁴⁰⁸

Open Door Policy

NRC's first initiative in this program – the open door policy – was initially created in 1976⁴⁰⁹ to provide staff with an opportunity to meet with supervisors beyond their immediate supervisor to discuss disagreements over technical issues and other matters.⁴¹⁰ 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,

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 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.*

⁴⁰⁷ 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.

⁴⁰⁸ 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>.

⁴⁰⁹ NRC Office of Enforcement, Review of the NRC Differing Professional View/Opinion Program, ML082190414, at 1 (2007) [hereinafter DPO 2007 Review].

⁴¹⁰ 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.

to discuss any matter of concern to the employee.”⁴¹¹ 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.⁴¹² Managers are also prohibited from retaliating against employees who utilize the program.⁴¹³ 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 1980,⁴¹⁴ the NRC developed the “differing professional opinions” (DPO) program⁴¹⁵ 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.⁴¹⁶ 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.⁴¹⁷ 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.⁴¹⁸ The adjudication is conducted by a ad hoc panel.⁴¹⁹ 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.⁴²⁰ If an adjustment is

⁴¹¹ NRC, Open Door Policy, Handbook 10.160, at 1, available at <http://pbadupws.nrc.gov/docs/ML0414/ML041490186.pdf>.

⁴¹² *Id.*

⁴¹³ Open Door Policy, Directive 10.160, *id.*, at 2.

⁴¹⁴ DPO 2007 Review, *supra* note 409, at 1.

⁴¹⁵ 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.

⁴¹⁶ *Id.* at 1 of Directive.

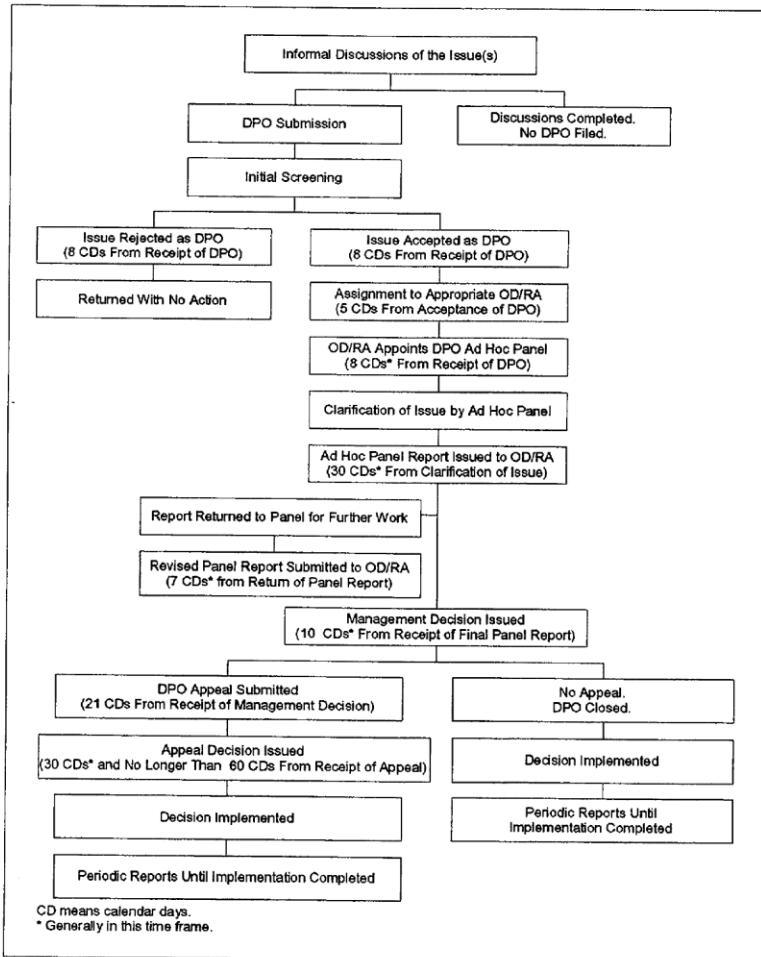
⁴¹⁷ NRC Management Directive 10.158, Non-concurrence Process, at 1 of the Handbook, available at <http://pbadupws.nrc.gov/docs/ML0706/ML070660506.pdf> [hereinafter NCP] (“The DPO Program applies only to positions that are no longer under staff review, and has certain prerequisites and exclusions that 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 415, 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 409, at v.

⁴¹⁸ 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 415, at 6-7 of Handbook.

⁴¹⁹ DPO review, *supra* note 409, 2007 at 6. Not surprisingly, the composition of this panel remains controversial in individual case and appears to be a continuing challenge in implementation of the program. NRC 2007 review at 8-9.

⁴²⁰ DPO Program, *supra* note 415, of Handbook at 6-7.

required, 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).⁴²¹



Although the volume of DPOs in the NRC is not terribly high,⁴²² the 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

⁴²¹ 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 409, 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.*

⁴²² 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 409, at v. [If there were still no DPOs filed after the change in the program, it seems the change wasn't very effective. Is there any evidence of an increase in DPO filings more recently?]

relatively critical evaluation of the program.⁴²³ The OIG concluded that there was underutilization of the program due to fears of retaliation and a perceived lack of effectiveness of the program.⁴²⁴ Multiple subsequent assessments of the DPO program,⁴²⁵ including the NRC OIG report published in 2000, have resulted in a number of changes to the program following the OIG's recommendations.⁴²⁶

Non-concurrence Process

Finally, in 2006 the 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.⁴²⁷ 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.⁴²⁸

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

⁴²³ 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 421, at 3-4.

⁴²⁴ *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.

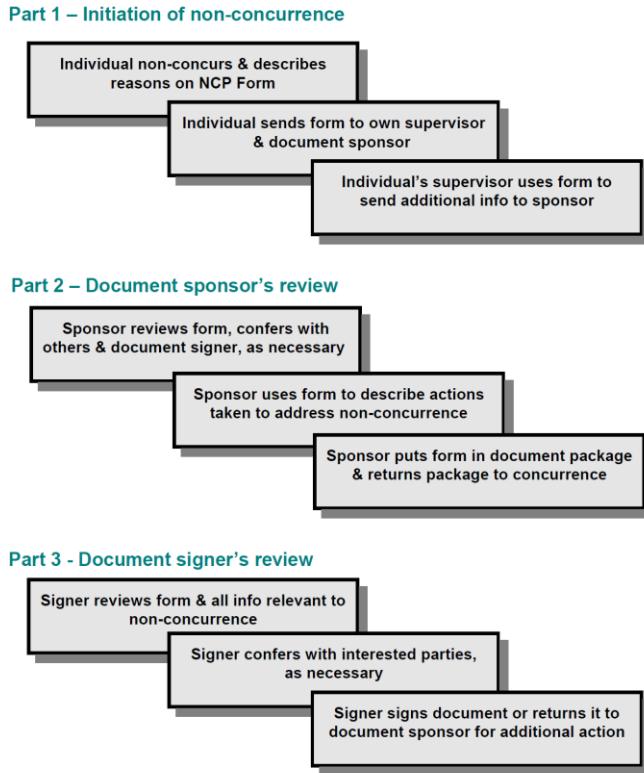
⁴²⁵ The agency has conducted its own internal evaluation of the program over the years, including annual reviews. The DPO program requires that NRC conduct an in-depth annual program review, including audits of office and regional performance records. DPO 2007 Review, *supra* note 409, at 3. For a summary of the more extensive reviews of the program, see *id.* at 1. There are some boilerplate similarities 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.

⁴²⁶ 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 409; 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 409, 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 409, 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 409 and *id.*, for example.

⁴²⁷ NPO, *supra* note 417.

⁴²⁸ *Id.* at 1 of Handbook. A sample of a Non-concurrence statement is provided at Appendix D.

sponsor who then describes any action taken, and both forms are then shared with the document signer for his/her consideration.⁴²⁹



Retaliation is explicitly discouraged in this policy by threats of disciplinary action in accordance with the NRC's policy. Employees are also provided a mechanism for submitting grievances if they perceive they have been retaliated against.⁴³⁰

⁴²⁹ 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).

⁴³⁰ *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

b. Continuing Challenges

The most substantial impediment to the NRC's efforts to provide an open workplace stems from employees' concerns about possible retaliation⁴³¹ and perhaps a natural inclination of employees to seek to "get along" and not anger colleagues or (even more so) supervisors.⁴³²

The NRC has taken a number of actions to address these concerns, including issuing awards to DPO submitters,⁴³³ publicizing success stories,⁴³⁴ buttressing its anti-retaliation oversight processes and policies,⁴³⁵ and attempting to publicize the successes of DPO submitters.⁴³⁶ The NRC also has policies that deter retaliation by levying sanctions against those who retaliate against another employee for expressing his/her concerns.⁴³⁷ And the NRC offers redress to employees who have been retaliated against.⁴³⁸

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 the NRC Commissioner Chairman Jackzo's management style.⁴³⁹ Indeed, in his statements

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 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 409, 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.

⁴³¹ 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 409, at 15.

⁴³² 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 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.

⁴³³ DPO 2007 Review, *supra* note 409, at 14.

⁴³⁴ *Id.* at 23.

⁴³⁵ *Id.* at 14-15.

⁴³⁶ *Id.*

⁴³⁷ NRC Management Directive 10.99, cited at p.2 of the Open Door Policy Handbook, *supra* 410.

⁴³⁸ These employees have remedies through either a negotiated or a formal grievance procedure.

Management Directive 10.101, cited at *id.*

⁴³⁹ See Appendix D for a copy of this nonconcurrence filing.

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 2011.⁴⁴⁰ 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.

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 the NRC's decisionmaking, they were not used.⁴⁴¹ 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.⁴⁴²

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 7 separate public comment periods	Typically 2 documents, each subjected to public	One public comment period; the recommended dose	None	In some informal rulemakings, there is an

⁴⁴⁰ Jackzo letter to Issa, dated Dec. 12, 2011, at p.1.

⁴⁴¹ See *supra* note 432.

⁴⁴² 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.

	on 4 documents	comment before the proposed decision	is not a rulemaking, however		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 decision publicly available?	Yes. Multiple drafts of 4 consecutive reports; external peer review comments; EPA considers all comments and responds to CASAC comments	Yes. Planning and risk assessment drafts; summary of comments; EPA's response	Draft assessment and revised assessment; all comments, including interagency comments; EPA response to all comments	Yes, but only after the proposed rule is published	Yes. Commission papers prepared by staff and other supporting documents are 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	Studies available through an	Limited availability:	Generally available, although availability	Generally available, although availability	Mixed availability: 1)

literature to public	electronic database	Unpublished studies by manufacturers require pre-clearance and cannot be viewed until after the registration decision has been made	of the unpublished studies was not investigated	of the unpublished studies was not investigated	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 underlying scientific analysis	OMB review can obscure this to some extent	Yes, although it is not clear that all policy-relevant choices are accessible to the nonscientist	Generally yes; although no to the extent that interagency review impacts the initial scientific analysis	It depends on the analyses included in the administrative record	Yes, for informal rulemakings
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.⁴⁴³ 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.⁴⁴⁴ Agencies are also establishing integrity policies that allow their staff to raise scientific differences with supervisors through various informal and formal mechanisms.⁴⁴⁵ Finally, agencies increasingly use the Internet to post the reference list used in their decision-making and

⁴⁴³ This is exemplified by the policy assessment in the NAAQS process, see Section III.A.1.a., *supra*.

⁴⁴⁴ 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*.

⁴⁴⁵ The NRC's collaborative workplace program provides a model example. See Section III.B.2, *supra*.

even to make copies of documents consulted during that process readily available through databases and hyperlinks.⁴⁴⁶

This study also reveals features of agency decision-making processes that would benefit from further improvements. First, while some agencies are innovating in their use of science, little of this innovation is recorded or shared across the government. One set of recommendations advocates for more systematic collation of innovative approaches to regulatory science and then catalogs the particularly impressive procedures that emerged from this particular study as either best practices or innovations. 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 minimal best practices can and should be adopted by all agencies engaging in scientific decision-making.

Second, the study exposes a number of external constraints on agency decision-making processes that limit the ability of the agencies to improve their decision processes in keeping with the President's scientific integrity initiative. A second set of recommendations advocate various forms of action with respect to these external barriers to good regulatory science. In this study alone, for example, 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 but are often nontransparent; and abbreviated statutory deadlines for rulemakings impede the ability of the agencies to develop rigorous and transparent processes for integrating science into regulation.

Third, in a number of health and environmental programs agencies necessarily must rely on scientific research produced by regulated parties, yet the agencies do not subject it to vigorous oversight processes. At the very least, this privately produced research should be subjected to the same types of requirements imposed on research published in scientific journals and research produced with federal monies.

Fourth, 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 that are highly recommended for future study are listed in the final section.

⁴⁴⁶ EPA has established a large database of all of the studies used to conduct the NAAQS review. See Section III.A.1.a., *supra*.

A. Capitalizing on Agency Successes

This section highlights various procedures and other innovations utilized wholly within agencies that significantly advance the “transparency in the [agency’s] preparation, identification, and use of scientific and technological information in policymaking.”⁴⁴⁷ These approaches, by and large, have neither been cataloged nor publicized; the report thus serves a valuable service simply in publicizing these advances. The section begins by noting this dearth of investigations of agency successes in science-based regulation and the resultant lack of models of particularly good integration of science into decision-making in the general literature. Several recommendations seek to address this oversight, at least preliminarily.

The second set of recommendations then identify widespread and seemingly fundamental features of nearly all agency regulatory decisions that seem to rise to the equivalent of best practices for science-intensive regulation. Ideally, these practices operate almost as presumptive prerequisite for science regulation that agencies should be expected to explain when they are not followed.

The third and final set of recommendations identifies innovative approaches found within the agencies that seem to significantly strengthen agency regulatory programs involving scientific or technical information. While each innovation offers an approach to regulatory science that generally advances both the transparent and robust incorporation of technical information into regulation, this final section refrains from hailing these innovations as clear “best practices” since the contexts and constraints on agencies are so variable that there will be situations in which one or more of the innovations is not practical or even advisable. Further experimentation and study of these practices will help fine tune and further develop these approaches for their more extensive use in the future. For the time being, however, these approaches are offered simply as innovations worthy of agency consideration.

1. Sharing Information on Agency Approaches

a. Providing a clear explanation of agency decision processes

In all programs studied, the flow charts and processes used 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 diagrammed multiple times in the course of congressional investigations, GAO reviews, and critical

commentary,⁴⁴⁸ the agency's incorporation of science into the assessment process is generally not explicated at the level of detail that is useful for understanding whether all of the best practices and innovations detailed in this study have been followed.

When practicable, agencies should provide an accessible summary of their processes for incorporating science into specific regulatory programs. Such an articulation of these basic processes 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.”⁴⁴⁹ An explication of agency processes should also guide staff and provide those outside the agency with an understanding of how science is being integrated into regulatory decisions.

An agency's explanations should include a description of how the agency conducts its literature search and the availability of those results, the analytical process the agency used to integrate scientific information into its decision-making, the respective role of scientific staff and political management in producing technical documents, the opportunity for robust internal discussions that encourage diverse viewpoints and dissent, the assurance of adequate peer review of agency technical documents, and the articulation of principles at the beginning of the analysis that guide the agency's decisions about how to incorporate the appropriate scientific literature at key points in the process, etc. In situations where the processes are particularly divergent,⁴⁵⁰ the agency should explain why the existing process is on net beneficial to advance the agency's goals.

Agencies should provide the public with an 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.

b. *Highlighting Agency Innovations*

⁴⁴⁸ See, e.g., Center for Progressive Reform, Corrective Lenses for Iris, Sept.2010, available at http://www.progressivereform.org/articles/IRIS_1009.pdf.

⁴⁴⁹ Obama Memorandum, *supra* note 6, at 1.

⁴⁵⁰ 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. 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, some centralized agency, like OSTP or the standing committee of the NAS Science, Technology, and Law should play a leadership role in publicizing 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, this central analyzing body could borrow from ACUS's other best practices project, which spotlights agency innovations, provides short summaries of these innovations, and offers a forum wherein agencies can describe their innovations.⁴⁵¹ 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.

This central analytical body 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 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, a standing NAS Committee, or some other body should take responsibility for identifying and publicizing the innovations developed by agencies for transparently incorporating science into their regulatory decisions.

⁴⁵¹ See ACUS best practices at <http://www.acus.gov/best-practices/>

2. Developing a Set of Best Practices for Science-Intensive Regulation

Through an examination of agency processes, several features continually stand out as a basic staple in the agency’s use of science for regulation; these process features should be considered presumptively required unless there is a reason against their use in a particular regulatory setting. In this subsection, a few process features are identified as “best practices” for science-intensive regulatory decisions. 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 omission), identifying several of these best practices helps draw out and might even fine tune some of these unrecorded procedural details, while attempting to preserve flexibility in how they are followed. Since these best practice principles impose few, if any new requirements, moreover, 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.

Each of these best practices draws its authority from three important, overlapping sources. First, each best practice is linked to the 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. Moreover, each of these best practices is being implemented in all 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.

a. 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, when scientifically appropriate, the relevant 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.⁴⁵² Agencies cannot always satisfy this expectation; but because it is a

⁴⁵² 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 in policy decisions”); Holdren Memorandum, *supra* note 7, 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 2, 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”).

fundamental obligation, agencies should explain when they are unable to provide a list of references used in the analysis or make unpublished studies publicly available.

Accordingly, where agency time and resources permit, agencies should attempt to post not only the bibliography of the literature it utilized in conducting its analysis, 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 where possible provide the public with information on how to request the information directly from 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.⁴⁵³

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.⁴⁵⁴ EPA, DOI, and the NRC generally provide bibliographies for their rulemakings (this feature was not examined in detail at the NRC), although in some cases the public or reviewers will have to go through extra steps to gain access.⁴⁵⁵ Like EPA, the 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.⁴⁵⁶

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,⁴⁵⁷ 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.⁴⁵⁸

⁴⁵³ See *supra* notes 29-30 and accompanying text (discussing these values in basic science).

⁴⁵⁴ See Section III.A.1.a.

⁴⁵⁵ 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*.

⁴⁵⁶ See Section III.A.3.

⁴⁵⁷ See Hall email, *supra* note 220, at 1 (describing this arrangement).

⁴⁵⁸ Interview with FWS Staff Member, Field Office, Feb. 15, 2012.

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.⁴⁵⁹ 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 an exected feature of any rigorous regulatory program. The absence of a reference list or the inaccessibility of references generally will deserve explanation.

In supporting its science-based regulatory decision, an agency should identify and make publicly available a list of the scientific literature it consulted, including even the literature it rejected when it is material to the scientific analysis, 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.

b. Ensuring Some form of 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.⁴⁶⁰ Both the President's directive and the Holdren memorandum on scientific integrity explicitly reference this critical role of expert peer review.⁴⁶¹ OMB's Peer Review Bulletin also underscores the value of expert review to the agency's use of science.⁴⁶²

In the federal government, agencies have at their disposal multiple tools for engaging this expert peer review, both within the agency and using external reviewers. These tools include: a) developing quality control processes, such as technical audits, for

⁴⁵⁹ 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).

⁴⁶⁰ See *supra* notes 29and 43 accompanying text.

⁴⁶¹ See Obama Memorandum, *supra* note 6, 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 7, 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 2, 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).

⁴⁶² See OMB Final Information quality Peer Review Bulletin at 2, 3 (Dec. 2004),

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.⁴⁶³

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.⁴⁶⁴ 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.⁴⁶⁵ Even when pressed by very short statutory deadlines for decisions, the FWS incorporates external peer review into its listing and habitat designation decisions.⁴⁶⁶ And it has persisted with this commitment to external peer review in the face of both congressional and stakeholder opposition.⁴⁶⁷ 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.⁴⁶⁸

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.⁴⁶⁹ 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.⁴⁷⁰ The merits of the agencies' choices will only become clearer once they are identified and explained.

⁴⁶³ See Section III.A.1.a. and A.3, *supra*.

⁴⁶⁴ See 42 U.S.C. § 7409(d)(2).

⁴⁶⁵ While some IRIS risk assessments are likely "influential" under OMB's peer review bulletin, it seems unlikely that all of them are. 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>. Yet EPA engages external peer review in all the IRIS assessments. See Section III.A.1.b., *supra*.

⁴⁶⁶ See Section III.A.2., *supra*.

⁴⁶⁷ *Id.*

⁴⁶⁸ 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.

⁴⁶⁹ See Section III.A.3., *supra*.

⁴⁷⁰ See Section III.A.1.b., *supra*.

Although some form of expert peer review, whether conducted wholly internally or externally, is considered fundamental in the agencies' use of science for important regulatory projects, 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 assessments⁴⁷¹ and scattered congressional mandates that require science advisory board review in narrow regulatory settings,⁴⁷² 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.⁴⁷³

Given the diverse regulatory settings that benefit from peer review, prescriptive requirements for expert peer review should be avoided, at least based on the current knowledge of these processes. Agencies should explain why they select a particular approach to expert review in their decision-making process. But beyond this explanation requirement, at this point the range of practices, uses, and needs for peer review simply defy generalization and hence more specific requirements.

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.⁴⁷⁴ 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, 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, agencies should be encouraged, not impeded, from having their scientific analyses reviewed by other experts, even if this oversight occurs wholly inside the agency. Any limitations on an agency's ability to have scientific work reviewed by scientific experts should be actively discouraged. Additionally and when possible, agencies should endeavor to explain how they ensured the rigorous review of their scientific products for each regulatory project.

⁴⁷¹ See OMB, Peer Review Bulletin, *supra* note 465, at 37-40.

⁴⁷² See *supra* note 463.

⁴⁷³ See National Performance Review, *supra* note 461, at 59 (recommending flexibility in agencies ability to use a variety of different peer review methods for regulatory science).

⁴⁷⁴ See Section IV.A.3., *supra*.

c. 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.”⁴⁷⁵ 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.⁴⁷⁶ 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 the NRC indicated that it utilizes deliberative process privileges only in exceptional cases involving privacy or security.⁴⁷⁷ 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,⁴⁷⁸ 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.⁴⁷⁹ 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

⁴⁷⁵ Obama Memorandum, *supra* note 6, at 1; *see also* Holdren Memorandum, *supra* note 7, at 2 (directing agencies to ensure the “free flow of scientific and technological information” which includes “[o]pen communication among scientists . . . and the public”).

⁴⁷⁶ *See Sections III.A.1.a. and b., supra.*

⁴⁷⁷ Statement of NRC Staff, Feb. 1, 2012.

⁴⁷⁸ *See Section III.A.1.c., supra.*

⁴⁷⁹ 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.⁴⁸⁰ 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.⁴⁸¹

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.⁴⁸² 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.⁴⁸³

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

⁴⁸⁰ Interview with EPA Staff, Office of Pesticide Programs, August 5, 2011.

⁴⁸¹ Interview with FWS Staff Member, Field Office, Feb. 15, 2012.

⁴⁸² Interview with FWS Staff Member, Field Office, Feb. 15, 2012.

⁴⁸³ *Id.*

index.”⁴⁸⁴ If instead OMB is allowed to claim deliberative process for all of 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.”⁴⁸⁵

To effectuate this best practice, agencies should develop written policies and regularized guidelines that instruct agency staff to place all important scientific and technical discussions on the record unless a very narrow set of circumstances is present that justifies an Executive Privilege.⁴⁸⁶ Each significant analytical step, draft, and change in scientific interpretation and analysis 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.⁴⁸⁷ 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

⁴⁸⁴ Center for Biological Diversity v. Office of Management & Budget, 546 F. Supp.2d 722, 729 (N.D. Cal. 2008) (emphasis added).

⁴⁸⁵ *Id.*; see also NRDC v. U.S. DOD, 442 F.Supp.2d 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).

⁴⁸⁶ 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.

⁴⁸⁷ *See Section III.A.2., supra.*

represent the policy or scientific position of the agency. Agencies should 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.

3. Agency Innovations that may develop into Best Practices with Experience

A number of other process innovations were also discovered in the course of the study for how agencies might use science in their regulatory decisions. These innovations are not presented as “best practices” in the report since there is far too much variation among agencies and it is not clear whether these innovations are feasible or even advisable beyond the particular regulatory programs in which they were first discovered. Yet the innovations do provide ideas that agencies may wish to consider in evaluating and reforming their own programs. The innovations may also seed other ideas and approaches that prove even more effective and resilient in the integration of science for policy. Thus the innovations should be considered carefully by agencies in the development of their own programs, but they are not established enough to constitute best practices.

a. *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 scientific evidence.⁴⁸⁸ Administrators can claim that “the science made me do it” when the opposite is 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.⁴⁸⁹

The antidote to these problems is for the agency to identify and explain its various assumptions, judgments, and other choices clearly and accessibly. Even though science and policy are often imperceptibly mixed in how the agency develops a science-based rule, an elaborated analytical process can expose these often important and/or contestable

⁴⁸⁸ See Section I, *supra* (discussing this problem).

⁴⁸⁹ See, e.g., Doremus, *supra* note 5; Holly Doremus, *Scientific and Political Integrity in Environmental Policy*, 86 TEXAS LAW REVIEW 1601 (2008); Peter L. Strauss, *Possible Controls over the Bending of Regulatory Science*, in Anthony, et. al eds., *VALUES IN GLOBAL ADMINISTRATIVE LAW* 126-27 (2011); Wendy Wagner, *The Science Charade in Toxic Risk Regulation*, 95 COLUMBIA L. REV. 1613 (1995); see also OIG MacDonald Report, *supra* note 11.

decisions at each step in the analysis for more vigorous internal and external scrutiny. While none of the analytical steps involve just “science” or just “policy”, by explaining the choices at each step of its process – how the agency articulated the problem; evaluated the literature; applied the literature to the problem at hand with models, etc; and identified the range of options – the messy merging of science and policy will be considerably more transparent and accessible. Indeed, this is precisely what is required by the President’s scientific integrity memorandum.⁴⁹⁰

While the NAAQS process may not have the ultimate solution to this implementation challenge of unpacking the inextricable science-policy weaving through an agency’s decision, the NAAQS process appears to have the best answer presently available within agency decision-making.⁴⁹¹ 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.

These sequential analysis steps are repeated in other areas of health policy. The strongest parallel occurs in clinical medicine, in which health care providers synthesize limited health research, some of which may be affected by significant conflicts of interest.⁴⁹² Like the NAAQS process, clinical researchers first identify specific policy questions to be resolved by the evidence.⁴⁹³ Clinical researchers then assemble the full research bearing on the question and weight it according to basic principles established in advance based on various quality and relevance related factors.⁴⁹⁴ For example, one a priori principle common in literature syntheses in clinical medicine downgrades or even

⁴⁹⁰ 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 7, at 2; *see also* Obama Memorandum, *supra* note 6, at 1 (directing agencies to “make available to the public the scientific or technological findings or conclusions considered or relied on in policy decisions.”).

⁴⁹¹ *See Section III.A.1.a, supra.*

⁴⁹² *See, e.g., DANIEL M. FOX, THE CONVERGENCE OF SCIENCE AND GOVERNANCE 84 (2010)* (noting conflicts of interest problems in clinical medicine); Tracey J. Woodruff & Patrice Sutton, *Pulling Back the Curtain: Improving Reviews in Environmental Health*, 118 ENVTL. HEALTH PERSPECTIVES 326 (2010) (discussing the pervasive conflicts of financial interests in clinical medicine and the need for principles for rating that evidence as part of the analysis in advance).

⁴⁹³ *See Tracey J. Woodruff, Patrice Sutton & The Navigation Guide Work Group, An Evidence-Based Medicine Methodology To Bridge the Gap Between Clinical and Environmental Health Sciences, 30*

HEALTH AFFAIRS 931, 934-35 (2011) (setting out almost identical analytical steps for clinical medicine).

⁴⁹⁴ For a discussion of these advanced principles, see FOX, *supra* note 492, at 88-89; Woodruff, et al., *supra* note 493, Appendix at 5-8.

excludes research produced with a financial conflict of interest. Conversely, another common a priori principle upgrades research when the magnitude of the effect on the test subjects is large or serious.⁴⁹⁵

National Academies of Science reports, as well as a recent consensus report from the Keystone Center, further reinforce the wisdom of this sequential, methods-based approach to synthesizing diverse evidence in a systematic way. In *Science and Judgment*, for example, the Committee emphasizes the importance of these same steps, beginning with a clear statement of the problem and data needs,⁴⁹⁶ establishing a clear statement of default rules and other a priori principles in advance,⁴⁹⁷ and providing a rigorous comparison of alternative models.⁴⁹⁸ The Keystone Center report similarly underscores – even more explicitly -- the importance of conducting a systematic review of the literature in framing the science-policy decision-making effort. The Keystone Center report also catalogues the steps entailed in this systematic review that parallel the first three steps of the NAAQS process.⁴⁹⁹

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.

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,⁵⁰⁰ yet for most rules that must be promulgated on a tight timeframe and small budget, articulating the science-policy questions could be done with relatively little effort in an initial paragraph of an agency’s report.⁵⁰¹ Both the BiPartisan Policy Center and Keystone Center reports also underscore the importance of identifying the basic questions that will be addressed with scientific research as a first step in the integration of science.⁵⁰² Ideally, agencies will also include these key

⁴⁹⁵ *Id.*, Appendix at 6-7.

⁴⁹⁶ NRC, SCIENCE AND JUDGMENT, *supra* note 1, at 144.

⁴⁹⁷ *Id.* at 254-55.

⁴⁹⁸ *Id.* at 186-87. See also *id.* at 257-58 (emphasizing the need for structured steps in an assessment and providing a series of steps that roughly parallel the NAAQS steps).

⁴⁹⁹ See Keystone Center, “Improving the Use of Science in Regulatory Decision-Making: Dealing with Conflict of Interest and Bias in Scientific Advisory Panels, and Improving Systematic Scientific Reviews” 18-25 (September 18, 2012), <http://www.keystone.org/images/keystone-center/spp-documents/Health/Research%20Integrity%20Roundtable%20Report.pdf>.

⁵⁰⁰ *Id.*

⁵⁰¹ 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*.

⁵⁰² See Keystone Center, *supra* note 499, at 20.

- questions in their requests soliciting relevant information from the general 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.
 - a) The first sub-step involves establishing the equivalent of a study design for the literature review, which includes identifying principles in advance for how different types of studies will be weighted.⁵⁰³ The Keystone Center report recommends, for example, that “[c]riteria established for relevance and credibility [and perhaps also for other features] should be developed and made public before the selection of studies to be included.”⁵⁰⁴ All studies should not be weighted equally but assessed against these ex ante criteria.⁵⁰⁵ Research produced under conflicts, for example, may deserve less weight than research produced independent of the sponsor’s influence.⁵⁰⁶ Beyond conflicts, however, a number of ex ante principles could be established, such as how to address gaps in research, whether to upgrade studies if they reveal significant risks, the development of stopping rules, etc.⁵⁰⁷
 - b) The second substep then involves summarizing and interpreting the literature within this study design. This literature assessment 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 phase will not only be a natural step in most cases, but will make the resulting analysis more transparent.⁵⁰⁸
 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)⁵⁰⁹ and then apply these application tools to the scientific evidence described in step 2. An application of the model(s) to the evidence should highlight the policy-relevant choices involved in

⁵⁰³ Lynn Goldman statement in NAS, Improving the Use of Science in the Administrative Process Transcript, Sept. 10, 2012, at 44-46; Tracey Woodruff statement in *id.* at 141-42.

⁵⁰⁴ Keystone Center, *supra* note 499, at 20; Bipartisan Policy Center, *supra* note 2, at 15-16.

⁵⁰⁵ *Id.* at 20 and 22.

⁵⁰⁶ See *supra* note 492 and *infra* Section IV.C.

⁵⁰⁷ See, e.g., Keystone Center, *supra* note 499, at 22-24 (providing examples and elaboration on the criteria to guide the relevance and the credibility assessments. See also Comments of Dr. Lynn Goldman, NAS Meeting, Transcript, *supra* note 503, at 44-45; Woodruff, NAS Meeting, Transcript, *id.*, at 141-42; see also NRC, SCIENCE AND JUDGMENT, *supra* note 1, at 156 (providing examples of how these a priori principles might work in data prioritization and synthesis).

⁵⁰⁸ Interview with EPA Staff, National Center for Environmental Assessment, Jan. 18, 2012; Interview with FWS Staff Member, Field Office, Feb. 15, 2012.

⁵⁰⁹ See Section III.A.1.b., *supra* (describing this feature of FIFRA risk assessment models, which are reviewed by EPA’s SAP).

selecting among plausible models or using multiple models, many of which will be the same as the a priori principles established in the design for the literature synthesis.⁵¹⁰ 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.⁵¹¹

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 choices that need to be resolved by policy considerations, as well as the range of plausible choices, before recommending a preferred course.⁵¹²

In most cases, 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.⁵¹³ The FIFRA and NAAQS programs are also the only programs that consistently articulate specific policy questions that serve to focus the resulting scientific analysis.⁵¹⁴ 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 initial 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, models from clinical medicine, and the more elaborate suggestions in the Keystone Center report for ideas on how this recommendation for a more regularized analytical process might be accomplished within their unique programs.⁵¹⁵

⁵¹⁰ Goldman, NAS Meeting, Transcript, *supra* note 503, at 45.

⁵¹¹ See NAS FORMALDEHYDE REPORT, *supra* note 1, at chapter 7.

⁵¹² 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*.

⁵¹³ See Sections III.A.1.a. and b., *supra*.

⁵¹⁴ *Id.*

⁵¹⁵ See Section III.A.1.a., *supra* (discussing these policy assessments and giving links to some recent policy assessments).

All significant science-policy choices made by an agency in reaching a decision should be identified and explained in clear and understandable terms. In order to provide this heightened level of transparency, agencies should consider following an analytical process that: a) identifies the policy-relevant questions that can be informed by science; b) identifies in advance a study design, such as criteria for weighting individual studies, as well as identifying other a priori analytical choices, like stopping rules; c) provides a synthesis of the available evidence and relevant literature guided by this study design; and d) identify other significant assumptions, choices of analytical techniques, and remaining uncertainties and how different plausible choices might change the resulting policy decision. If possible, the agency should also follow the model of the NAAQS policy assessment in bridging science and policy in a final report, although this final step will likely involve more effort and experimentation.

Making these analytical steps explicit may not be practicable in some science-policy decisions and may not be practicable in other regulatory settings. This recommendation simply encourages agencies to consider this staged approach in their processes. Ultimately, with experience, this analytical approach may develop into a best practice. Until then, agencies are strongly encouraged to consider this analytical approach in conducting their work.

b. *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.”⁵¹⁶ 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. A “stopping rule” does not put an end to research or to the accumulation of new information by regulators; it merely sets the point at which a policy decision will be reached in the interim. The resulting regulatory decision will be revisited with new evidence at some future date, often established in the stopping rule itself.

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

⁵¹⁶ The concept of stopping rules were introduced into the social studies of science literature by Sheila Jasanoff. See *supra* notes 45-46 and accompanying text for a discussion of stopping rules.

project back to the starting point, requiring the agency to conduct a re-analysis, reopen the comment period, etc. Second, the agency may occasionally find it necessary to close debate, even when important scientific issues have not been resolved. In this second setting, it is unresolvable disagreements between experts rather than the emergence of new evidence that prevents closure on an issue. Rather than suspending the regulatory project in the hope that the experts will reach some agreement, a decision that the agency must proceed despite these disagreements – the equivalent of a stopping rule – may be necessary to move the project forward.

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.⁵¹⁷ 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 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.⁵¹⁸ 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.⁵¹⁹ In pesticide registration reviews, by contrast, new science is considered up to the point of the proposed decision.⁵²⁰ The pesticide registration review process is new enough that there is not a lot of experience to determine whether

⁵¹⁷ 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.

⁵¹⁸ 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.

⁵¹⁹ Interview with EPA Staff, National Center for Environmental Assessment, Jan. 18, 2012.

⁵²⁰ Interview with EPA Staff, Office of Pesticide Programs, Jan. 27, 2012;

earlier stopping rules are needed and whether this more open-ended approach could create the possibility of extended delays.⁵²¹ A best practice would suggest that agencies establish their stopping rules for emerging science *ex ante* – 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 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.⁵²² 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.⁵²³

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 transparency problem in EPA's pesticide program to be the agency's insufficient and unjustified dismissal of some of their comments.⁵²⁴ 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.⁵²⁵ Again, part of 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.⁵²⁶

⁵²¹ *Id.*

⁵²² 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).

⁵²³ *Id.*

⁵²⁴ See Section III.A.1.b, *supra*.

⁵²⁵ Interview with EPA Staff, National Center for Environmental Assessment, Feb. 3, 2012.

⁵²⁶ 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

In an effort to significantly increase the transparency and productivity of their regulatory work, agencies should endeavor to establish clear stopping rules for technically complicated regulatory decisions at the beginning of the regulatory project that guides it. This exercise is particularly when the agency operates without judicially enforceable statutory deadlines.⁵²⁷ While agencies may deviate from these *ex ante* goals as the regulatory process unfolds, they will be expected to explain their deviations as against this initial goal.

With some explication of stopping rules, agencies should thus be clear in their decision-making 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.⁵²⁸ 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,⁵²⁹ it appears that the CASAC’s closure role continues today.⁵³⁰ 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

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 152, at Appendix III (identifying the important role that OMB has played in some IRIS assessments).

⁵²⁷ 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.

⁵²⁸ *See* Section III.A.1.a., *supra*.

⁵²⁹ 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.

⁵³⁰ Interview with EPA Staff, Office of Air Quality Planning and Standards, Jan. 17, 2012. See Section III.A.1.a., *supra*.

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.⁵³¹ 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.

Like the right to dissent and the importance of authorship, the concept of stopping rules is new enough that agencies should be urged to set these rules, but they do not yet rise to the level of a best practice. Over time, the use of stopping rules may be capable of being routinized across agencies and regulatory missions, but we are not at that point yet.

In regulatory settings, particularly in cases when agencies are not bound by judicially enforceable deadlines, the agencies should be encouraged to establish explicit stopping rules on regulatory projects, both with regard to when they will close their consideration of emerging research and when they will close otherwise unresolvable scientific debate in order to reach a decision. External peer review bodies may be particularly useful to agencies in establishing scientifically credible points at which debate should cease.

c. Checkpoints that Identify Future Research Needs

Working in tandem with “stopping rules” are research “checkpoints,” which consist of a list of specific research projects that should be conducted in the near term to advance regulatory understanding on a particular issue.⁵³² The NAAQS Policy Assessment, for example, provides this type of explication of future research questions in need of study.⁵³³ These checkpoints would ideally be identified by an agency when the record closes (as set by the stopping rules). Without adding this explicit “research checkpoint,” there is a risk that the most important gaps in regulatory understanding will be lost or forgotten after the rule is promulgated and the agency turns to other issues and problems.

⁵³¹ Interview with EPA Staff, National Center for Environmental Assessment, Feb. 3, 2012. *See also* Section III.A.1.b., *supra*.

⁵³² Dr. Louis coined this term, See NAS Meeting Transcript, *supra* note 503, at 148-49, but as it developed through discussions, the idea of checkpoints became primarily focused on future research needs.

⁵³³ *See supra* note 71 and accompanying text.

For science-intensive rules, an agency should identify specific types of future research projects that will advance understanding on the regulatory issue. This identification of research questions and priorities should influence the agency’s research agenda as well as provide a benchmark for measuring regulatory progress. While agencies may need to experiment with when and how they incorporate “research checkpoints” into their regulatory analysis, the most fruitful time may occur at the point the record is closed, as determined by stopping rules.

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

Agency managers should consider and, where possible, capitalize on the scientific and organizational benefits of affording authorship credits or at least attribution to staff scientists, particularly for assessments of the relevant scientific literature that precede rule proposals. Providing authorship or at least attribution to the agency staff who prepare a technical analysis provides a means of accountability and well-deserved credit to government scientists.⁵³⁴ 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.⁵³⁵ In some regulatory settings, these authorship credits are not beneficial to the agency’s work or to the staff careers. For this reason, managers should seriously consider providing some form of authorship credit, but are not expected to justify when authorship proves undesirable or impracticable.

Authorship provides important benefits to regulatory science. In interviews, 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.⁵³⁶ Authorship also serves to afford agency staff a stake in the final product, thus sharpening

⁵³⁴ Within science, authorship is fundamental to ensuring transparency, integrity, and accountability. Journals place significant weight on this authorship. See *supra* note 32 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 7, 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 6, at 1 (directing agencies to develop retention policies that attract talented scientists).

⁵³⁵ *Id.*

⁵³⁶ 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

debate, internal scrutiny, and the quality of the final product within the agency.⁵³⁷ At the same time, these agency managers cautioned that since the reports were 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).⁵³⁸ 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.⁵³⁹ 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.⁵⁴⁰ 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.⁵⁴¹ They can also, at least informally (see below), prepare a dissent for the report and the public record.⁵⁴²

To the extent that management – either political, career, or both – are involved in authorship or in the review of the report and afforded an opportunity to make changes, this fact should be noted in the document as well. Under this approach, technical reports would contain indicia of authorship, a list of reviewers and their roles, and would thus provide full disclosure of the role of all contributors, much as a disclosure of conflicts and sponsorship provides in published articles in scientific journals. This disclosure of authorship is a standard prerequisite for publication in most scientific journals;⁵⁴³ in the abstract, then, it seems like an appropriate expectation for scientific analyses conducted by agencies.

In contrast to the EPA, 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

⁵³⁷ 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.

⁵³⁸ Interview with EPA Staff, National Center for Environmental Assessment, Office of Research and Development, Feb. 3, 2012

⁵³⁹ *Id.*

⁵⁴⁰ *Id.*

⁵⁴¹ *Id.*

⁵⁴² Interview with EPA Staff, Office of Pesticide Programs, August 5, 2011.

⁵⁴³ See, e.g., Authorship Standards for ICMJE (biomedical journals), at http://www.icmje.org/ethical_1author.html

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.⁵⁴⁴ 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.⁵⁴⁵ 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. For that reason, authorship and attribution is presented in this report as an innovation that deserves consideration by agencies but does not rise to the level of a standard, best practice at this point in its development.

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.⁵⁴⁶ In at least one very well-documented occasion 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 political management.⁵⁴⁷ 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.⁵⁴⁸ Though it is merely one example, this experience suggests that science-

⁵⁴⁴ Interview with FWS Staff, Endangered Species Program, Jan. 9, 2012.

⁵⁴⁵ Id.; Interview with FWS Staff Member, Field Office, Feb. 15, 2012. In the abstract, 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 represent the views of the agency, even after it has been internally peer reviewed by other agency staff. See Section III.A.1.a., *supra* (discussing how the NAAQS analyses contain this disclaimer).

⁵⁴⁶ 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.

⁵⁴⁷ See Section III.A.1.a. (discussing this example in more detail).

⁵⁴⁸ *Id.*

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.⁵⁴⁹

To the extent possible, agency analyses should track the principles and norms of science and scientific and technical assessments conducted by the agency should confer consensus-type authorship rights on the staff who prepares them. At the same time, the agency should identify as authors all of those who contributed in a significant way to a scientific report, including staff attorneys and economists if they in fact contributed to the final product. Although the concept of explicit authorship and acknowledgement is still too preliminary to rise to the level of a best practice, it is an innovation that is grounded in the norms of science and should be carefully considered by all of the agencies engaged in science-intensive regulation.

Agency staff plays an important role in producing the agency's analyses. When practicable and appropriate, agency managers should consider providing staff with some form of consensual authorship right or attribution for reports or analyses to which they contribute in a significant way. All staff authors who contributed in a significant way to a technical or scientific report should be acknowledged, including economists, lawyers, and other nonscientists. In a similar vein, reviewers and other contributors should also be identified by name and general contribution.

e. *The Right to Dissent*

Agencies should also develop policies to ensure that they encourage vigorous and diverse debate among agency scientists.⁵⁵⁰ 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.”⁵⁵¹ 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.⁵⁵²

⁵⁴⁹ *Id.*; Interview with EPA Staff, Office of Air Quality Planning and Standards, Jan. 17, 2012.

⁵⁵⁰ See, e.g., Obama Memorandum, *supra* note 6, 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 7, 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.”).

⁵⁵¹ 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).

⁵⁵² See *supra* notes 29 and accompanying text (underscoring the central role that vigorous scrutiny by diverse peers plays in science).

The NRC's open and collaborative workplace policy offers the most comprehensive approach to address this challenge.⁵⁵³ 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.⁵⁵⁴ 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.⁵⁵⁵ On the other hand, surveys of job satisfaction at the NRC are generally quite high.⁵⁵⁶

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.⁵⁵⁷ There was at least one example of this practice in the FWS and in the EPA pesticide program.⁵⁵⁸ The EPA and FWS also purport to nurture diverse, open, robust debate among scientists.⁵⁵⁹ The FWS in particular suggests that this open and vigorous give-and-take between management and staff defines the scientific culture of the Service.⁵⁶⁰ 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.⁵⁶¹

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

⁵⁵³ See Section III.B.2., *supra*.

⁵⁵⁴ *See id.*

⁵⁵⁵ *See id.*

⁵⁵⁶ 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-uJG8PO2wXZzoXmAg&usg=AFQjCNFvL50u5xPjLXdopYqMhYwMc16WEw&sig2=JGIpo7HZhdEmEJuEdH3BEA> (reporting on this high job satisfaction report).

⁵⁵⁷ Interview with FWS Staff, Endangered Species Program, Jan. 26, 2012; Interview with EPA Staff, Office of Pesticide Programs, August 5, 2011.

⁵⁵⁸ *Id.*

⁵⁵⁹ 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.

⁵⁶⁰ Interview with FWS Staff, Endangered Species Program, Jan. 9, 2012; *see also* Hall memo, *supra* note 204.

⁵⁶¹ Interview with FWS Staff, Endangered Species Program, Jan. 26, 2012.

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.⁵⁶²

However it is accomplished, agency managers should ensure that agency staff can engage in vigorous debates that include diverse points of view, and where possible provide for the opportunity for dissent from a technical analysis or finding. 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 prohibits retaliation against dissenters would seem to be helpful to encourage vigorous debate and provide enhanced scientific autonomy for agency staff.⁵⁶³ Managers should defer to dissenters' requests to place dissents in the public record whenever possible. To ensure some peer review of these dissenting positions, dissenting employees should also be allowed and encouraged to publish their views in the peer reviewed literature. This right to dissent is particularly important when agencies do not provide authorship or contribution rights to scientists, and thus scientists 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.⁵⁶⁴

Much like attribution and authorship, the role of dissent and the approaches to encouraging diverse, rigorous debate among agency scientists are only beginning to be explored. It is thus premature to suggest that the right to dissent from a technical analysis should be regarded as a best practice that deserves some explanation when it is not followed. On the other hand, the importance of scientific autonomy and inviting diverse scientific views is vital to rigorous scientific work;⁵⁶⁵ thus agency managers should feel obliged to ensure that their processes provide for this type of debate and free exchange.

Agencies should encourage vigorous debate among agency scientists that may include developing written policies that allow agency staff to dissent

⁵⁶² See Section IV.B.5., *infra* (discussing best practices for the development of administrative records).

⁵⁶³ 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.

⁵⁶⁴ 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.

⁵⁶⁵ *See supra* Section I.B.4.

or express their non-concurrence on a technical analysis to which they contributed. In cases where written dissents are permitted, agency managers should take seriously a staff member's request to place a dissent or non-concurrence into the public record. Dissenting employees should also be allowed and encouraged to publish these dissenting positions in the peer reviewed literature, provided that confidential governmental deliberations are not compromised. In all cases and regardless of the public availability of these discussions, dissenting staff members should be protected from reprisals.

B. Interagency and External Constraints on Agencies that might impair the Rigorous and Transparent Incorporation of Science into Regulation

Various external constraints impede the ability of the agencies to “be transparent[t] in the preparation, identification, and use of scientific and technological information in policymaking.”⁵⁶⁶ Although this study focused only on five programs in 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.

The first set of constraints arises from a variety of congressional and executive branch limits to agency decision-making processes themselves, such as precluding disclosures or capping the number of science advisory boards an agency can empanel. The second set of constraints involves White House oversight of science-intensive rules that pose challenges for ensuring both the transparency and integrity of the use of science. This section discusses these challenges and suggests potential reforms.

1. 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 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

⁵⁶⁶ Obama Memorandum, *supra* note 6.

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.⁵⁶⁷ Recall that the FWS is required by statute to make a listing decision within a little over a year after receiving a petition.⁵⁶⁸ 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.⁵⁶⁹ 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.⁵⁷⁰ Even the development of complete administrative records supporting listing decisions may be compromised as a result of the whirlwind timeframe that governs these decisions.⁵⁷¹

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.⁵⁷² 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.⁵⁷³ 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.⁵⁷⁴ EPA summarizes each of these studies in data tables, but there is effectively no external oversight over this internal review of manufacturer data.⁵⁷⁵

In the programs examined in this study, the Paperwork Reduction Act (PRA) and Data Quality Act (DQA) were also implicated in imposing additional statutory

⁵⁶⁷ See Section III.A.2.

⁵⁶⁸ *See id.*

⁵⁶⁹ 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.

⁵⁷⁰ *See id.*

⁵⁷¹ *See id.*

⁵⁷² 7 U.S.C. § 136h(g)(1). *See Section III.A.1.b.*

⁵⁷³ *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).

⁵⁷⁴ 7 U.S.C. § 136a(c)(2)(A). There are some exceptions, *id.* at 136h(d), but they appear to be unusual.

⁵⁷⁵ *See Section III.A.1.b.*

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.⁵⁷⁶ 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.⁵⁷⁷ 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,⁵⁷⁸ and 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.⁵⁷⁹

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.⁵⁸⁰ 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.⁵⁸¹ 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.⁵⁸² Although estimates of the costs of EPA's programs were not available,⁵⁸³ informal 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.⁵⁸⁴ 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.

⁵⁷⁶ See *id.*

⁵⁷⁷ Interview with EPA Staff, Office of Pesticide Programs, August 5, 2011.

⁵⁷⁸ 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).

⁵⁷⁹ See, e.g., GAO, CHEMICAL ASSESSMENTS, *supra* note 152, at 24-26.

⁵⁸⁰ Interview with FWS Staff, Endangered Species Program, Jan. 9, 2012.

⁵⁸¹ *Id.*

⁵⁸² See OIG, License Renewal Report, *supra* note 273, at 4.

⁵⁸³ Estimates of the costs for the review of pesticide registrations may be available and the author is still tracking that figure down.

⁵⁸⁴ Interview with EPA Staff, Office of Air Quality Planning and Standards, Jan. 17, 2012.

Constraints arising purely within the Executive Branch further obstruct the agencies' effort to develop robust processes for their use of science. For example, to the extent that important non-written conversations between OMB and the agency lead to changes in science-based rules during OMB review under Executive Order 12866, these communications are non-divulged or explained as they are at other stages in the process; at best one must speculate at why various changes were made to an agency rule before publication. 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.⁵⁸⁵ 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.⁵⁸⁶ EPA officials in particular lament that the FACA limitations, such as the arbitrary cap on the total number of discretionary advisory committees an agency may host, render it difficult to use advisory committees 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.⁵⁸⁷ Caps on discretionary FACA committees, however, cause agencies to abandon efforts to convene advisory committees in favor of employing independent reviewers. The use of individual peer reviewers who are not able to confer, in turn, may serve exacerbate the already unwieldy and even conflicting comments that the agency must address, yet this time coming from external experts.⁵⁸⁸

There are statutory and regulatory constraints that limit the ability of the agencies to ensure that their decisions are scientifically robust and transparent in keeping with the President's Directive. The 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 and OSTP or other centralized agencies can take responsibility for collecting information and proposing government-wide recommendations.

⁵⁸⁵ 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>.

⁵⁸⁶ 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.

⁵⁸⁷ Interview with EPA Staff, National Center for Environmental Assessment, Office of Research and Development, Feb. 3, 2012.

⁵⁸⁸ *Id.*

2. Review by OIRA and Other White House Offices and Agencies

Evidence reveals that OIRA review can lead to material changes to science-based rules that are not always disclosed consistent with the directives of Section 6(a)(3)(E) of Executive Order 12866. A process that allows potentially significant changes to be made to science-based rules without public or expert review heightens the risk that some of these changes will be made in ways that conflict with public understanding and the scientific record.⁵⁸⁹ At the very least, substantive changes that are made to important science-based rules at the suggestion of OIRA should be clearly identified in the public record and some justification should be provided for each change for the public, consistent with the letter and spirit of Executive Order 12866 and President Obama’s memorandum on transparency. This section offers recommendations to improve the rigor and transparency of the decision-making process for science-intensive rules, from the beginning to the end of the regulatory action.

Before proceeding, it is important to remind the reader that the arguments in this report are concerned only with changes made by White House offices to technical or scientific features of a regulation. Deliberations between agencies and White House offices over the appropriate choice of political values, issues of statutory or other legal interpretations, and economic and social considerations are beyond the scope of this analysis except in cases that they impact on the agencies’ use or characterization of technical or scientific information.

a. Improving the Transparency of OIRA Review

There is a solid body of evidence that OIRA review can lead to material changes to scientific or highly technical features of some proposed and final rules, but these changes are neither explained nor even disclosed.⁵⁹⁰ Indeed, this lack of transparency of OMB review seems particularly inappropriate for standards like NAAQS that are subjected to repeated rigorous peer and public review during their development, but then are negotiated out of the public eye once the rules undergo review by OMB. The

⁵⁸⁹ See, e.g., House Report.

⁵⁹⁰ See, e.g., Section III.A.1.a., *supra*; see generally Mendelson, *supra* note 76, 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); Majority Staff, Nipping IRIS In the Bud, *supra* note 359, at 1 (detailing the extensive secrecy that surrounds OIRA review, even with respect to Congress’ effort to understand OIRA’s role in programs like IRIS); 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 (Nov. 2011), available at 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); see also GAO 2003, *supra* note 307, at 100 (“Overall, we often found it difficult to identify the changes that had been made to agencies’ rules during OIRA’s review and/or at the suggestion or recommendation of OIRA by reviewing material in the agencies’ rulemaking dockets”).

NAAQS rules examined here are not the only example of science-intensive rules that have been subjected to undisclosed changes at the suggestion of OIRA, however.⁵⁹¹ In the IRIS program, which actually falls outside the reach of Executive Order 12866 review since it does not produce a final regulation,⁵⁹² there is still no accounting for all of the changes that have been made to IRIS profiles as a result of OMB's and other interagency suggestions since significant discussions still occur by phone or through meetings which are withheld as deliberative process.⁵⁹³

⁵⁹¹ 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 EPA’s regulatory projects. 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. One EPA staff member suggested that many of OMB’s comments were actually useful in tightening the scientific analysis for IRIS assessments, but they were often not material enough to justify the extended delay and added transaction costs. The EPA scientist noted that because OMB formerly had final clearance authority over the draft assessment, the agency was at its mercy; OMB typically requires the agency to make every change it suggested, whether major or minor before it will clear the draft or final IRIS assessment for publication. 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.*

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, but in ways that are not subjected to rigorous public or expert oversight. *See, e.g.*, GAO, Chemical Assessments, *supra* note 152, at Appendix III (discussing OMB’s role in several EPA IRIS assessments); Kitrosser, *supra* note 590, at 2407 (discussing OMB’s potentially negative role in compromising scientific integrity of publicly provided information in the BP oil spill); Mendelson, *supra* note 76, 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); 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 (Nov. 2011); 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 76.

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.” 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).

⁵⁹² The IRIS program does not result in published binding standards and thus is not a “regulatory action” as defined by Executive Order 12866, yet OMB has appeared to play a significant role in the development of these standards over the last few decades. See *supra* Section III.A.2.; Majority Staff, Nipping IRIS In the Bud, *supra* note 359, at 1.

⁵⁹³ 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. For a few profiles, EPA’s responses to “selected major interagency” are available for at least the first round of interagency review. See EPA’s Response to Selected Major Interagency Comments on the Interagency Science Consultation

Fortunately, existing requirements already anticipate and seek to prevent at least some of these lapses in transparency; the recommendations offered here simply call upon the agencies to come into full compliance with these existing requirements. Recall that Executive Order 12866 requires agencies to provide a record of the substantive changes made during OIRA’s review,⁵⁹⁴ and OMB’s own peer review bulletin requires significant science-based decisions to undergo peer review.⁵⁹⁵ Yet currently the agencies and OMB are not in full compliance with many and in some cases all of these requirements of Section 6 of the Executive Order. As discussed in the next section, OMB may also not be in compliance with its own Peer Review Bulletin.

The most important noncompliance with Section 6 occurs within the agencies. For at least the rules included in this study, there was no meaningful compliance by the agencies with the requirements of Section 6(a)(3)(E)(iii).⁵⁹⁶ Specifically, there was no documentation or attribution of the “changes made at the suggestion or recommendation of OMB”, or at least the documentation was not discovered after a relatively time-intensive search of the rulemaking dockets. Even agency compliance with Section 6(a)(3)(E)(ii), which requires “complete, clear, and simple” documentation of “the substantive changes between the draft submitted to OIRA for review and the action subsequently announced” was incomplete; red-lined documents that highlight changes made during the formal review were available only for two-thirds of the rules and a 2009 GAO study reports even lower compliance rates across a larger number of agencies.⁵⁹⁷ Moreover, in no case was any of this documentation required by these subsections easy to locate or provided in “plain understandable language” as required by Section 6(a)(3)(F) and 6(b)(5).

To ensure agency compliance with Executive Order Section 6(a) in the future, the agencies should produce a memorandum or similar document that outlines, in plain, understandable language, all of the major, substantive changes made as a result of OIRA’s review.⁵⁹⁸ While agencies tend to produce red-lined documents to satisfy this

Draft IRIS Toxicological Review of 1,4-Dioxane (inhalation exposure route only), September 15, 2011, available at http://cfpub.epa.gov/ncea/iris_drafts/recordisplay.cfm?deid=237251. A similar document does not appear to be available for the second round of interagency review. See, e.g., the list of documents posted for the interagency discussion for the same profile, available at

http://cfpub.epa.gov/ncea/iris_drafts/recordisplay.cfm?deid=122848

⁵⁹⁴ Section 6(a)(3)(E)(ii).

⁵⁹⁵ OMB, Peer Review Bulletin, *supra* note 465.

⁵⁹⁶ See *supra* Section III.A.4.a.; see also GAO 2003, *supra* note 307, at 101 (reaching a similar conclusion).

⁵⁹⁷ See *id.* at 13

⁵⁹⁸ See also GAO 2009, *supra* note 316, at 35 (recommending that the transparency requirements should be applied to the “informal review period when OIRA says it can have its most important impact on agencies’ rules”); Mendelson, *supra* note 76, 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

requirement, additional, more accessible identification of all major, substantive changes is needed as well. Although there were no “best practice” models of this type of documentation arising in this study, there are possible best practices models for (E)(ii) disclosure in other agency programs.⁵⁹⁹ Samples of more complete documentation are provided in Appendix I. In these samples, the agencies provide a red-lined version of all changes made during OIRA review, but supplement it with a cover memorandum that identifies all of the major changes to the preamble and rule in a clear, understandable form. While this disclosure appears to provide an identification of only the changes occurring during OIRA’s formal review, the same memorandum format could be used for changes made outside of the formal window as well.

Moreover, to make both documents practically accessible to the public (rather than theoretically available), the agency should post them in a centralized website dedicated to documenting all major changes made at the suggestion of OIRA throughout the rulemaking and documenting all substantive changes occurring during formal OIRA review, regardless of the source of the change.⁶⁰⁰ Where possible and in keeping with some current agency practices, the agency’s docket should also contain all significant, substantive documents exchanged between the agency and OMB. This documentation ideally will provide the public with a means to ensure that the agency has in fact complied with the requirements of Section 6(a)(3)(E) in its identification of changes and other disclosures. This document repository should also be cataloged as its own, separate category of documents in the regulations.gov classification of documents. That category would separate out those documents relevant to OMB review and allow, with one click, for OMB-agency documents to be searched and extracted from a larger public docket.

The agencies should also extend these transparency requirements to other significant, science-intensive agency support projects, such as IRIS profiles and science-intensive guidances and policy documents, as well as the reports and studies that inform these projects and other rulemakings. The literature suggests that agencies may already be inclined to avoid informal rulemakings to avoid formal notice and comment requirements and ultimately the threat of judicial review.⁶⁰¹ To redress the substantially

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.”).

⁵⁹⁹ See, e.g., GAO, 2003, *supra* note 307, at 101 (discussing EPA’s Office of Water documentation of the changes arising in OIRA review, which appear much more extensive than the documentation encountered in this study); see also GAO 2009, at 36 (providing a similar recommendation – see recommendation #7). EPA initiated such a site, although it is not clear if it is regularly updated and it does not provide all of the information suggested in this report, even for the rules that appear relatively up-to-date. See <http://yosemite.epa.gov/opei/RuleGate.nsf/>.

⁶⁰⁰ GAO has made a similar recommendation. See GAO 2009, *supra* note 316, at 36 (recommendation #6).

⁶⁰¹ See, e.g., Jerry L. Mashaw & David L. Harfst, *Regulation and Legal Culture: The Case of Motor Vehicle Safety*, 4 YALE J. ON REG. 257, 273-74 (1987) (discussing how judicial review has caused NHTSA to avoid rulemaking in favor of recalls); Peter H. Schuck, *When the Exception Becomes the Rule: Regulatory Equity and the Formulation of Energy Policy Through an Exceptions Process*, 1984 DUKE L.J. 163, 165-68, 194-98 (discussing how the procedural obstacles posed primarily by judicial review and

reduced transparency requirements governing agency decision-making in these alternative forms of regulatory requirements, the default rule should be that these same transparency requirements of Section 6 – namely at least the identification of all major changes made at the suggestion of OIRA -- apply to all significant regulatory projects, regardless of whether the agency product is an informal rule or some other type of regulatory product, like an IRIS profile, or supporting study or analysis. Agencies should also comply with the Section 6 requirements for rules that have been withdrawn from OIRA review or where OIRA encouraged agencies not to submit rules in the first place.⁶⁰²

Finally, since there is evidence of noncompliance with the requirements of Executive Order 6 by the agencies, some centralized mechanism of tracking compliance and sanctioning noncompliance should be instituted. Ideally, agencies should maintain a separate webpage dedicated to Section 6(a) compliance for their rules; the webpage would identify for each proposed and final rule the “substantive changes” made during OIRA review as well as the major “changes made at the suggestion or recommendation of OIRA” at any point in the regulatory process in publicly accessible ways. Alternatively, agencies should at least routinize their documentation so that these documents are easier to locate and understand within individual rulemaking dockets.

It is important to note that the GAO identified these same lapses in compliance with the Executive Order in two separate reports, and yet its detailed recommendations – directed exclusively at OMB – have been largely ignored.⁶⁰³ Although the recommendations offered for enhancing Section 6(a)(3)(E) compliance in this report largely parallel these GAO recommendations, they are different in one important respect; the recommendations here are directed primarily at the agencies, rather than OMB. It is the agencies that are the responsible parties under Executive Order 12866 for documenting the changes made at the suggestion of OIRA and occurring during OIRA review.⁶⁰⁴ This structure, by design, places the agencies in the central role of disclosing the effects of OIRA review rather than placing that responsibility on OIRA, which is presumably more conflicted in documenting its own influence, although the agencies may be somewhat conflicted themselves.⁶⁰⁵ OMB’s failure to coordinate, oversee, or counsel

executive order led the Department of Energy to abandon policymaking through rulemaking in favor of policymaking through individual adjudications by an office authorized to make special exceptions to existing rules).

⁶⁰² GAO makes a nearly identical suggestion. *See* GAO 2009, *supra* note 316, at 36 (recommendation #4).

⁶⁰³ In its first report in 2003, GAO made eight separate recommendations to improve compliance, all of which were directed at OMB as the coordinator of the Executive Order. As of 2009, only one of the recommendations had been adopted by OMB and in 2013, it appears that the seven (most of which parallel the recommendations here) were still unaddressed. *Id.* at 35 and 39.

⁶⁰⁴ See Sections 2(a) and 6(a) of Executive Order 12866.

⁶⁰⁵ OMB not only reviews and coordinates the agencies’ budget requests, but it is a direct arm of the White House and thus exerts an authoritative institutional presence. OMB is thus likely to command considerable respect from the agencies.

agencies on their compliance obligations under Section 6(a) – particularly when repeatedly confronted with a series of specific recommendations that it provide this leadership by GAO – reinforces the import of ensuring that agencies follow through on their Section 6 responsibilities.

Under Section 2(a) and 6(a) of Executive Order 12866, the agencies are responsible for interpreting and complying with Section 6(a). The agencies' compliance under Section 6(a) should include at the very least:

- 1) documentation of the major changes made at the suggestion or recommendation of OIRA at any point in the lifecycle of the regulation as required by Section 6(a)(3)(E)(iii) and 6(a)(3)(F). If there are no major changes, then the agency should provide a statement to that effect;**
- 2) an identification of all substantive changes made between the draft submitted to OIRA for review and the action subsequently announced in compliance with Section 6(a)(3)(F)(ii). This includes but is not limited to a red-lined version of the document undergoing OIRA review;**
- 3) for both #1 and 2, the agencies should provide a “complete, clear, and simple” identification and explanation of each major change in “plain, understandable language” for the public. Explication of these major changes should be accessible to the public – through for example a cover memorandum --- and not buried in hundreds of pages of red-lined documents. Although the Executive Order technically requires this accessible explication of all changes (and not simply the major changes) made at the suggestion of OIRA, a disclosure of the major changes is considerably less burdensome and appears consistent with the thrust of the Executive Order;**
- 4) a library of all significant, substantive documents exchanged between OIRA and the agency throughout the life cycle of the regulatory action to ensure that the agency is in full compliance with Section 6(a)(3)(E)(ii) and (iii).**
- 5) centralized public access to the information specified above to ensure practical, as opposed to merely theoretical, compliance with the general requirements of Section 6(a)(3)(E) and (F). Both reginfo.gov and regulations.gov should link to or provide the public with document libraries that enable simple access to and searching of documents required under Section 6.**

Agencies should apply these same requirements of Section 6(a)(3)(E), as interpreted above, to all significant science-intensive regulatory actions, including agency guidances and other standards and policies, whether or not they are published in the Federal Register, as well as to all significant, supporting studies and projects that inform science-intensive agency rules, guidances, policies and related products. The requirements should also apply to all rules that are withdrawn, whether ORIA has reviewed them or not.

b. Ensuring the Transparency and Scientific Integrity of Influence in Science-intensive rules from White House Offices, beyond OMB, and Other Agencies

Executive Order 12866 and the OMB Peer Review Bulletin ensure increased transparency and scientific integrity for OIRA review, but they do not apply to the other White House offices or to suggestions made by other agencies. To the extent that some changes to science-intensive rules are made at the behest of these other offices, such as the Office of the President, CEQ, or OSTP or other agencies, there appears to be no requirements to ensure that the changes are disclosed, justified or reviewed.⁶⁰⁶ Additionally, as OMB’s influence in science-intensive rules is documented more completely under Section 6 of Executive Order 12866, the resulting heightened transparency surrounding OMB review may simply cause these other offices and agencies to play an even greater behind-the-scenes role in editing high stakes agency rulemakings. When rules are highly technical and complex, it is important to ensure the rules are subjected to vigorous public and scientific oversight, up until their final promulgation. This is not possible if changes can be inserted without disclosure and at the eleventh hour.

While further analysis and research is needed to determine how best to strike the balance between the President’s need for deliberative processes versus the benefits of transparency of material changes to science-intensive rules, in the interim the agencies should disclose changes made at the suggestion of White House offices and other agencies if doing so does not undermine the deliberative process. In some and perhaps many cases substantive changes are made and whose public recognition would not threaten deliberative processes and that would benefit from disclosure and heightened public and scientific review. The agencies should work closely with White House offices and other agencies to ensure that when changes are made that can be disclosed, they are catalogued as well in keeping with the direction and spirit of Section 6.

Beyond extending Section 6(a)(3)(E)(iii) disclosures to some of the other changes made at the suggestion or recommendation of White House offices and other agencies, the other recommendations produced in this report may help mitigate some risks of nontransparent changes of science-intensive rules. For example, adopting the NAAQS analytic process discussed earlier will at least draw out the ways that science informed the rule through the course of its development, which in turn make the identification of last minute changes easier to locate in a voluminous record. Additionally, ensuring that the agency’s assessments of the literature provide attribution to agency staff provides these authors with some stake in ensuring the reports and accompanying literature is not misrepresented later in the process. And a dissent policy, if framed broadly enough, can

⁶⁰⁶ This may be problematic to the extent there are allegations of “politicization of science” stemming from the White House. See generally Percival, *supra* note 355 (describing more recent incidences, which include some politicization of science); OIG MacDonald Report, *supra* note 11.

allow staff to take issue with changes to rules that diverge from the scientific evidence developed during rulemaking process. While none of these reforms are magic bullets for this broader problem of the politicization of science, they are at least steps in the right direction.

The agency should disclose material changes made at the suggestion or recommendation of White House offices or other agencies, consistent with Section 6(a)(3)(E)(iii), when doing so does not impair the deliberative processes.

C. Enhancing the Transparency of Research produced by Regulated Parties

Agencies often rely on research produced by private parties in reaching science-intensive regulatory decisions, yet there is considerable evidence that this sponsor-produced research can be permeated with various biases – both overt and covert – that affect the ultimate outcomes.⁶⁰⁷ Meta analyses of studies in biomedical medicine, for example, reveal strong statistical evidence of a “funding effect”, in which research funded by a sponsor produces research outcomes that are much more favorable to that sponsor than research produced independently, without any financial conflicts.⁶⁰⁸

While agencies review this applicant-submitted information carefully,⁶⁰⁹ in a number of cases this sponsored research is not accessible to outside parties for additional verification and oversight. Indeed, in some cases the agency scientists themselves may not be fully apprised of the circumstances surrounding the sponsor’s role in influencing the research design, implementation, or reporting. Trade secret and related classifications, as well barriers to public access to manufacturer research under FIFRA, only serve to drive a further wedge between the parties producing this research and the ability of others, even those within government, to review it.

Despite evidence of bias in sponsored research, existing federal laws and regulation treat private research gingerly with respect to disclosure requirements; indeed, private research is exempted from virtually all of the transparency requirements imposed on federally funded research.⁶¹⁰ The laws and regulations, in other words, do precisely the opposite from what the underlying quality of the research would demand. They tend to insulate private research from scrutiny and focus attention on public research.

⁶⁰⁷ See, e.g., Justin E. Bekelman, Yan Li, & Cary P. Gross, *Scope and Impact of Financial Conflicts of Interest in Biomedical Research*, 289 JAMA 454 (2003).

⁶⁰⁸ Wendy Wagner and David Michaels, *Equal Treatment for Regulatory Science: Extending the Controls governing the Quality of Public Research to Private Research*, 30 AMERICAN JOURNAL OF LAW & MEDICINE 119, 122 (2004); see also *infra* note 616 (citing numerous sources).

⁶⁰⁹ Interview with EPA Staff, Office of Pesticide Programs, Jan. 27, 2012.

⁶¹⁰ Wagner & Michaels, *supra* note 608, at 129 (documenting this).

A first, simple reform to address this nontransparency of private research used for regulation is a set of rules that treat private and public research similarly with regard to the public accessibility of the data and studies and that require disclosures regarding the provenance of the research used for regulation. While additional interventions may ultimately be needed to address more entrenched features of sponsor bias (like rejecting all research in which sponsors reserve the right to influence or control research),⁶¹¹ the recommendations offered here take only the first step and are thus extremely modest in their reach. These recommendations are not only anchored in an extensive literature, but are excerpted generously from the Bipartisan Policy Center⁶¹² and the Keystone Center reports.⁶¹³

It should be noted that this short but dense set of recommendations owes its origins to the NAS meeting and to OSHA Administrator David Michaels in particular, who suggested that the report also address of the most egregious transparency issues associated with privately produced research used for regulation.⁶¹⁴ In sharp contrast to some of the issues identified in the final section of this report that are in need of further study – especially external expert review⁶¹⁵ – the disparate treatment of private versus public research has been studied extensively. To avoid adding still more volume to the final report, the reader is referred to some of the extensive documentation of these problems that serve as the basis for reform.⁶¹⁶

⁶¹¹ See, e.g., Woodruff et al., *supra* note 492 (advocating this exclusionary rule for literature analyses in clinical medicine).

⁶¹² See Bipartisan Policy Center, *supra* note 2.

⁶¹³ Since both projects were bipartisan, they provide the primary source of recommendations even though there are other excellent reports (to which I contributed) that provide still more fodder for recommendation, most notably the Center for Progressive Reform Report Perspective: Clean Science, available at <http://www.progressivereform.org/perspscience.cfm>, and CPR, Saving Science from Politics: Nine Essential Reforms of the Legal System, available at <http://www.progressiveregulation.org/articles/SavingScience805.pdf>.

⁶¹⁴ See NAS Transcript, *supra* note 503, at 146-47 (statement of Dr. Michaels).

⁶¹⁵ The last rigorous study of external peer review of regulatory science was done by Sheila Jasanoff in 1990. SHEILA JASANOFF, THE FIFTH BRANCH: SCIENCE ADVISERS AS POLICYMAKERS (1990). In this outstanding study, Prof. Jasanoff identifies a number of critical issues that deserve further study – few if any of which have been addressed since. Moreover, as expert review has become increasingly popular, more issues and concerns have arisen regarding its proper implementation. For example, Prof. Jasanoff pays only limited attention to the problems of conflicts in expert reviewers in her 1990 study, but this issue currently appears to rank as the most difficult and important problem with expert advisory review, at least according to the emphasis placed on the issue by both the Bipartisan Center and the Keystone Center reports.

⁶¹⁶ See, e.g., SHELDON KRIMSKY, SCIENCE IN THE PRIVATE INTEREST (2003); DAVID MICHAELS, DOUBT IS OUR PRODUCT (2008); NAOMI ORESKES & ERIK CONWAY, MERCHANTS OF DOUBT (2009); THOMAS O. McGARITY & WENDY E. WAGNER, BENDING SCIENCE: HOW SPECIAL INTERESTS CORRUPT PUBLIC HEALTH RESEARCH 233-39 (Harvard University Press 2008); RESCUING SCIENCE FROM POLITICS (Wendy Wagner & Rena Steinzor eds. 2006); Wagner & Michaels, Equal Treatment, *supra* note 608.

1. Disclosure of Conflicts of Interest⁶¹⁷

Studies reveal that sponsorship can bias results; yet despite the value of transparency about the provenance of regulatory research, the disclosure of sponsor influence is generally not required or even requested by federal regulatory agencies. The EPA, the Occupational Safety and Health Administration, the Mine Safety and Health Administration, the Consumer Product Safety Commission, and the National Highway Traffic Safety Administration have no formal mechanisms to identify potential conflicts of interest, nor do they provide any incentive to encourage the conduct of research that is free of sponsor control. The Food and Drug Administration (FDA) has instituted a conflict policy requiring financial disclosures for safety research conducted by private parties in support of a license to market a drug or food additive.⁶¹⁸ These disclosures do not, however, distinguish between research where the sponsor controls the design or reporting of the research and research where sponsors have no control.

Regulatory agencies should adopt, at a minimum, requirements for disclosure comparable to those of biomedical journals.⁶¹⁹ The Keystone report reinforces this conclusion: “information on what entities or individuals funded a study should be readily available.”⁶²⁰ “[E]stablishing and documenting the funder’s involvement with any given study, and any restrictions placed on the study’s release” is also central to a comprehensive literature review.⁶²¹ Disclosure of conflicts of interest should be required for all research, regardless of whether it is federally or privately funded. Scientists should disclose whether they have a contractual right to publish their findings free of sponsor control and should identify the extent to which their work was reviewed by an affected party before publication or submission to the agency. Sponsors who submit data should similarly disclose if their investigators had the contractual right to publish without sponsor consent or influence. Finally, other parties (i.e., trade associations, unions, or public interest groups) who submit scientific results should disclose all known conflicts of interests of the scientists conducting the studies.

Regulators should not use conflict disclosures to exclude research; they have the obligation to consider all evidence, according greater importance to studies of higher quality and relevance. Federal agencies should, however, develop policies that strongly encourage clear disclosures that counteract the strong incentives for sponsors to influence research. “[Without these basic disclosures,] agencies and scientific advisory committees

⁶¹⁷ This section is taken almost verbatim from David Michaels and Wendy Wagner, *Disclosure in Regulatory Science*, 302 SCIENCE 2073 (2003).

⁶¹⁸ 21 C.F.R. Part 54.

⁶¹⁹ See, e.g., ICJME Uniform Requirements for Conflicts of Interest, available at http://www.icmje.org/ethical_4conflicts.html; ICJME Uniform Requirements for Authorship, available at http://www.icmje.org/ethical_1author.html

⁶²⁰ Keystone, *supra* note 499, at 20.

⁶²¹ *Id.* at 24.

should be extremely skeptical of a scientific study unless they are sure that the principal investigator(s) (as opposed to the sponsor or funder) had ultimate control over the design and publication of the study.”⁶²² Only then can agencies accurately weight studies and encourage research independence.

Due to the difficulties of applying a conflict disclosure to past research, agencies should require conflict disclosures for future research as a first step. These disclosures will necessarily involve varying levels of detail depending on the import of the information. The disclosure should be required at least when the information is appended to comments or submitted as part of an application to obtain a license or permit.

Agencies should require conflict disclosures on all future research submitted to inform an agency’s licensing, regulatory, or other decision-making process -- whether published and unpublished. This conflict of interest disclosure should be similar to the conflict of interest disclosure required by the biomedical journals. See See ICJME Standards. The regulatory conflict of interest disclosure should also, where possible, identify whether a sponsor reserved the right to participate in the design of the research; the collection of data; the interpretation of data; the writing or disseminating the report, or any other material features of the research. Finally, “[a]gencies and scientific advisory committees should be extremely skeptical of a scientific study unless they are sure that the principal investigator(s) (as opposed to the sponsor or funder) had ultimate control over the design and publication of the study.”⁶²³

2. Data Disclosures in line with OMB Circular A-110 for All Regulatory Research⁶²⁴

Although some of the private data underlying regulation are already available in theory, in practice, public access to these data can be quite limited. In licensing programs for drugs, pesticides, and toxic substances, for example, the FDA and the EPA do demand access to data in advance as a condition to accepting studies for regulatory purposes, but the data often remain buried in agency files, or in some and perhaps many cases is stored in company files rather than in agency files, where it is insulated from FOIA requests.⁶²⁵

⁶²² Bipartisan Policy Center Report, *supra* note 2, at 42.

⁶²³ *Id.*

⁶²⁴ This section is drawn almost verbatim from McGARITY & WAGNER, BENDING SCIENCE, *supra* note 616, at 244.

⁶²⁵ Thomas O. McGarity, *Federal Regulation of Mad Cow Disease Risks*, 57 ADMINISTRATIVE LAW REVIEW 292, 318–319 (2005).

Under the Data Access Act, all publicly grant-funded research that informs regulation must be publicly accessible with very limited exceptions.⁶²⁶ “[I]n general, the data on which conclusions are based should be available, regardless of who funded or conducted the study.”⁶²⁷ This second recommendation simply extends the Data Access Act to privately submitted research. In extending the Data Access Act to all research, it might also be appropriate to take the additional step of requiring the privately produced data submitted in at least an application for a license or permit to be posted on the internet to ensure ready public access. While legislation or an OMB directive would provide the most centralized means for extending the Data Access Act in this fashion, agencies can extend the reach of the Data Access Act in their implementation of individual programs or through their inherent authorities.

“Studies used in the formulation of regulation should be subject to data access requirements equivalent to those under the Data Access Act (Shelby Amendment) and its implementing circular (OMB Circular A-110) regardless of who funded the study. If a study is used by an agency to inform the development of a regulation, then the same kinds of information about that study should be available upon request, regardless of whether the study was funded by the federal government, industry, or some other entity.”⁶²⁸

⁶²⁶ Wagner & Michaels, *Equal Treatment*, *supra* note 608, at 137-38.

⁶²⁷ Keystone Center Report, *supra* note 499, at 20.

⁶²⁸ Recommendation copied verbatim from Bipartisan Policy Center Report, *supra* note 2, at 43.

3. Minimizing Unsupported and Outdated Confidential Business Information Claims⁶²⁹

Considerable evidence reveals that companies use the nebulous “trade secret” claim to unjustifiably insulate from public view some of the information they must nevertheless share with regulators, like basic information on chemical structure or even some toxicity information.⁶³⁰ In most EPA programs, classifying information as trade secret protected is easy to do: a company need only stamp the information “confidential business information” and the claim automatically applies, unless an outside party seeks the information under the FOIA.⁶³¹ In fact, even if the agency discovers that a claim is wholly without basis—usually in the course of responding to an FOIA request—there is no penalty.⁶³² As a result, from a company’s perspective, there is little to lose and a great deal to be gained from routinely claiming trade secret protection, since the classified information is at least temporarily removed from public view. A number of companies in fact appear to be taking full advantage of this permissive program. Investigations conducted by the EPA, the General Accounting Office, and an outside consulting group all found a significant amount of unjustified overclaiming.⁶³³

Some regulated parties have candidly conceded that they sometimes illegitimately claim trade secret protection.⁶³⁴ Furthermore, they defend the EPA’s overly protective approach on the ground that any agency-imposed requirement to justify the numerous trade secret claims already in existence would violate the Regulatory Flexibility Act

⁶²⁹ The text is borrowed almost verbatim from McGARITY & WAGNER, BENDING SCIENCE, *supra* note 616, at 116.

⁶³⁰ See, e.g., Wagner & Michaels, *Equal Treatment*, *supra* note 608, at 129-35, 151-54.

⁶³¹ See Environmental Protection Agency, “Public Information and Confidentiality: Advance Notice of Proposed Rulemaking; Withdrawal of 1994 Proposed Rule,” 65 Fed. Reg. 80394, 80395 (December 21, 2000).

⁶³² See generally 40 C.F.R. §§ 2.201–2.310. See also Christopher J. Lewis, *Comment, When Is a Trade Secret Not So Secret?: The Deficiencies of 40 C.F.R. Part 2, Subpart B*, 30 ENVIRONMENTAL LAWYER 143, 171–172 (2000).

⁶³³ Environmental Protection Agency, “Public Information and Confidentiality Regulations,” 59 Fed. Reg. 60446, 60446–60447 (November 23, 1994); U.S. General Accounting Office, *Toxic Substances Control Act: Legislative Changes Could Make the Act More Effective* 56-58 (Washington, D.C.: GAO, 1994); Hampshire Research Associates, Inc., *Influence of CBI Requirements on TSCA Implementation* 4 1 (March 1992) (report obtained from EPA through FOIA and on file with authors); see also Environmental Protection Agency, Confidential Business Information (CBI) Review, Pesticides: Freedom of Information Act, www.epa.gov/pesticides/foia/cbi.htm (listing environment-related information that is commonly claimed as confidential).

⁶³⁴ Both the Keystone and the bipartisan reports acknowledge that CBI is overused today. See Keystone Center Report, *supra* note 499, at 21; Bipartisan Center Report, *supra* note 2, at 43. Underlying these bipartisan acknowledgements is extensive documentation of the overuse of CBI to classify information that has no conceivable trade secret value, much less trade secret value that overrides the public’s interest in learning more about the toxicity of various products or drugs.

because of the enormous work burden it would create for small manufacturers to sort out which of their trade secret claims are actually valid and which are not.⁶³⁵

To reduce this problem, “[a]gencies should review their laws, regulations, policies, and practices to ensure that CBI and other proprietary claims are not being used to protect information that need not be confidential. . . . Agencies have a responsibility to inform all stake-holders of the methods and manner they employ to determine what material is granted CBI status, and how it is reviewed and analyzed”⁶³⁶ in as clear and publicly understandable methods as possible.

“Confidential Business Information (CBI) claims can . . . make it difficult for the interested public to evaluate studies that contribute to regulatory policy.”⁶³⁷ Agencies that provide CBI protections for studies or data that inform regulation should ensure that the CBI claims are justified. Given the strong incentives to regulated parties for overclaiming CBI protection and the resultant costs from this overclaiming to public health protection and research, it is important that the agencies’ CBI programs not provide a safe haven for unjustified suppression of relevant regulatory research.⁶³⁸ To that end and as a first step, the agencies should review their CBI programs to ensure that there is rigorous oversight of CBI and related trade secret claims on health and environmental research. Agencies should, where possible, penalize those CBI claims that, upon review, appear unjustified.

D. Future Questions for the Study of Regulatory Science

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 that would benefit significantly from further study and attention are described below:

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.⁶³⁹ In a far larger number of regulatory projects, the agencies themselves determine that some form of expert peer review will be helpful, and

⁶³⁵ See, e.g., Warren E. Stickle, president, Chemical Producers and Distributors Association, & Bill Balek, president, International Sanitary Supply Association, letter to EPA, www.cpda.com/TeamPublish/uploads/CPDAISSA%20Comments.pdf. [Note; This letter has apparently been removed from the Internet and was not located on Regulations.gov. To access the letter, one may need to file a FOIA request with EPA].

⁶³⁶ Keystone Center Report, *supra* note 499, at 21.

⁶³⁷ Bipartisan Policy Center Report, *supra* note 2, at 43.

⁶³⁸ *Id.*

⁶³⁹ See Sections III.A.1.a. and 3., *supra*.

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.⁶⁴⁰

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.⁶⁴¹ 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.⁶⁴² 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 various challenges in assembling panels, particularly under FACA, is slim.⁶⁴³

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.⁶⁴⁴ Agency programs also appear to vary in the point(s) in the process they decide to use expert review⁶⁴⁵ and in how these advisors will be used, such as: commenting on agency products (e.g., EPA's IRIS)⁶⁴⁶ versus actually advising the agency in a more iterative way as a collaborator (e.g., EPA's CASAC in the NAAQS)⁶⁴⁷ versus actually suggesting projects and priorities (e.g., NRC's ACRS)).⁶⁴⁸ There also appear to be significant differences in the amount of work expected of these

⁶⁴⁰ See Section IV.A.3., *supra*.

⁶⁴¹ 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).

⁶⁴² See Bipartisan Policy Report, *supra* note 2, at chapter 2 (devoting much of its coverage of science advisory boards to these conflict challenges).

⁶⁴³ See, e.g., GAO, Federal Advisory Committees, Additional Guidance Could Help Agencies Better Ensure Independence and Balance (April 2004).

⁶⁴⁴ Interview with EPA Staff, Office of General Counsel, Jan. 13, 2012.

⁶⁴⁵ Compare CASAC w/ NRC's ACRS, for example. See Sections III.A.1.a. and 3., *supra*.

⁶⁴⁶ See Section III.A.1.c., *supra*.

⁶⁴⁷ See Section III.A.1.a., *supra*.

⁶⁴⁸ See Section III.A.3., *supra*.

advisors,⁶⁴⁹ as well as the duration of the advisory committees, which range from standing committees to one-shot reviews.⁶⁵⁰

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. This topic is extremely important and should be considered high priority for further research.

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.⁶⁵¹ 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.⁶⁵² 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,⁶⁵³ 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.⁶⁵⁴ 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

⁶⁴⁹ See *id* (identifying the commitment required of scientists to serve on advisory boards for NRC).

⁶⁵⁰ 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*.

⁶⁵¹ 7 U.S.C. § 136h(g)(1).

⁶⁵² See Section III.A.1.b., *supra*.

⁶⁵³ 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.

⁶⁵⁴ 16 U.S.C. § 1536(a).

undertake the project.⁶⁵⁵ Stakeholders and the FWS concede that the quality and comprehensiveness of these assessments are not always up to the FWS's standards.⁶⁵⁶ 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.⁶⁵⁷ Many of these preliminary assessments are not subject to notice and 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.⁶⁵⁸

Similarly, in the re-licensing of nuclear reactors, the NRC staff has been criticized for not verifying technical statements and assessments contained in an operator's application.⁶⁵⁹ 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.⁶⁶⁰ Moreover, none of this underlying technical information was available to the NRC personnel located off-site.⁶⁶¹ 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,⁶⁶² 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.⁶⁶³

⁶⁵⁵ Interview with former staff of Environmental Defense, Jan. 19. 2012; Interview with FWS Staff, Endangered Species Program, Jan. 26, 2012.

⁶⁵⁶ Interview with FWS Staff, Endangered Species Program, Jan. 26, 2012.

⁶⁵⁷ 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 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.

⁶⁵⁸ 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 for 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).

⁶⁵⁹ See Section III.A.3., *supra*.

⁶⁶⁰ *Id.*

⁶⁶¹ *Id.*

⁶⁶² Interview with EPA Staff, Office of Pesticide Programs, Jan. 27, 2012.

⁶⁶³ Interview with staff, PEER, Aug. 5, 2012; Interview with former Environmental Defense employee, Jan. 19, 2012.

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.⁶⁶⁴ 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.⁶⁶⁵ To the extent that there is no external oversight of these internal assessments of applicant-provided data and research, added procedural protections may be needed.⁶⁶⁶

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.⁶⁶⁷ 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.⁶⁶⁸ 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

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

⁶⁶⁴ Interview with EPA Staff, Office of Pesticide Programs, Jan. 27, 2012.

⁶⁶⁵ *Id.*

⁶⁶⁶ For example, in situations like trade secret when the public and independent reviewers cannot access underlying studies or data, prophylactic 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.

⁶⁶⁷ See Frye Paper at Appendix B

⁶⁶⁸ *See id.*

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 the 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 interviewees⁶⁶⁹ and was reinforced by critical commentary,⁶⁷⁰ is a concern that the agencies may in some cases be almost too focused on scientific information developed within the natural sciences, and that this type of scientific information becomes "privileged" at the expense of other vital information, including social science research, 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.⁶⁷¹

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

⁶⁶⁹ 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.

⁶⁷⁰ 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).

⁶⁷¹ 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).

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

A long-standing challenge for regulatory science is to ensure that policy decisions can be assessed and set against the scientific record. Interested observers who are not intimately involved in the rule should be able to trace the use of science into the final regulation and, through this step-by-step explication judge the veracity of the use of science at every turn. This scientific transparency 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 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.