OIG

OFFICE OF INSPECTOR GENERAL

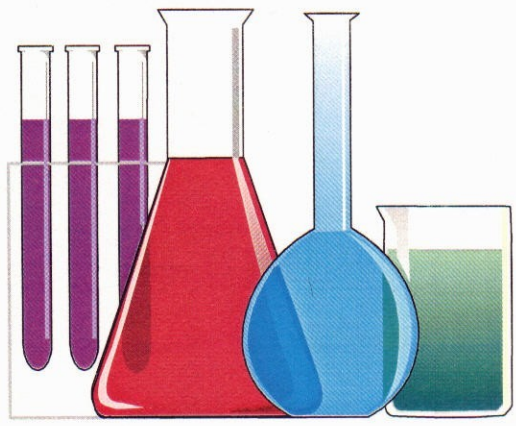
Catalyst for Improving the Environment

Pilot Study

Science to Support Rulemaking

Report 2003-P-00003

November 15, 2002



Abbreviations	
CAA	Clean Air Act
CWA	Clean Water Act
EPA	Environmental Protection Agency
EPCRA	Emergency Planning and Community Right to Know Act
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
IQ Guidelines	Information Quality Guidelines
NAAQS	National Ambient Air Quality Standards
NESHAP	National Emission Standard for Hazardous Air Pollutant
NOx	Nitrogen Oxides
NPDWR	National Primary Drinking Water Regulations
OAR	Office of Air and Radiation
OMB	Office of Management and Budget
OPEI	Office of Policy, Economics, and Innovation
OPPTS	Office of Prevention, Pesticides, and Toxic Substances
ORD	Office of Research and Development
OSWER	Office of Solid Waste and Emergency Response
OW	Office of Water
RAPIDS	Rule and Policy Information Development System
RCRA	Resource Conservation and Recovery Act
SDWA	Safe Drinking Water Act
TSCA	Toxic Substances Control Act

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
INSPECTOR GENERAL

November 15, 2002

MEMORANDUM

SUBJECT: Report 2002-P-0003
Pilot Study: Science to Support Rulemaking

FROM: Jeffrey Harris, Director, Cross-Media Issues
Office of Inspector General

TO: Thomas Gibson, Associate Administrator for
Policy, Economics, and Innovation

Paul Gilman, Science Advisor to the Agency

This report concludes the pilot study for an evaluation of science to support rulemaking conducted by the Office of Inspector General (OIG) of the U.S. Environmental Protection Agency (EPA). It addresses the role played by science, the genesis of this science, and the extent to which the science was peer reviewed. Although this was only a pilot study, we believe the results are sufficient to offer suggestions to improve the transparency and consistency with which science is applied to rulemaking in the EPA. Some of the suggestions elaborate on recommendations made in June 2001 to the Administrator by EPA's internal task force on improving rulemaking. Our report also discusses the strengths and weaknesses of the methodology we used in conducting the pilot study.

We appreciate the cooperation we received from the primary contacts for the rules covered by the pilot study, and those others involved in these rulemakings who took the time to answer our questions.

Since this report does not include recommendations to which you must respond, no action is required. In accordance with EPA Order 2750, we are closing the report in our tracking system upon issuance. We have no objections to the further release of this report to the public. For your convenience, this report will be available at http://www.epa.gov/oigearth/eroom.htm.

If you have any questions about this report, please contact Christine Baughman at 202-566-2902.

Executive Summary

Rules, also known as regulations, are a critical cornerstone of the Environmental Protection Agency's (EPA's) mission. By statute and executive order, they are to be based on the best reasonably obtainable scientific, technical, economic, and other information. EPA Administrator Whitman noted that the Agency's ability to "accomplish our mission and continue to have a meaningful impact on the quality of life for all Americans to a large extent is based on our ability to more fully integrate science into our programs, policies and decisions."

By identifying the science that was critical to rules promulgated by EPA in the past, we hoped to determine whether better research planning, application of science to rules, and explanation of the role of science in rules could achieve improvements in the science behind future environmental regulations. By critical, we do not mean that the rules were promulgated *because of* the science, but that without the science the rules would have been different, or even impossible to promulgate. We completed a pilot study consisting of 15 case studies involving 16 of EPA's significant rulemakings to determine whether a full study would be useful and feasible.

Results In Brief

The rules included in the pilot study were not a representative statistical sample of EPA rules, and we did not identify all of the critical science inputs for every rule. However, we made observations that we believe transcend these limitations and will be useful to EPA rulemakers:

Role of Science: Science played an important role in the rules, but that role was not always clear. Even though the rules included in this pilot study depended on hundreds of scientific documents, because the role of science often was not presented in a manner consistent with the conventions of communicating scientific information, it may be unclear what science was critical and why.

Sources of Science: Although critical science originated from a variety of sources, research performed under contract to EPA and the regulated community by private sector firms was the most common source. Grants and cooperative agreements accounted for about 8 percent of the work.

Data: Some of the rules would be based on fewer assumptions if EPA had more data and fewer scientific "blind-spots."

Peer Review: The critical science supporting the rules often was not independently peer reviewed. Consequently, the quality of some science remains unknown.

The pilot study identified significant challenges to identifying target populations of EPA's non-significant rules and identifying critical science consistently, and we do not intend to pursue a full study at this time.

Suggestions

Based on our observations in the pilot study, we offered several suggestions:

- EPA should ensure that science in rulemaking is presented in a way that is apparent and consistent with the conventions of science.
- Information technology could be better used to ensure that the Administrator, Congress, and the public could determine that the science behind rulemaking is adequate.
- The critical science behind EPA's rules should consistently be independently peer reviewed.

Agency Comments and OIG Evaluation

We received both formal and informal responses from EPA management. Generally, the comments from Agency officials were supportive of the suggestions, although they identified some concerns about the details of their implementation. EPA's Science Advisor has committed to review the Agency's progress in implementing its Peer Review policy during the coming year, and ensure that Agency decisions are based on sound science. We have incorporated many of the specific Agency comments directly into the report and its Addendum to improve clarity and factual accuracy. Because of the commitments made by Agency management in their comments, we believe the report's observations may serve as a baseline against which the Agency can chart progress.

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What We Did and Why

Rules (also called regulations)[1] are a cornerstone of the Environmental Protection Agency's (EPA's) mission. Rules are, first and foremost, legal documents written to meet legal goals. Nonetheless, they are to be based on the best reasonably obtainable scientific, technical, economic, and other information. In June 2001, a Regulatory Development Task Force established by the EPA Administrator to improve EPA regulations offered several recommendations to ensure that science has a more prominent role in EPA decision-making, and that there is timely and thorough analysis of issues. The recommendations included improving existing processes to more effectively ensure broader Agency involvement and executive input on cross-cutting scientific, economic, or policy issues, as well as involving EPA scientists in determining needed analyses and research, identifying alternatives, and selecting options. As noted in a May 2002 memorandum from the EPA Administrator, the ability of the Agency to "accomplish our mission and continue to have a meaningful impact on the quality of life for all Americans to a large extent is based on our ability to more fully integrate science into our programs, policies and decisions."

By understanding what science was critical to the rules promulgated by EPA in the past, we hoped to determine whether better research planning, application of science to rules, and explanation of the role of science in rules could achieve improvements in the science behind future environmental regulations. By critical, we do not mean that the rules were promulgated *because of* these documents; rather, without the documents, the rules would have been different, or even impossible to promulgate.

We believed that such a study should answer the following questions:

- What role does science play in supporting rules?
- What science provided the most critical support for the rules and what was its genesis?
- What were the most significant gaps in the science underpinning the rules, and could they have been filled with better research planning and communication?
- How was the quality of the science evaluated?
- Do rules with better scientific underpinnings exhibit measurably better outcomes?

[1] "Regulations," or "rules," are agency statements of general applicability and future effect, which the agency intends to have the force of and effect of law, and that are designed (1) to implement, interpret, or prescribe law or policy, or (2) to describe the procedure or practice requirements of an agency. "Rulemaking" is synonymous with "regulatory action."

In August 2001, we started a pilot study to determine whether we could answer the above questions and, if so, the level of resources required. Early in the pilot we consulted two Agency groups. The Research Strategies Advisory Committee of the EPA Science Advisory Board is comprised of representatives of the various advisory boards that advise on science in rulemaking in EPA. EPA's Regulatory Steering Committee is the cross-agency group most closely involved with rulemaking in EPA. With the advice of both groups, we designed this pilot study, which we completed June 2002.

We began by identifying EPA's significant rules finalized after 1989, and then selected a small sample to pursue as case studies. For each rule in the sample, we identified primary contacts involved in the rulemaking and contacted each individual via e-mail for assistance in identifying the critical science documents underlying the rule. For each document, we established: who conducted the study, how the study was funded, and whether and how the document was peer-reviewed. Each step is discussed in more detail below, and the findings for each selected rule are summarized in the case studies located in an Addendum to this report available at http://www.epa.gov/oigearth/eroom.htm.

Except for the limitations identified in this paragraph, the pilot study was conducted in accordance with the *Government Auditing Standards* for performance audits. Our research into the management controls over developing regulations was limited to a general understanding of the process, both for rules in general and the rules in the sample. We did not test any controls (e.g., comparing the planning requirements to the actual plans for the rules in the pilot study). Also, because this was only a pilot study, not all of the attributes of a finding were pursued, such as those related to cause (e.g., why there was a lack of peer review).

We gained an understanding of rulemaking at EPA

EPA develops many types of regulations based on a variety of mandates, but certain processes are common to most rulemakings. Typically, once a rulemaking is triggered by a statute, court order, petition, or executive initiative, the appropriate program office(s) and the Office of Policy, Economics, and Innovation (OPEI) prioritize staff time and resources, determine the regulatory strategy to be pursued, identify the science and data needed and available, identify a set of regulatory options, select an option, and propose the rule in the *Federal Register*. The notice of proposed rulemaking in the *Federal Register* includes a preamble that describes the basis and purpose of the rule, the alternatives considered, and the underlying supporting information. To send a clear message, the preamble must be written in plain language. The underlying supporting information is found in the "dockets" for the rulemaking (drawers of paper files available for public perusal and, for more recent rules, the equivalent electronic files available on EPA's website). The dockets also contain all public comments received, EPA's responses to public comments, and other information EPA

considers relevant to its decisions. After allowing for public comment (typically 60 days), EPA finalizes the rule by publishing it in the *Federal Register*, with a new preamble responding to important comments and identifying any changes in the rule since its proposal.

EPA's OPEI estimates that EPA publishes *Federal Register* notices for between 1,000 and 1,300 rules each year. Approximately 20 of these rules each year are "significant" under Executive Order 12866 (see box). These significant rules must be reviewed by the Office of Management and Budget, unless they were specifically exempted. EPA proposes or finalizes approximately 200 rules each year that have a lower level of impact than the significant rules but are still generally national in scope. The remaining notices are for rules that primarily impact individual States, Tribes, sites, or manufacturers, or involve minor modifications and corrections to existing rules. Many proposed rules never become final, and proposed significant rules may become non-significant on finalization if their estimated costs decrease, they are determined to modify existing significant rules, or the Office of Management and Budget determines the rule is not significant.

We identified significant rules promulgated after 1989 and selected a sample for 15 case studies

To develop a sample of rules to study, we first needed to identify a target population of rules of interest. We decided to focus on significant rules (see box) finalized after 1989. OPEI maintains a database of planned and ongoing rulemakings – the Rule and Policy Information Development System (RAPIDS) – but at the time of the study, did not maintain a list of rules finalized over the previous 10 years and was not able to construct a complete list of the significant rules before 1998 using RAPIDS.

We used the *Federal Register* and EPA's website to identify the 89 significant rules finalized in 1990 through 2001, which are listed in Exhibit 1. The list of rules promulgated before 1994 may be incomplete since EPA's web-based materials tended to be dated 1994 and later. Focusing on the 75 rules finalized from 1994 on, we show in Figure 1 that more than half (39) of these rules were issued under the Clean Air

Under Executive Order 12866, "Significant" rules:

- Have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy; a sector of the economy; productivity; competition; jobs; the environment; public health or safety; or State, local, or tribal governments.
- Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency.
- Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof.
- Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

Act. Most of the rest involved either the Clean Water Act (16) or Safe Drinking Water Act (6). Of these 75 rules, 39 met the significant criteria because of their expected economic impact. (Note: because one of the rules involved two laws, Figures 1 and 2 total 76 and 40, respectively.) As shown in Figure 2, a slightly higher proportion of the *economically* significant rules involve the Clean Air Act, but the economically significant rules are otherwise similar to the larger population of significant rules.

Figure 1

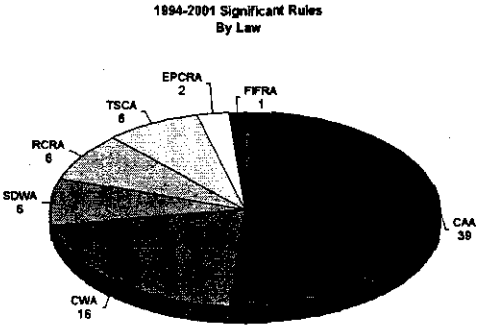
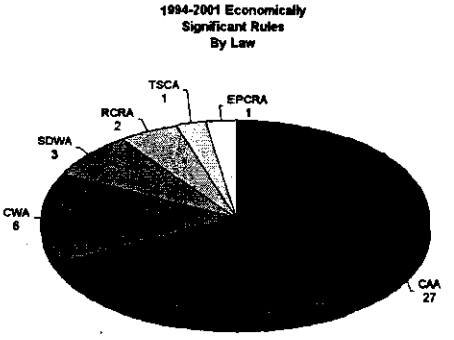


Figure 2



CAA: Clean Air Act
CWA: Clean Water Act
EPCRA: Emergency Planning and Community Right to Know Act
FIFRA: Federal Insecticide, Fungicide, and Rodenticide Act
RCRA: Resource Conservation and Recovery Act
SDWA: Safe Drinking Water Act
TSCA: Toxic Substances Control Act

For the pilot study, we selected 16 significant rules finalized during 1991 through 2001. Three of the rules concerned related land disposal restrictions for solid wastes, so we combined them into one case study. The Integrated Pulp and Paper rule involved two different laws, so we divided it into two case studies. Thus, there was a total of 15 case studies in the pilot. Each case study is identified in Table 1 and detailed in the Addendum report, which is available at http://www.epa.gov/oigearth/eroom.htm.

Table 1:
Case Studies

Year	Law	Subject	Case
1991	CAA	Municipal Waste Combustors	1
1991	SDWA	Synthetic Chemicals Monitoring	2
1993	CAA	Acid Rain Permits	3
1994 1996 1998	RCRA	Land Disposal Restrictions	4
1994	CAA	Reformulated Gasoline	5
1995	CWA	Great Lakes Water Quality	6
1996	CAA	Municipal Solid Waste Landfills	7
1997	TSCA	Biotechnology	8
1998	CAA	Pulp and Paper (Air)	9
1998	CWA	Pulp and Paper (Water)	10
1998	SDWA	Disinfectants and Byproducts	11
1998	TSCA	Polychlorinated Biphenyls	12
1998	CAA	Regional Ozone	13
1998	CAA	Nonroad Diesel Engines	14
2001	FIFRA	Plant-Incorporated Protectants	15

This judgment sample was selected to represent as wide a range of statutes as possible, and to span the decade for rules under the Clean Air, Clean Water, and Safe Drinking Water Acts, but it is not statistically representative of EPA's significant rules during the period. For example, there was only one rule in the sample establishing a National Emission Standard for Hazardous Air Pollutant (NESHAP), whereas six NESHAPs were finalized between 1994 and 2001. Notably, there are no National Ambient Air Quality Standards (NAAQS) in the sample, even though three were finalized by EPA during this period. NAAQS are especially science-rich rules, but we excluded them because the particulate matter and ozone NAAQS were under remand to the District of Columbia Circuit Court during the study.

We sought to identify the critical science behind each rule

For purposes of the pilot project, "science" included scientific and technical work products addressing, for example, pollutant emissions, environmental transport, cost impacts, exposure to humans and ecosystems, the effects of such exposure, risk assessments, monitoring methods, and databases, i.e., the kinds of documents that would be produced by scientists or engineers. We included economic analyses only when they had a critical impact on the rule. As noted earlier, by "critical," we do not mean that the rules were promulgated *because of* these documents; rather, without the documents, the rules would have been different, or perhaps would have even been impossible to promulgate.

We had planned to identify the critical science documents supporting each rule by relying on a variety of people involved in developing the regulation to identify the documents. We asked the primary contact to identify one or more additional contacts from the following groups: scientists from the program office who worked on the rulemaking; EPA Office of Research and Development (ORD) scientists who provided expertise to the rulemaking team; the Senior Executive from the program office immediately responsible for the rule; independent peer reviewers; environmental stakeholders; and representatives of the regulated community. With this range of perspectives on the critical science, if there was wide consensus, we could be reasonably sure we had identified all the critical science. It also would require less reliance on an evaluation team to make independent judgments about what science was critical.

We started by identifying primary contacts for each rule (the people from the EPA program office who led the rulemaking). After 6 weeks, we had identified 83 contacts (including the primary contact for each case study). We sent e-mails to the contacts, asking each of them to identify 5 to 10 science references (e.g., papers, reports) that they believed *most critically* influenced the rulemaking and, without which, the rules would have been substantively different. We asked that they consider several categories of science that may be relevant to the rules. We also asked – if they had the discretion, funds, and "20/20" hindsight – what science gaps would they have tried to fill that might have made the rule substantially different. Finally, we asked how they would rate the scientific quality of the rule, on a scale of 1 (low) to 5 (high).

We received at least one detailed response for only 7 of the 15 case studies by late November 2001, but we received no helpful responses from 58 of the contacts. We received no useful e-mail responses from any of the EPA executives, peer reviewers, environmental stakeholders, or representatives of the regulated community. We then conducted interviews with primary contacts and other EPA staff. The interviews yielded specific references and more general explanations of how the rulemaking proceeded, and advice to look in the docket for reports on particular studies. We were thus able to identify additional critical science documents. Of the critical documents, we identified almost half from reading the materials in the dockets. The pilot team identified all of the critical documents for two of the rules (Cases 2 and 8). Because we were not able to interview peer reviewers or stakeholders, and because we relied on only one or two Agency contacts and the preambles and technical support documents developed by EPA, our results may reflect an EPA bias on what science was critical.

Our process did not result in the identification of *all* of the critical science documents for *all* of the rules. We believe we did identify all of the major technical support that embodied the final process of gathering together the science and other information to support the rules for all of the case studies (see Exhibit 2). These documents had titles such as background information documents,

technical support documents, regulatory impact analyses, and economic impact analyses. They were often, but not always, cited in the preamble. If the preamble was the only place where the science was brought together, we identified the preamble as a critical document.

We encountered more difficulty as we identified the critical documents cited in the major support documents. These documents included other documents developed specifically to support the rule (e.g., databases, regulatory methods, health criteria documents), as well as documents from the primary science literature (e.g., toxicology data supporting a criterion, models used to do an analysis, or even the data or mechanisms necessary to the model itself). For example, two of the rules involved the development of National Primary Drinking Water Regulations (Cases 2 and 11). The standards under the regulations (maximum concentrations of chemicals in the finished water) depend in part on the risk to human health posed by the chemical. Health Criteria Documents summarize and interpret the available toxicology and epidemiology available in the literature to arrive at various "criteria" values that put the heaviest weight on (reliable) studies that show effects at the lowest chemical concentrations. These underlying studies then become critical documents (there are usually more than one per health criteria document because of the different types of effects, e.g. cancer, reproductive effects, etc.). Thirty-four of these underlying criteria documents were identified for Cases 2 and 11 alone. Because the number of critical documents increases exponentially as one goes backward through the citation chain, locating all of them becomes a very time-consuming process.

We believe we identified all of the critical documents cited in the major technical support documents for six of the rules ("level 2" documents in Exhibit 2). In three of the case studies, we went into the references for this second group of documents, and identified the most critical references identified as "level 3" documents in Exhibit 2 (e.g., the chemical mechanism upon which a component of a model used to support a rule was based, or research that led to the identification of a problem that led to the recognition of the problem that the rule was promulgated to address).

Exhibit 2 shows a wide range in the numbers of critical documents per case. Two of the cases for which we believe we have a complete list of level 2 documents include only 10 and 12 critical documents, while two of the cases for which we believe the lists are incomplete include as many as 25. Adding level three documents also increases the number. We believe this wide range arises from a combination of: differences in the scientific complexity of the rules, which affects the type of critical documents needed to support the rule; and failure to identify all of the critical documents for each rule.

These factors complicate the interpretation of the statistics for this or any full study in the future. Because we did not identify all of the critical documents for

all the rules, comparative statistics on critical science documents (e.g., proportions of critical science documents funded under grants, or performed by other federal agencies) could be subject to bias, and interpretations based on such calculations could be misleading. Overcoming this problem would present a challenge for expanding the pilot study.

We identified the sources of the critical science

Once a critical science document was identified, we had to find a hard or electronic copy. We then examined it to determine who performed the science work, who funded it, the funding mechanism used, and whether and how it was peer reviewed. We categorized the resulting information for statistical analysis.

Who performed the research often was identified on the title page of reports, the by-lines in journal articles, or in the acknowledgments (e.g., a report might state that valuable contributions had been made by a company or organization). Funding information (both who and what mechanism) often could be found on the title page of reports or the acknowledgments section of journal articles. We found that some documents had an EPA cover, but inside indicated that the document had been prepared for EPA by a contractor. In those cases, we classified the report as funded by EPA, but prepared by a private sector firm under contract. If instead, the report only acknowledged substantial support from a contractor, we classified the report as having been produced by EPA, with a contract as the funding mechanism. The criteria for the classifications are more fully explained in the Addendum.

The document did not always address one or more of these characteristics. In some cases, we were able to conclude that a program office funded a technical support document (no other organization would have reason to fund it), or that the only allowable or likely mechanism to support a scientific study was a contract. When all else failed, we asked those who had responded to our inquiries, either during the development of the case study or upon final review.

We asked the respondents about science gaps and science quality

At the outset of the pilot study, we had hoped to identify indicators of the scientific quality of final rules that we could relate to the characteristics of the critical science inputs. For example, did more rigorous peer review or the extensive use of science from academic labs lead to "better" rules? We were unable to identify any objective indicators, so at the suggestion of the Research Strategies Advisory Committee, we asked respondents (some of whom were not on our initial list of contacts) to: (1) identify any additional science that would have been useful if it had been available ("gaps"); and (2) rate the science quality of the rules on a scale of one to five, with five being the highest quality.

We identified the type of peer review undergone by the critical science

Science used by EPA to support rules should be credible. Peer review is EPA's preferred method of ensuring credibility. Peer review is the documented, critical review of a work product, performed by experts who are independent of those who developed the product. In a 1994 policy, EPA specifically required peer review for scientifically and technically based work products intended to support EPA decisions. EPA's December 1998 *Peer Review Handbook* expanded this policy. Regulatory Management Guidance based on the 1998 Handbook was issued by EPA's Office of Policy in June 1999, requiring that all rules undergoing Final Agency Review must include either a statement that "no major scientific or technical documents were utilized to support the rulemaking," or a statement of compliance with peer review requirements. In a fact sheet related to this guidance, the criteria identified for such documents are very similar to those for significant rules in Executive Order 12866. The December 2000 *Peer Review Handbook* for the first time required that the final work product itself must describe the peer review to which it was subjected, or note that it was not peer reviewed. A regulation itself is not subject to EPA's peer review policy, even though the major scientific work products that support it are.

Peer review will become even more important as EPA implements recent guidance from the Office of Management and Budget (OMB) developed to comply with the Treasury and General Government Appropriations Act of Fiscal Year 2001. The OMB "Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies" state:

> *As a general matter, in the scientific and research context, we regard technical information that has been subjected to formal, independent, external peer review as presumptively objective.*

EPA's related guidelines, which became effective on October 1, 2002, are consistent with many existing practices and policies, including the above mentioned peer review policy, according to the Associate Administrator for Policy, Economics, and Innovation.

Some documents indicated they had been peer reviewed, and by whom. Critical documents in scientific journals were subject to the peer review policies of the journals. For the many documents that did not indicate their peer review method or status, we consulted EPA's Peer Review Database and asked respondents.

What We Learned About the Science Behind the Rules

The rules included in the pilot study were not a representative statistical sample of EPA rules, and we did not identify all of the critical science inputs for every rule. However, we made observations that we believe transcend these limitations and will be useful to EPA rulemakers:

- Science played an important role in the rules, but that role was not always clear.
- Although critical science originated from a variety of sources, the private sector was the most common source.
- More data and fewer scientific "blind-spots" could reduce assumptions.
- The critical science supporting the rules often was not independently peer reviewed.

At the end of this section, we provide some suggestions that, based on our observations, should help EPA improve its use of science in making rules.

Science played an important role in the rules, but that role was not always clear

We found that science played an important role in the rules, but that role was not always clear. Even though the rules included in this pilot study depended on hundreds of individual scientific documents, because the role of science was generally not presented in a manner consistent with the norms of science, it may be unclear to the public what science was critical or why.

The role of science

We identified 452 critical science documents for the 16 rules in the pilot study. Each of these documents, had the results been different, may have affected who was subject to the regulation, their cost of compliance, or risk to the public and the environment.

The number of documents used per case study ranged from 8 to 85[2]. Even though the 16 rules in the pilot are not a representative sample numerically, they are based on the same statutes as those for EPA's other significant rulemakings in the 1990s (Exhibit 1), so we believe the number of critical documents for these rules is not atypical of the importance of science in the formulation of EPA rules.

Some examples of critical documents follow.

- Four of the rules in this pilot study set water quality standards for drinking water under the Safe Drinking Water Act (Cases 2 and 11) or for discharges to lakes and rivers under the Clean Water Act (Cases 6 and 10). Criteria documents summarized and interpreted the available toxicology and epidemiology available to arrive at "criteria" values – concentrations deemed "safe" for exposure to people and ecosystems. Other documents synthesized the likelihood of exposure of people and ecosystems to pollutants, as well as treatment costs. These data were used to set the enforceable standards. Had any of the 186 critical science documents been different, it is reasonable to expect that one of the enforceable standards could have been set at a different number.

- One rule involved setting emissions caps for nitrogen oxides (NOx) for 22 eastern States by demonstrating that the caps would significantly reduce contributions to nonattainment of the NAAQS for ozone in downwind states (Case 13). There was no requirement to assess the risk of non-attainment of the NAAQS on health or welfare[3]. Instead, most of the 42 critical science documents focused on establishing NOx emissions inventories and modeling the chemistry and downwind transport of ozone and its precursors. This was to show which of the States would be required to reduce emissions, and that the proposed caps would significantly reduce nonattainment in the downwind states. Without the inventories and modeling, there would be no scientific basis for showing which states were significant contributors, and some of the estimates would have been different. That could have resulted in some States not being subject to the rule. We also identified critical science documents without which it is reasonable to believe the section authorizing the rule might not have been included in the Clean Air Act.

- Several rules (Cases 1, 7, and 9) required that a particular technology must be used, or an emissions limit equivalent to using that technology achieved. These rules, involving a total of 50 critical science documents, required that EPA develop databases to characterize the universe of sources to be regulated

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2 Case 4, which had 85 critical documents, represents a cluster of 3 related significant rules on land disposal restrictions that were finalized over a span of 5 years.

3 The ozone NAAQS was the subject of a significant 1997 rulemaking.

(municipal waste combustors, municipal landfills, and pulp and paper mills, respectively) and models to estimate emissions from these sources. Without the data and models, decisions about which sources would not be regulated, and the technology required for those that were regulated, would almost certainly have been different. In the first two cases, EPA could have made an administrative decision whom to regulate, but the decision would likely have been different. In the mills instance, law requires all sources to be regulated, but emissions limits for new mills must be no higher than those at the best existing mills, and standards for existing mills not at the "best" level also needed upgrades. Without an emissions model and database, EPA would have no legal basis to set the standards.

Role of science not always clear

Even though science played a role in all of the rules in this pilot study, it may not always be clear because of the way the role of science is presented in the preambles. Science is communicated according to widely accepted professional norms. For example:

- The question to be answered is introduced, along with any previous scientific results that the current study builds on. Such results are explicitly referenced.

- The methods used in the study are described in sufficient detail so that the study can be reproduced by others.

- The results are presented in the form of graphs and tables (not just the data that support the authors' conclusions), usually with estimates of statistical uncertainty. Authors discuss how the data in each figure and table support and do not support alternative answers and reach carefully bounded conclusions.

However, we saw little evidence of any of these conventions in communicating the scientific underpinnings of the rules in the preambles, which form the legal basis for the rule. We found that the preambles did not consistently present the scientific and technical questions to be answered in terms of exactly how the answers would be used to support the rule. The methods were not presented in sufficient detail to reproduce the studies, or to understand how the studies were done. Preambles for only 5 of the 16 rules presented any data tables, and only one presented any indication of uncertainty estimates.

Two of the preambles provided examples of good practices in the presentation of data:

- The preamble of the regional ozone rule (Case 13) describes the scientific approach taken to modeling, and tabulates the results of the model runs in terms of the quantitative contributions of upwind States to non-attainment of

the ozone NAAQS in each downwind State. The cost effectiveness of various ozone control options are compared in two other tables.

- The preamble to the disinfectant and byproduct rule (Case 11) also presents data tables comparing compliance forecasts between the 1994 proposal and the final rule, different systems costs, populations potentially exposed, and cancer cases expected under different options. One figure shows the *ranges* of estimated benefits, the only example of uncertainty seen in any of the preambles, and others show how many households will incur different costs of treatment.

The preamble of a rule regulating emissions of air pollutants from landfills (Case 7) instead illustrates an opportunity lost.

- The preamble explained that EPA decided to exclude 90 percent of the smallest landfills from the regulation, and to require that best demonstrated technology be applied to any of the larger landfills with estimated emissions of NMOC (non-methane organic hydrocarbons, which contributes to the formation of ozone) of more than 50 Mg/yr. The intent was to reduce these emissions from all landfills by 53 percent at a particular cost per ton removed. However, no data were presented showing the estimated emissions from landfills of different size classes, the estimated emissions reductions from each class at different control levels, the corresponding costs, or any indication of the uncertainty in any of the estimates (emissions estimates were based on a mathematical model rather than actual measurements). Such a table would have made it clearer why EPA had chosen the particular mix of landfill size and emissions caps in the final rule, based on a combination of science and economics.

Many of the technical support documents contained data supporting decisions, but for many of the rules in the pilot study, we observed no referencing or inconsistent referencing of even the major critical science documents developed to support the rule. Although most of the preambles were meticulously referenced to previous *Federal Register* notices and case law, only six preambles referenced the science underpinnings.

- The municipal waste combustor rule (Case 1) cited seven documents at the beginning of the preamble, but did not tie the technical arguments in the preamble to the documents.

- The nonroad diesel rule (Case 14) cited specific science reports using footnotes and made some of the technical support documents available on the EPA web site.

- The disinfectant and byproduct rule (Case 11) was referenced in the manner of a scientific paper, to a bibliography in a section in the preamble.

- The pulp and paper rule (Cases 9 and 10) referenced documents by the docket index number, but not by report title. Many of these documents were available on-line, but the docket index was not, so one could not go right from the citation to the on-line document.

- The biotechnology rule (Case 8) and the plant-incorporated protectant rule (Case 15) both cited references by number, which corresponded to a reference section in the preamble.

Finally, we found it difficult to determine the relative importance of science and administrative discretion when preambles contained statements that began, "EPA believes . . ." or "EPA concludes. . . ." In these cases, it was not always clear when a decision was based on science or on administrative discretion and, if it was based on administrative discretion, whether the science really mattered. Two quotes from the regional ozone rule (Case 13), a rule with substantial scientific underpinnings, are illustrative:

> *...these four jurisdictions rank among the six highest jurisdictions in the OTAG (Ozone Transport Assessment Group) region in terms of NOx emissions density. EPA believes that this high density provides an appropriate basis for concluding that each of these four jurisdictions should be included as a significant contributor.*
>
> *Because no highly cost-effective controls are available to eliminate the remaining amounts of NOx emissions, EPA concludes that those emissions do not contribute significantly to downwind nonattainment or maintenance problems.*

The scientific basis for EPA's decision about which States to include as significant contributors was air quality model runs that identified the degree to which upwind States contributed to ozone formation episodes in downwind states. In these quotations, it appears that EPA is arguing that emissions density, or even cost-effectiveness of controls, are equally suitable criteria.

In summary, even though the rules included in this pilot study depended on hundreds of individual scientific documents, because the role of science was not presented consistently in the preambles in accordance with the norms of science, it may be unclear exactly what science was critical and why. We could find no explicit guidance on the presentation of scientific findings necessary to support EPA's rules on the "Process Guidance" section of EPA's on-line Regulatory Reference Library, but OPEI in its comments indicated that EPA's Risk Characterization Guidelines may in part meet this need.

Although critical science originated from a variety of sources, the private sector was the most common source

We determined (where possible) who performed the science, who funded it, and the funding mechanism used for the critical science documents identified for the 15 case studies. For reasons explained earlier, we cannot generalize from the rules in the pilot to EPA rulemaking overall. Nonetheless, we can still make some useful observations about the roles played by the various organizations conducting and funding critical science, and the funding mechanisms used for the rules in the pilot. *Minimum* numbers are cited in recognition that we did not identify all critical science documents in support of some of the rules.

Who performed the critical science?

As summarized in Table 2 and detailed in Exhibit 3, critical research was performed by the private sector, EPA program offices, ORD, other Federal agencies, and other (non-Federal) government organizations (such as States). We counted work as performed by an organization if the report was under the organization's cover and did not indicate it was prepared by a contractor for the organization. If more than one organization performed the work, we counted each so the total exceeds the number of critical documents (i.e., 452).

Table 2:
Who Performed the Critical Science

Organization	No.
Private sector	238
EPA in-house - program office	95
Academia	68
EPA in-house - ORD	28
Other (non-Federal) government	25
Other Federal agency	24
Unknown	5

Program offices or their contractors developed virtually all of the technical support documents that made the scientific case for the rule (Exhibit 3). Even for the two rules where State and Federal government agencies worked on research teams to develop technical support documents (the Great Lakes water quality guidance [Case 6] and regional ozone rule [Case 13]), the EPA program offices developed the final technical support documents. EPA's ORD contributed 28 critical documents, including health criteria documents, monitoring methods, assessment protocols, engineering studies, and air quality models and field studies.

Other Federal agencies contributed 24 critical studies to the rules in the pilot. Almost half of these supported the Great Lakes water quality guidance, and involved the National Oceanic and Atmospheric Administration and the U.S. Fish

and Wildlife Service, who have research laboratories in the Great Lakes region. Other (non-Federal) government organizations contributed 25 critical studies, over half of which involved the two rules in which interstate pollution issues were the main focus (Great Lakes and regional ozone).

The large number (238) of critical science documents developed by the private sector includes both reports contracted by EPA program offices and ORD, and reports contracted by the regulated community (state and local governments, and private industry). It also includes reports completed in-house by private industry. Thus, the private sector was the most common source of the critical science behind the rules.

Who funded the critical work?

As summarized in Table 3 and detailed in Exhibit 4, EPA program offices funded the vast majority of the critical science documents. Other organizations (primarily State governments and industry) funded 100 documents. Many industry contributions involved data gathering to support the various emissions rules (e.g., pulp and paper, reformulated gasoline, and regional ozone). In some cases, the regulated industry agreed with EPA beforehand to a research or data gathering strategy. ORD funded at least 85 critical science documents, including criteria documents, early development of the model used to support the regional ozone rule, development or evaluation of monitoring methods, and research grants and cooperative agreements that produced findings that proved critical. Other Federal organizations, including the National Institutes of Health, National Science Foundation, Department of Energy, Department of Agriculture, and Department of Interior, funded the smallest number.

Table 3:
Who Funded the Critical Science

Organization	No.
EPA program office	260
Other	100
EPA ORD	85
Other Federal agency	31
Unknown	10

If more than one organization funded the work, we counted each so the total exceeds the number of critical documents (i.e., 452).

What mechanisms were used to fund the critical work?

As summarized in Table 4 and detailed in Exhibit 5, the most common funding mechanism was a contract. Contracts were used to support critical science by all funding organizations. Some reports or technical appendices were developed by contractors and delivered as finished products (Table 2). In other instances contractors gathered data, ran models, conducted analyses, provided specific

expertise, or otherwise contributed substantial input to work products that were ultimately authored by EPA program office or ORD staff. Of the 230 critical documents provided through contracts, 212 were funded by an EPA program office or ORD.

Table 4:
Funding Mechanisms for Critical Science

Type Of Mechanism	No.
Contract	230
EPA in-house	85
Other	63
Unknown	41
Grant	25
Cooperative agreement	15
Interagency agreement	2

If more than one funding mechanism was used, we counted each so the total exceeds the number of critical documents (i.e., 452).

Internal EPA funding was used by program offices to develop at least 85 of the technical support documents, including rule preambles. Since rulemaking is an inherently governmental function, program personnel should exercise control over the final application of science to the rule. The "Other" category primarily included internal funding by other Federal and other governmental organizations, particularly those who do much of their own research.

Grants and cooperative agreements by law cannot be used for the primary purpose of securing goods or services for the government, so it was not surprising that we identified them in only nine of the rules. More than half of these documents funded under assistance agreements were published eight years or more before the rule was finalized. Some of the documents were quite old. For example, an epidemiology study done in 1950, long before passage of the Clean Water Act, served as the basis for a Maximum Contaminant Level in the 1991 drinking water standards on synthetic chemicals. This suggests that much of the science funded by assistance agreements pays off many years in the future, and that it is not funded specifically to support a rule, but to address the larger environmental problem that was the target of the rulemaking.

More data and fewer "blind spots" could reduce assumptions

For 12 of the rules, respondents indicated additional science would have made their rules better. On a scale of 1 to 5, with 5 being the highest, the respondents gave the rules included in this pilot study quality scores ranging evenly between 3 and 5. Therefore, we concluded that, in the view of the EPA respondents who worked on

the rules, these were good rules that could be even better if more science had been available[4]. The most frequently expressed desires were for:

- Data on emissions rates, characterization of regulated sources, and toxicity that could lead to less uncertainty (9 rules).

- Science to fill "blind-spots" (6 rules).

Based on the responses, we concluded that having more data would have resulted in more efficient rules, because they would have required fewer conservative assumptions. Scientific "blind spots" are areas where no body of scientific research was available at the time of the rulemaking to adequately assess some of the potential risks, or the particular risk was not anticipated at the time of rulemaking. In most cases, there was a sense that while the rulemakers believed EPA was doing a good job under the circumstances, the science and data were being generated under undue pressure. The desire for additional scientific information in so many of the rules included in this pilot study suggests this desire may be common to many Agency rulemakings.

Critical science supporting the rules often was not independently peer reviewed

A regulation itself is not subject to EPA's peer review policy, even though the major scientific work products that support it are subject to peer review. Public comments are taken on almost all regulatory actions, but according to the *Peer Review Handbook*, public comment does not substitute for peer review. This is because public comment does not necessarily draw the kind of independent, expert information and in-depth analysis expected from a peer review. Nonetheless, we were told by EPA staff members involved in 6 of the 15 case studies, that their documents did not require peer review because they had been subjected to public comment. As noted in the Response to Comments, we acknowledge that the guidance on this issue has been evolving over the decade in which the rules in the case studies were finalized.

[4] These scores do not reflect input from peer reviewers, environmental organizations, or the regulated community, and they should not be assumed to hold true for EPA's rules in general.

A large number (276) of the critical documents supporting the rules either were not peer reviewed (144) or their peer-review status was indeterminate (132). Details on peer review actions are summarized in Table 5 and Exhibit 6. Lack of peer review, or of information about peer review, may cast doubt on the quality of this science.

Table 5:
Peer Review Actions

Actions	No.
No peer review was done	144
Unknown whether a peer review was done	132
Peer review was done by an external group in a non-public manner, such as a refereed journal or external experts hired by EPA	119
Peer review was publicly done by a Federal advisory committee, such as the Science Advisory Board or National Research Council	29
Peer review was done by some other public review process by external experts	17
Independent internal EPA review done, such as through the risk assessment forum or by having ORD review a program office's document	11

EPA has a database – the Peer Review Product Tracking System – to track peer review of its scientific and technical work products. It is a single repository for product-specific peer review reporting and tracking, and uses a common reporting form for all entries. Work products that were completed since 1991 should be reported in one of four categories:

List A: Work products for which peer review was completed.
List B: Candidate work products for future peer review.
List C: Work products not subject to peer review.
List D: Scientific articles or reports by EPA staff that were peer reviewed outside EPA.

This database should be the primary means of tracking the present, past, and future peer review status of the critical science documents identified in the pilot. However, we could find very few of these documents in this database. We searched the database using combinations of titles and keywords for documents supporting the 10 cases included in this pilot study with rules finalized since 1994. We were able to find only 4 of the 272 critical documents for these rules:

- Two technical support documents for the pulp and paper National Emission Standard for Hazardous Air Pollutant (NESHAP) marked "peer review not needed."

- The primary modeling technical support document for the regional ozone rule, listed as Category "C" (a non-major scientific/technical product), marked "peer review not needed."

- The BEIS2 model, a critical document in the regional ozone rule listed as category "C," marked "peer review not needed."

The peer review status for these documents was signed off on as "complete" by the requirements reviewer from the ORD's Office of Science Policy. We also searched on "DBP," "disinfection," and "chlorinated," and found several entries related to the disinfectant and byproducts rule, including studies of by-products resulting from ozonation; a 1994 regulatory impact assessment; engineering and cost studies; and a study on cancer and chlorinated drinking water. However, these entries did not correspond by title or date to any of the 59 critical documents identified by the primary contacts and ORD scientists, so we were not sure whether these documents ultimately were superceded by publication in different form or later versions.

We concluded that: there was little correspondence between the entries in the Peer Review Product Tracking System and the items in the docket; keyword searches were not effective in identifying the important science behind the rules included in this pilot study; and there was no consistency in the classification of items in the database, either with respect to their importance, intended use, or need for peer review. Therefore, we determined that oversight of peer review of the critical science documents to support the rules included in this pilot study was limited and ineffective.

Suggestions

We offer the following suggestions to the Associate Administrator for Policy, Economics, and Innovation, and to EPA's Science Advisor, regarding science behind EPA's rulemaking:

1. Consider presenting the scientific findings that support a rule in specific sections of the preambles. These findings should be organized according to the norms of science, in summary form, and indicate:

    - Why the science is required to support the rule, and how the results will be used.
    - The methods used.
    - The important results (showing key data and their uncertainty).
    - Interpretation of the findings, and comparison with other studies that appear to support or contradict the results.
    - Scientific referencing of underlying scientific and technical documents.

- A separate section of the preamble that would bring in issues of law, policy, economics, and administrative discretion that *do not depend on* the scientific findings.

2. Focus more attention in the development phase of regulations on collecting data and doing research to address "blind spots" to support rulemakings.

3. Take advantage of EPA's information technology capabilities to:

   - Hotlink references in preambles to documents in the docket.
   - Link scientific and technical documents in the docket to the Science Peer Review Database.
   - Link RAPIDS to the Science Peer Review Database.
   - Maintain through RAPIDS an inventory of all rules proposed and finalized each year.

4. Reinforce EPA's current peer review policy, ensuring that *all* EPA-generated documents critical to significant and substantive rulemakings are independently peer reviewed, and that the responses to the significant comments appear in the documents.

Agency Comments

OPEI, the EPA organization responsible for oversight of the Agency's regulatory activity, provided comments on the draft report, as did the Office of Water (OW); the Office of Prevention, Pesticides and Toxic Substances (OPPTS); and the EPA Science Advisor. The Office of Air and Radiation (OAR) and the Office of Solid Waste and Emergency Response (OSWER) provided informal comments. Many of the comments led to improvements in the clarity and factual accuracy of the report. In general, the comments supported the suggestions in the draft report, but identified both opportunities and concerns regarding details of their implementation. The comments are included in their entirety in Exhibits 7-10, but we summarize the main points in this section.

On behalf of EPA, OPEI commented:

> The report does an excellent job of recognizing Agency institutional mechanisms which ensure that regulations are based on sound science. The role of peer review and the peer review process in the development of credible science is discussed in depth, and the Office of Policy, Economics and Innovation (OPEI) agrees with the heavy emphasis the report places on the utility and importance of independent peer review. Not emphasized are two other key "good science" processes: Analytic Blueprints and the Risk Characterization Policy. The former was designed, in part, to ensure that critical science needs are identified early in the process and developed in

time to inform regulatory decisions, and the latter requires that both the risk assessment process and risk the analyses are transparent, clear, reasonable and consistent. Taken together, these three existing mechanisms can assure that:

- Critical science is identified early, and developed in time to inform decisions (Analytic Blueprint),

- Critical science is of sufficient quality for regulatory decision making (Peer Review Process),

- The quality of the science and the associated uncertainty is clearly described (Risk Characterization Policy).

Further, these three mechanisms appear to directly address three of the four findings of your report, i.e., that critical science supporting the rules often was not independently peer reviewed, that more data and fewer "blind spots" could reduce assumptions, and that the role of science (was) not made clear. Your report "determined that the oversight of peer review of the critical science documents to support the pilot rules was limited and ineffective." Applying the same logic suggests that shortfalls in identifying critical data needs, and the lack of transparency and clarity in science is due to inefficiencies or limitations in the two Agency processes intended to identify, develop and make critical science transparent.

The OPEI comments go on to address each of these issues. We have also incorporated the significant comments from the other EPA Programs and the EPA Science Advisor.

With regard to **the presentation of science in the preambles,** OPEI recommended that we consider using EPA's risk characterization policy as a framework for presenting the results and suggestions in the report. They said:

Some of the science supporting rulemaking deals with health and environmental risks. EPA adopted its policy on "Risk Characterization" in February 1992, via a memorandum from Henry Habicht, Deputy Administrator, and an accompanying document, prepared by a cross-office work group. The policy was reiterated and elaborated in the mid 1990s. At its core, the policy states that significant risk assessments should:

- Describe how the estimated risk is expected to **vary** across population groups, geographic areas, or other relevant break-outs,

- Describe the sources of **uncertainties** in the risk estimates, and quantify them, to the extent possible, and

- Explicitly identify the impact of **science and data, as opposed to policy choices**, as the source of various elements of the risk assessment.

We have found that this standard has been followed in an incomplete fashion in documents supporting regulations, as well as other EPA risk assessments. The draft Office of the Inspector General (OIG) report refers repeatedly to the second and third elements of EPA's Risk Characterization Policy, both in describing its findings and in its recommendations. We recommend that OIG examine this policy (in effect during most of the time period covered by the pilot study), and use it as a framework for presenting its results and suggestions.

The EPA Science Advisor strongly agreed:

The key issue is that the preamble should present a clear summary of the science supporting the regulatory decision, including properly characterizing risks and the supporting science for risk management. The preamble should list the documents from which its science-based statements are made and the docket should contain the complete record. This would allow readers to refer to the source material, including the original primary science documents referenced in the critical documents (using "primary document" as traditionally used in the science community).

OPEI also brought up EPA's new Information Quality Guidelines, which were recently implemented:

This suggestion is consistent with the Agency's efforts related to the use of and dissemination of information covered by the new Information Quality Guidelines (IQ Guidelines). ....[The Act] direct[s] Federal agencies to:

- adopt a basic standard of quality as a performance goal and take appropriate steps to incorporate information quality criteria into agency information dissemination practices; [and]

- issue guidance for ensuring and maximizing the *quality, objectivity, utility,* and *integrity* of information disseminated by the agency; establish administrative mechanisms allowing affected persons to obtain correction of information that does not comply with the guidelines....

OPEI believes that a full implementation of the IQ Guidelines will improve the Agency's performance related to its discussion regarding the use of science in rulemakings. This is also an area where OPEI and ORD together can develop more complete recommendations regarding the presentation of

scientific findings in preamble discussions. OPEI and ORD are both increasing their presence in Agency rulemakings as a result of last year's Task Force on Improving Regulation Development. OPEI believes that this increased participation by ORD and OPEI analysts will improve the attention to and discussion of the results of the underlying analysis, including but not limited to science, used to support EPA regulations could be improved. This discussion would be consistent with the IQ Guidelines, existing policies such as the risk characterization policy, and some of the key findings of your report.

Finally, OPEI suggested developing "Principles of Analytic Integrity":

> Recently, the Administrator reaffirmed the "Princip[le]s of Scientific Integrity" establishing clear and ethical standards that should govern the conduct of scientific studies within the Agency. To date, there is no parallel document establishing standards for the use of research in a policy analytic setting. OIG may wish to recommend that such a document be developed expanding on its recommendations for clarity of presentation, etc. and drawing on other Agency guidelines such as *The Guidelines for Preparing Economic Analyses.*

There was considerable comment from the program offices on exactly how the science in the preambles should be presented.

OW commented:

> We believe there is merit in the proposal to improve the consistency of the presentation of scientific data and conclusions in regulatory preambles. However, more work is needed to determine how to implement such a proposal given the wide variety of types of regulations the Agency develops. We also need to consider the impact on the cost of developing rules and on the length of preambles.

OW also noted:

> Depending on statutory requirements for a given rule, the optimal preamble structure for communicating the role of science may be quite different. Any recommendations to revise the format for rule preambles across the Agency should be flexible and take this consideration into account. To achieve the same objectives of the report, we recommend modifying the recommendation to suggest that norms of science be applied consistently throughout current preamble formats where science is discussed, in order to improve the understanding of the scientific basis for rules.

OPPTS commented:

> The preamble to the rulemaking is not, nor has it ever been, considered the proper vehicle for communicating the science in the manner prescribed on page 11 [page 12]. The proper vehicle for communicating the science in that detail is in separate documents that are made available to the public as part of the rulemaking docket, with a general description provided in the preamble. The preamble must provide a layman's explanation of the basis for the rulemaking, including the science, economic and technical analyses and other considerations that informed the decisions represented in the rulemaking.
>
> The suggested addition of these science discussions in the preamble is cost prohibitive and impractical..... most stakeholders consulted in 1994, when we evaluated the level of detail, format, and function of the preamble as part of the government wide streamlining initiative, indicated that they prefer for the preamble to contain a succinct summary of the science, economic and technical analyses and other considerations that went into the rulemaking. This allowed those responsible for or interested in the different disciplines to obtain a general understanding of all of these considerations, as well as the details of the one of most interest to them. Since the primary audience for the rulemaking is not the scientists, including the detailed scientific information in the preamble would not serve as an effective way to communicate the scientific information to the primary audience.

The EPA Science Advisor agreed:

> .... while Agency preambles should effectively communicate the scientific underpinnings of the rules, the description of the professional norms for such communication is not accurate. The norms as described accurately reflect how scientists communicate in their primary documents, but not how science is communicated in what is described as critical primary documents.

OAR, while in broad agreement with the other comments, provided the following caveat, "However, noting that the preamble to a rule may be the only source of background data that our stakeholders read, it would seem appropriate to ensure that a complete (albeit brief) discussion of the critical science is included in future rulemakings as suggested..."

With respect to **focusing more attention in the development phase of regulations on collecting data and doing research to close "blind spots" to support rulemakings,** OPEI commented:

> The purpose of an analytic blueprint is to identify research needs and guide data collection and research studies during the development phase of

> regulations. While a requirement for developing, updating, and following an "analytic blueprint" has been a formal part of EPA's rule-making process for more than a decade, it has been OPEI's experience that most analytic blueprints are treated as little more than formalities. As a result of last year's review and reassessment of EPA's rule-making process, OPEI and the program offices are taking steps to make the blueprints more central and relevant to actual rule-making decisions. We suggest that the OIG report consider referring to the analytic blueprints as one means to achieve the results desired in (this) suggestion.

None of the other comments spoke of the analytic blueprint process. However, OW commented:

> Many EPA regulations are based on years of research and data gathering by EPA, other Federal agencies, academia, and industry. For example, we have been working on the arsenic drinking water standard steadily since the 1970s. OW and other programs have extensive processes of joint planning with ORD and outside stakeholders to anticipate information needs as much as possible. Yet, there are always data gaps and uncertainties which we must grapple with. This is in the nature of the rulemaking enterprise. While the Pilot Study cited respondents who said they would have liked to have had more data, it did not identify any particular ways of obtaining it without increasing costs or slowing down action. Allocating resources to closing "blind spots" means something else will not be done, and delaying action means the status quo will continue.

OW also noted that:

> The 1996 SDWA Amendments require EPA to use "the best available, peer-reviewed science and supporting studies conducted in accordance with sound and objective scientific practices" when setting drinking water standards (sec. 1412 (b)(3)(A)). The US Court of Appeals for the District of Columbia Circuit determined that Congress's intent was best available evidence at the time of rulemaking.

They noted that otherwise, "it could also negatively impact the ability to meet statutory deadlines."

The EPA Science Advisor commented that ORD is increasing its involvement in the Agency's decision-making process.

With respect to the suggestion to **take advantage of EPA's information technology capabilities,** OPEI commented about the characterization of the RAPIDS data base and its capabilities:

RAPIDS tracks all substantive rulemakings appearing in the *Semi-Annual Regulatory Agenda* as well as a number of actions not in the Agenda, such as Reports to Congress, Policy Plans, etc. RAPIDS does not track every non-substantive rulemaking (SIPs, SNURs, FIPs, State Approvals, etc.), but a sister database to RAPIDS (Federal Register Tracking Database - FR Dailies), also maintained by OPEI's Regulatory Management Staff (RMS), tracks *every* EPA action sent to and published in the Federal Register. These rules are not economically significant or normally reviewed by OMB and therefore are classified as "not significant."

RAPIDS records go back a number of years (1996 forward) with some rulemaking records from earlier years available. RAPIDS also tracks NPRMs published in many of those same years. The Regulatory Management Staff (RMS) has built numerous views in RAPIDS and has a view (list) of rules finalized each year.

The report seems to confuse or not clearly differentiate between "significant" rulemakings (those OMB reviews) and "economically significant rulemakings" (economic impact of greater than $100 million per year). RAPIDS separates out those rules identified as "economically significant." This designation has only been in effect for rules in the *Semi-annual Regulatory Agenda* as Priority "A" (Economically Significant) since 1995. Although for years before 1995, it is more difficult to clearly identify economically significant rules, RAPIDS identifies 50 final rules as economically significant for the years 1994-2001 and can produce lists of economically significant rules published final for the years 1990 to the present.

OPEI went on to say:

OPEI is currently evaluating and enhancing RAPIDS in order to improve the management information that is available or potentially obtainable. To date, RAPIDS has focused on tracking regulation development progress and facilitating EPA's submission of its portion of the *Semi-Annual Regulatory Agenda* to OMB. OPEI is interested in adding features that enhance management accountability and improved performance metrics. RAPIDS currently links to relevant guidance and policy documents. OPEI will continue to improve RAPIDS and seek to take advantage of other information technology capabilities over the next year. Much of this work will be coordinated through the Regulatory Steering Committee or Regulatory Policy Council. We will follow up with you over the next several months to more fully understand these recommendations and identify what specific changes or opportunities we can adopt.

OW commented, "We support the report's third recommendation to make better use of the Agency's information technology capabilities. Consistent use of these tools throughout the rulemaking process will improve communication and access to the critical scientific support documents," and that, "We would support an effort to identify and implement ways to improve the information the Agency makes available on rulemaking."

OAR commented that:

> The value of the new Science Inventory Database is obvious. An up-to-date, searchable system (as is in place currently) is a valuable tool when researching the science behind rulemaking.....[but that] the Science Inventory database was designed to be a "data-lean" system which provides enough information to direct the reader to the correct source for more details; it was not designed to be the repository of all information related to critical documents, especially those not issued by EPA. Whether or not this system should be linked to other databases should be the subject for the Science Inventory Work Group to consider.

OPEI commented on **reinforcing EPA's current peer review policy** ensuring that *all* EPA-generated documents critical to significant and substantive rulemakings are independently peer reviewed, and that the responses to the significant comments appear in the documents:

> OPEI fully supports this recommendation on peer-review of critical documents and in fact has recently extended this peer-review policy to include economic analyses. OPEI is working closely with the Agency's Program Offices to ensure that a full review of supporting economic analyses for all economically significant rules occurs prior to the rule's submission to OMB. In this way, the application of sound and consistent economic practices is ensured and the Agency's position on the use of sound science strengthened.

With respect to the Agency's peer review policy, OW commented:

> We support the report's fourth suggestion to reinforce the Agency's peer review policy. Because the current policy does not explicitly require peer review, it may be appropriate to recommend updating the policy to require peer review in certain situations to ensure it is applied more consistently across the Agency.

OW further commented:

> EPA's Peer Review Policy was first issued in 1992, after some of the rules considered in the Pilot Study. Full implementation has taken time and

> continuous effort. Thus, it would not be surprising that compliance was limited in the earlier period, but we would hope that it had been improving as we approach the present time. Unfortunately, the report does not present information on peer review performance over time, so we cannot tell whether this has happened.

OSWER also commented on the changing peer review guidance over the course of the study, and urged that we appropriately caveat that fact in the summary of the report. In fact, they questioned whether the observations on peer review were meaningful, given that we did not compare the peer review status of the documents with the policy then in effect.

The EPA Science Advisor commented, "I am concerned about the OIG's finding.... that critical science supporting the rules often was not peer reviewed. I plan to review the Agency's progress in implementing its Peer Review Policy during the coming year."

On a more general note, the EPA Science Advisor also stated:

> .... the Administrator named me to serve as the Agency's Science Advisor. I take this role very seriously and plan to make important strides in ensuring that Agency decisions are based on sound science, and that science is presented and characterized properly in our rules and other important documents.

Response to Agency Comments

The OPEI, the program offices, and the EPA Science Advisor were in general agreement with our suggestions, but expressed some concerns about details regarding their implementation. Even better, it appears that the mechanisms are in place, and some steps have been taken, to make substantial progress in implementing them. We believe that the observations in the report may serve as a baseline against which progress can be charted.

We have incorporated many of the specific Agency comments directly into the report and its Addendum to improve their clarity and factual accuracy. We made corrections in several of the case studies that led to small changes in the overall statistics on the critical documents, but they did not significantly alter the qualitative observations or the suggestions. To simplify the report, we dropped the distinction between primary and secondary documents that appeared in the draft report. We also added an explanation of the different levels (one, two, and three) of documents we reviewed.

Several questions were raised about the treatment of economics in the pilot study. We had considered dealing with economics as thoroughly as the biological and

physical sciences in the pilot study. Initial perusal of the primary economic studies (e.g., cost-benefit analyses and regulatory impact analyses) tended not to reveal many citations from the primary literature. Consequently, we only included critical economics documents when they obviously had an impact on the rule (i.e., using the same criteria used for critical science documents) and did not cite any of the references contained therein. We agree with the OPEI comments that economic science is as critical as the physical, biological, and engineering sciences, and refer the reader to a recent report, *Economic Analyses at EPA: Assessing Regulatory Impact*[5], that includes analyses of two of the rules (case studies 5 and 6) in the pilot study.

Rather than making changes in the suggestions based on the comments, given the generally positive responses to them, we have chosen instead to view the Agency responses as a road map toward acting on them. In that spirit, we are responding more specifically to the comments on the four suggestions.

We understand that preambles (as the embodiment of what is essentially a legal process) cannot take on the appearance of a science journal, or be extended by many pages to provide extensive graphs and data tabulations. Well-organized, well-referenced, and peer reviewed technical support documents that carry the weight of the scientific underpinnings of the rule are suitable for this task. We do believe, however, that the critical scientific underpinnings of EPA's rules should be explained, in plain English, in terms of the methods used to gather data, the results obtained, and the applicability and uncertainty associated with their application to the rule. There are examples of good practices in communicating the scientific basis for regulations in many of the preambles of the rules in the pilot study, and we encourage OPEI to work with the programs and the Science Advisor to bring all preambles up to the highest standard possible. Referencing of this science (including economics) should be as careful as the legal referencing in the preambles.

Also related to presentation of the role of science, we agree with the Agency comments that effectively implementing the Risk Characterization Guidelines should improve the explanation of the application of science to regulatory decisions. We would add that even though the Guidelines focus on risk assessments, the principles apply as well to science and technology applications that do not involve risk (e.g., establishment of the maximum achievable control technology for the Pulp and Paper NESHAP, or even the adoption of monitoring technology in the Acid Rain regulation). We agree that the new Information Quality Guidelines should have a positive influence on the application of science to regulations. We urge OPEI and the Science Advisor to pursue the concept of developing a "Principles of Scientific Integrity" document, as suggested by OPEI.

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5 Morganstern, R. [Ed.]. 1997. Resources for the Future: Washington, DC

We agree with OPEI that the regulatory blueprint represents an opportunity to identify and close science and data gaps during the relatively short period between the time a rulemaking is initiated and the final rule is proposed. Many of the rules in the pilot study demonstrate how much can be accomplished during this period. We urge OPEI and the Science Advisor to ensure that regulatory blueprints are "more than formalities" in the future, and that they become central to identifying the scientific data and analyses needed to support the regulation, and to plan and ensure their independent peer review. The statistics on the critical science documents funded under assistance agreements (grants and cooperative agreements) suggest that Requests for Assistance must be planned 5-8 years in advance of proposed rulemakings, which may be too late for regulatory blueprints. ORD's multi-year planning process must take this time lag into account in planning research that may be supportive of rulemaking in the future. We also note that it was not just science gaps, but *data* gaps, that were highlighted by many of the contacts in the pilot study. Monitoring data were often as important as research in supporting the rulemakings in the pilot study (e.g., Cases 1, 3, 7, 9 and 13).

We are encouraged that OPEI has made improvements to RAPIDS since we began the pilot study, and that several of the programs agree that integrating and linking EPA's databases on regulation, science, and peer review would be helpful. We have one caveat, however. OPEI commented that the FR Dailies database now allows identification of all EPA rules, significant and otherwise, and that RAPIDS now identified 50 economically significant rules (greater than $100 million/yr) finalized since 1994. We had identified only 37 in the draft report. We checked the list in the pilot against RAPIDS, and based on the information in the preambles relating to Executive Order 12866, we determined that we failed to identify one of the rules in Exhibit 1 as economically significant, and one more was questionable (the expected impact was $99 million the first year to the economy and $1 million to EPA, and $50 Million/yr thereafter). We changed the listings in Exhibit 1 to reflect these errors. However, we determined that 11 of the rules in RAPIDS were not economically significant, and that two economically significant rules were missing for this period. This reflects the human factor in information management - information management systems are only as good as the quality of the data that are input by the people who use them. We encourage the Agency teams developing and integrating RAPIDS, the Science Inventory, and the Peer Review Databases to not lose sight of this critical fact.

Finally, we are encouraged that OPEI, the programs, and the EPA Science Advisor are in agreement about the need for more consistent independent peer review. Three of the programs raised the point that EPA's peer review guidelines were in flux during the ten years of rulemaking covered by the pilot study, and that we should have taken that fact into account in interpreting the peer review statistics. One program office even questioned whether the observations about peer review had any validity, under those circumstances. It was beyond the scope of the pilot study to compare Agency practice with then-current guidance, and we made no

such observation. Rather, the statistics should be seen as a baseline against which progress may be measured. The EPA Science Advisor commented, "I am concerned about the OIG's finding.... that critical science supporting the rules often was not peer reviewed. I plan to review the Agency's progress in implementing its Peer Review Policy during the coming year." We encourage the Science Advisor in his efforts regarding peer review and his commitment to ensure that Agency decisions are based on sound science.

Pilot Lessons Learned

We conducted the pilot study to determine whether a full study could provide answers to the questions in the introduction to this report and, if so, the level of resources required. Proceeding with a full study would be resource-intensive. We had intended for the pilot study to be completed in four months with less than half a staff year of effort. Because we were not able to get timely responses to our e-mail queries, and because it proved harder than we expected to determine funding sources and peer review, the field phase of the pilot took 10 months and 1.5 staff years, and we were still unable to identify all of the critical science documents and their corresponding data for the 14 rules. For those reasons, we do not intend to pursue a full study at this time.

However, if such a study were to be pursued at some future date, we believe:

- Developing a list frame for a target population of substantive or minor rules is not straightforward given the current capabilities of RAPIDS. We were not able to confirm that it would be possible to easily identify using RAPIDS, a target population of rules, either current or past, on which to conduct any future studies. An alternative would be to draw sample rules out of RAPIDS (or the *Federal Register* for older rules). This approach would have to be pilot tested.

- There should be strict decision criteria for defining critical documents, and there should be periodic group review and agreement about which documents meet the criteria.

- A decision should be made about how far back in the decision process for a rule you can go before you can no longer determine with confidence that a science document was critical, but you should go back at least that far.

- Interviews should be conducted with all parties involved with the rulemaking. Special effort should be made to interview peer-reviewers and stakeholders. E-mail is not an effective mechanism to elicit detailed responses.

- There should be follow-up interviews with all respondents, asking them to confirm preliminary information about each document.

- There should be at least one research scientist on the team to facilitate identifying critical documents.

- There should be an advisory committee of scientists who understand both research and rulemaking, to assist the review team.

- All the pertinent documents applicable to rulemaking during the period covered should be reviewed, including the preamble to the proposed rule. Critical science identified in the proposed rule was not always cited in the preamble to the final rule, or in the major technical support documents.

- A different method would need to be devised to address the original questions regarding research planning and rulemaking outcomes.

Exhibit 1

Significant Rules Finalized – 1990-2001

[ ] = Rule in pilot study $ = Rule is significant because of its economic impact

Year	Act	Title	Citation	$
1990	RCRA	Land Disposal Restrictions for "Third Third" Schedule Wastes	55 FR 22520	$
1990	CAA	Volatility Regulations for Gasoline and Alcohol Blends Sold in Calendar Years 1992 and Beyond	55 FR 23658	$
1991	SDWA	NPDWR (National Primary Drinking Water Regulations): Synthetic Organic Chemicals and Inorganic Chemicals; Monitoring for Unregulated Contaminants; NPDWR Implementation; NPDWR Regulations	56 FR 3526	$
1991	RCRA	Solid Waste Disposal Facility Criteria	56 FR 50978	$
1991	CAA	Standards of Performance for New Stationary Sources: Municipal Waste Combustors	56 FR 5488	$
1991	CAA	Tier 1 Light-Duty Tailpipe Standards and Useful Life Requirements	56 FR 25724	$
1992	CAA	Operating Permits Regulations Title V of the Clean Air Act	57 FR 32250	$
1993	CAA	Accelerated Phaseout of Class I & II Ozone Depleting Substances and Methyl Bromides	58 FR 65018	$
1993	CAA	Acid Rain Permits, Allowance System, Emissions Monitoring, Excess Emissions and Appeals Regulations Under Title IV of the Clean Air Amendments of 1990	58 FR 3590	$
1993	CAA	Conformity of General Federal Actions to State Implementations Plans	58 FR 63214	$
1993	CAA	Control of Air Pollution from New Motor Vehicles and New Motor Vehicle Engines, Regulations Requiring on-Board Diagnostic Systems on 1994 and Later Model Year Light-Duty Vehicles	58 FR 9468	$
1993	CAA	Evaporative Emission Regulations for Gasoline-Fueled and Methanol-Fueled Light Duty Vehicles, Light-Duty Trucks, and Heavy Duty Vehicles	58 FR 16002	$
1993	CWA	Oil and Gas Extraction Point Source Category, Offshore Subcategory, Effluent Limitations Guidelines and New Source Performance Standards	58 FR 12454	$
1993	RCRA	Corrective Management Units (CAMU)	58 FR 8658	
1994	CAA	Control of Air Pollution: Determination of Significance for Nonroad Sources and Emission Standards for New Nonroad Compression-Ignition Engines at or above 37 Kilowatts	59 FR 31306	
1994	CAA	Fuel and Fuel Additives: Standards for Reformulated Gasoline	59 FR 7716	$
1994	RCRA	Land Disposal Restrictions - Phase II - Universal Treatment Standards, and Treatment Standards for Organic Toxicity Characteristics	59 FR 47982	$
1994	CAA	List of Substances and Threshold Quantities for Accidental Release Prevention	59 FR 4478	$
1994	CAA	NESHAP: Source Categories: Organic Hazardous Air Pollutants from the Synthetic Organic Chemical Manufacturing Industry (SOCMI) and Other Processes Subject to the Negotiated Regulation for Equipment Leaks	59 FR 19402	$

Year	Act	Title	Citation	$
1994	CAA	On-Board Control of Refueling Emissions from Light Duty Vehicles and Light Duty Trucks	59 FR 16262	
1994	CAA	Organic Air Emission Standards for Tanks, Surface Impoundments, and Containers at Hazardous Waste Treatment, Storage, and Disposal Facilities and Hazardous Waste Generators	59 FR 62896	$
1994	CAA	Renewable Oxygenates for Reformulated Gasoline	59 FR 39258	
1994	EPCRA	Toxic Chemical Release Reporting, Community Right-to-Know	59 FR 61432	
1995	CAA	National Emission Standards for Chromium Emissions From Hard and Decorative Chromium Electroplating and Chromium Anodizing Tanks	60 FR 4948	
1995	CAA	Emission Standards for Marine Tank Vessel Loading Operations	60 FR 48388	$
1995	CAA	New Source Performance Standard (NSPS): Municipal Waste Combustion - Phases II and III (Large Units)	60 FR 65381	$
1995	CAA	Ozone Transport Commission: Emission Vehicle Program for Northeast Ozone Transport	60 FR 4712	$
1995	CWA	Water Quality Guidance for Great Lakes System	60 FR 15366	$
1995	CAA	NESHAP: Petroleum Refineries	60 FR 43244	
1995	CWA	Water Quality Standards for San Francisco Bay and Delta	60 FR 4664	
1996	CAA	Acid Rain Program: Phase II Nitrogen Oxides Reduction Program	61 FR 67112	$
1996	CAA	Control of Emissions of Air Pollution: Emission Standards for Gasoline Spark-Ignition and Diesel Compression-Ignition Marine Engines	61 FR 52087	$
1996	CAA	Federal Test Procedure for Emissions From Motor Vehicles and Motor Vehicle Engines: Review	61 FR 54851	$
1996	RCRA	Land Disposal Restrictions - Phase III: Decharacterized Wastewaters, Carbamate Wastes, and Spent Aluminum Potliners	61 FR 15566	$
1996	CAA	NSPS: Municipal Solid Waste Landfills Amendments	61 FR 9905	
1996	CAA	Regulation of Fuel and Fuel Additives: Certification Requirements for Deposit Control Additives	61 FR 35310	$
1996	TSCA	Lead: Requirements for Disclosure of Known Lead-Based Paint and/or Lead-Based Paint Hazards in Housing	61 FR 9064	
1996	TSCA	Lead: Requirements for Lead-Based Paint Activities in Target Housing and Child-Occupied Facilities	61 FR 45788	
1996	CAA	Risk Management Program for Chemical Accidental Release Prevention	61 FR 31668	$
1996	CWA	Oil and Gas Extraction Point Source Category: Final Effluent Limitations Guidelines and Standards for the Coastal Subcategory	61 FR 66085	
1996	CAA	SO2 NAAQS Review and Implementation Plan	61 FR 25566	
1997	CAA	National Ambient Air Quality Standards for Particulate Matter	62 FR 38651	$
1997	CAA	Compliance Assurance Monitoring Rule (Previously Enhanced Monitoring Rule)	62 FR 54900	
1997	CAA	Hospital/Medical/Infectious Waste Incinerators	62 FR 48348	$
1997	CAA	NAAQS: Ozone	62 FR 38856	$
1997	CAA	Protection of Stratospheric Ozone (Motor Vehicle Air Conditioners)	62 FR 68026	
1997	TSCA	Microbial Products of Biotechnology	62 FR 17910	
1997	CAA	Transportation Conformity Rule Amendments: Flexibility & Streamlining	62 FR 43780	
1997	CAA	Control of Air Pollution From New Motor Vehicles and New Motor Vehicle Engines: Voluntary Standards for Light-Duty Vehicles	62 FR 31191	$
1998	CAA	Control of Emissions of Air Pollution From Nonroad Diesel Engines	63 FR 56967	$

Year	Act	Title	Citation	$
1998	CAA	Finding of Significant Contribution and Rulemaking for Certain States in the Ozone Transport Assessment Group (OTAG) Region for Purposes of Reducing Regional Transport of Ozone	63 FR 57355	$
1998	CAA, CWA	Integrated NESHAP and Effluent Guidelines: Pulp and Paper	63 FR 18504	$
1998	CAA	Locomotive Emission Standards	63 FR 18977	$
1998	RCRA	Land Disposal Restrictions Phase IV: Final Rule Promulgating Treatment Standards for Metal Wastes and Mineral Processing Wastes; Mineral Processing Secondary Materials and Bevill Exclusion Issues; Treatment Standards for Hazardous Soils, and Exclusion of Recycled Wood Preserving Wastewaters	63 FR 28555	
1998	SDWA	NPDWR: Stage I Disinfectant/Disinfection By-Products Rule	63 FR 69389	$
1998	TSCA	Lead: Requirements for Hazard Education Before Renovation of Target Housing	63 FR 29908	
1998	TSCA	Polychlorinated Biphenyls (PCBs) Disposal Amendments	63 FR 35384	
1998	SDWA	NPDWR: Interim Enhanced Surface Water Treatment	63 FR 69477	$
1998	CWA	Pharmaceutical Manufacturing Category Effluent Limitations Guidelines, Pretreatment Standards, and New Source Performance Standards	63 FR 50387	$
1998	SDWA	NPDRW: Consumer Confidence Reports	63 FR 44511	
1999	CAA	Findings of Significant Contribution and Rulemaking on Section 126 Petitions for Purposes of Reducing Interstate Ozone Transport	64 FR 28250	$
1999	CWA	National Pollution Discharge Elimination System (NPDES) Comprehensive Storm Water Phase II Regulations	64 FR 68722	$
1999	CAA	Acid Rain Program: Continuous Emissions Monitoring Rule Revisions	64 FR 28564	
1999	EPCRA	TRI: Reporting Threshold Amendment for Certain Persistent and Bioaccumulative Toxic Chemicals (PBTs)	64 FR 58666	$
1999	CWA	Underground Injection Control Regulations for Class V Injection Wells, Revision	64 CR 68545	
1999	CWA	NPDES: Regulations for Revision of the Water Pollution Control Program Addressing Storm Water Discharges	64 CR 68721	$
1999	CWA	Water Quality Standards: Establishment of Numeric Criteria for Priority Toxic Pollutants; States' Compliance--Revision of PCBs Criteria	64 FR 61181	$
1999	CWA	NPDES Permit Application Requirements for Publicly Owned Treatment Works and Other Treatment Works Treating Domestic Sewage	64 CR 42433	$
2000	CAA	Control of Emissions of Air Pollution from 2004 and Later Model Year Heavy-Duty Highway Engines and Vehicles: Revision of Light-Duty Truck Definition	65 FR 59895	$
2000	CAA	Nonroad Spark-Ignition Engines At or Below 19 Kilowatts (25 Horsepower) (Phase 2)	65 FR 24267	$
2000	CAA	Protection of Stratospheric Ozone: Incorporation of CAA for Reduction in Class I, Group VI Controlled Substances	65 FR 70795	$
2000	RCRA	Hazardous Waste Management System - Identification & Listing - Chlorinated Aliphatics Production Waster, Land Disposal Restrictions, CERCLA	65 FR 67067	
2000	CAA	Rulemakings for the Purpose of Reducing Interstate Ozone Transport	65 FR 2674	

Year	Act	Title	Citation	$
2000	CAA	Tier II Light-Duty Vehicle and Light-Duty Truck Emission Standards and Gasoline Sulfur Standards	65 FR 6698	$
2000	SDWA	NPDWR: Radionuclides	65 FR 76707	
2000	CWA	Effluent Limitations Guidelines, Pretreatment Standards, and New Source Performance Standards for the Centralized Waste Treatment Point Source Category	65 FR 81241	
2000	CWA	Effluent Limitations Guidelines, Pretreatment Standards, and New Source Performance Standards for the Transportation Equipment Cleaning Point Source Category	65 FR 49665	
2000	CWA	Revisions to the Water Quality Planning and Management Regulation and Revisions to the NPDES Program in Support of Revisions to the Water Quality Planning and Management Regulation	65 FR 43585	
2001	CAA	Heavy-Duty Engine Emission Standards & Diesel Fuel Sulfur Control Requirements	66 FR 5002	$
2001	TSCA	Lead: Identification of Dangerous Levels of Lead Pursuant to TSCA Section 403	66 FR 1205	$
2001	FIFRA	Plant-Incorporated Protectants	66 FR 37772	
2001	CAA	NESHAP: Chemical Recovery Combustion Sources at Kraft, Soda, Sulfite and Stand-Alone Semichemical Pulp Mills	66 FR 3179	$
2001	CWA	Further Revisions to the CWA Regulatory Definition of Discharge of Dredged Material	66 CR 4549	
2001	SDWA	NPDWR: Arsenic and Clarifications to Compliance and New Source Contaminants Monitoring	66 FR 6975	$
2001	CWA	Effluent Limitations Guidelines and New Source Performance Standards for the Oil and Gas Extraction Point Source Category; OMB Approval Under the Paperwork Reduction Act: Technical Amendment	66 CR 6849	
2001	SDWA	NPDWR: Filter Backwash Recycling Rule	66 FR 31085	
2001	CWA	NPDES: Regulations Addressing Cooling Water Intake Structures for New Facilities	66 FR 65256	
2001	RCRA	Hazardous Waste Management System: Identification and Listing of Hazardous Waste: Inorganic Chemical Manufacturing Wastes; Land Disposal Restrictions for Newly Identified Wastes; and CERCLA Hazardous Substance Designation and Reportable Quantities	66 FR 58257	
2001	RCRA	Amendments to the Corrective Action Management Unit Rule		

Exhibit 2

Numbers and Completeness of Critical Documents

Subject	Case	Number Of Critical Documents	How many levels of references were reviewed to identify critical documents?
Municipal Waste Combustors	1	15	Some level 2
Synthetic Chemicals Monitoring	2	49	All level 2 and some level 3
Acid Rain Permits	3	12	All level 2
Land Disposal Restrictions	4	85	All level 2
Reformulated Gasoline	5	19	Some level 2
Great Lakes Water Quality	6	64	All level 2
Municipal Solid Waste Landfills	7	25	Some level 2
Biotechnology	8	25	Some level 2
Pulp and Paper (Air)	9	10	All level 2
Pulp and Paper (Water)	10	14	Some level 2
Disinfectants and Byproducts	11	59	Some level 2 and some level 3
Polychlorinated Biphenyls	12	10	Some level 2
Regional Ozone	13	42	All level 2 and some level 3
Nonroad Diesel Engines	14	8	Some level 2
Plant-Incorporated Protectants	15	15	Some level 2
TOTALS		452	

Level 1 = Major support document (e.g., regulatory impact statement)
Level 2 = Document referenced in the major support document
Level 3 = Document referenced in a level 2 document

Exhibit 3

Who Performed the Science Work

Year	Act	Rule Short Title	AC	IP	IO	OF	OG	PS	U	Total
1991	CAA	Municipal Waste Combusters	0	6	1	0	1	9	0	17
1991	SDWA	Synthetic Chemicals Monitoring	4	7	5	3	2	27	3	51
1993	CAA	Acid Rain Permits	0	2	1	0	0	10	0	13
1994	RCRA	Land Disposal Restrictions	0	4	0	0	0	81	0	85
1994	CAA	Reformulated Gasoline	3	5	0	0	1	10	0	19
1995	CWA	Great Lakes Water Quality	21	14	5	12	5	11	0	68
1996	CAA	Municipal Solid Waste Landfills	1	3	0	0	1	21	0	26
1997	TSCA	Biotechnology	12	7	0	2	0	5	0	26
1998	CAA	Pulp and Paper (Air)	0	3	0	0	0	7	0	10
1998	CWA	Pulp and Paper (Water)	0	9	0	0	0	5	0	14
1998	SDWA	Disinfectants and Byproducts	16	7	11	4	6	19	2	65
1998	TSCA	Polychlorinated Biphenyls	0	4	1	0	0	5	0	10
1998	CAA	Regional Ozone	6	10	4	3	7	20	0	50
1998	CAA	Nonroad Diesel Engines	1	4	0	0	1	5	0	11
2001	FIFRA	Plant-Incorporated Protectants	4	10	0	0	1	3	0	18
Total Number			68	95	28	24	25	238	5	483

AC: Academia
IP: EPA in-house – Program Office
IO: EPA in-house – ORD
OF: Other Federal Agency
OG: Other (non-Federal) government entity
PS: Private sector
U: Unknown

Exhibit 4

Who Funded the Science Work

Year	Act	Rule Short Title	PO	ORD	OF	O	U	Total
1991	CAA	Municipal Waste Combusters	12	5	0	2	0	19
1991	SDWA	Synthetic Chemicals Monitoring	21	21	3	4	1	50
1993	CAA	Acid Rain Permits	12	8	0	0	0	20
1994	RCRA	Land Disposal Restrictions	84	1	0	0	0	85
1994	CAA	Reformulated Gasoline	11	0	0	7	1	19
1995	CWA	Great Lakes Water Quality	14	9	17	26	2	68
1996	CAA	Municipal Solid Waste Landfills	12	5	0	7	1	25
1997	TSCA	Biotechnology	11	5	2	5	4	27
1998	CAA	Pulp and Paper (Air)	5	0	0	5	0	10
1998	CWA	Pulp and Paper (Water)	10	1	0	4	0	15
1998	SDWA	Disinfectants and Byproducts	22	16	4	21	1	64
1998	TSCA	Polychlorinated Biphenyls	9	1	0	0	0	10
1998	CAA	Regional Ozone	16	13	4	17	0	50
1998	CAA	Nonroad Diesel Engines	7	0	0	1	0	8
2001	FIFRA	Plant-Incorporated Protectants	14	0	1	1	0	16
		Total Number	260	85	31	100	10	486

PO: EPA Program Office
ORD: EPA Office of Research and Development
OF: Other Federal Agency
O: Other
U: Unknown

Exhibit 5

Funding Mechanisms Used

Year	Act	Rule Short Title	G	CA	IAG	C	I	O	U	Total
1991	CAA	Municipal Waste Combusters	0	0	0	8	5	0	2	15
1991	SDWA	Synthetic Chemicals Monitoring	2	0	0	33	9	1	4	49
1993	CAA	Acid Rain Permits	0	0	0	10	2	0	0	12
1994	RCRA	Land Disposal Restrictions	0	0	0	81	4	0	0	85
1994	CAA	Reformulated Gasoline	1	1	0	6	5	5	1	19
1995	CWA	Great Lakes Water Quality	11	2	0	10	12	20	11	66
1996	CAA	Municipal Solid Waste Landfills	2	1	0	11	3	0	8	25
1997	TSCA	Biotechnology	2	4	1	7	7	1	5	27
1998	CAA	Pulp and Paper (Air)	0	0	0	7	0	3	0	10
1998	CWA	Pulp and Paper (Water)	0	0	0	8	1	4	1	14
1998	SDWA	Disinfectants and Byproducts	3	3	0	16	12	20	6	60
1998	TSCA	Polychlorinated Biphenyls	0	0	0	5	5	0	0	10
1998	CAA	Regional Ozone	3	3	1	24	4	8	2	45
1998	CAA	Nonroad Diesel Engines	1	0	0	4	3	1	0	9
2001	FIFRA	Plant-Incorporated Protectants	0	1	0	0	13	0	1	15
Total Number			25	15	2	230	85	63	41	461

G: Grant
CA: Cooperative Agreement
IAG: Interagency Agreement
C: Contract
I: EPA in-house
O: Other
U: Unknown

Exhibit 6

Peer Review Actions Taken

Year	Act	Rule Short Title	N	U	FACA	OEP	ENP	II	Total
1991	CAA	Municipal Waste Combusters	1	12	1	0	1	0	15
1991	SDWA	Synthetic Chemicals Monitoring	6	16	3	0	19	5	49
1993	CAA	Acid Rain Permits	0	0	12	0	0	0	12
1994	RCRA	Land Disposal Restrictions	85	0	0	0	0	0	85
1994	CAA	Reformulated Gasoline	0	9	0	0	10	0	19
1995	CWA	Great Lakes Water Quality	5	16	6	0	37	0	64
1996	CAA	Municipal Solid Waste Landfills	0	24	0	0	1	0	25
1997	TSCA	Biotechnology	9	8	3	0	5	0	25
1998	CAA	Pulp and Paper (Air)	10	0	0	0	0	0	10
1998	CWA	Pulp and Paper (Water)	13	0	0	0	0	1	14
1998	SDWA	Disinfectants and Byproducts	0	18	0	4	33	4	59
1998	TSCA	Polychlorinated Biphenyls	8	1	0	1	0	0	10
1998	CAA	Regional Ozone	7	12	1	11	10	1	42
1998	CAA	Nonroad Diesel Engines	0	6	0	1	1	0	8
2001	FIFRA	Plant-Incorporated Protectants	0	10	3	0	2	0	15
Total Number			144	132	29	17	119	11	452

N: No peer review done
U: Unknown whether peer review done
FACA: Peer review done by Federal advisory committee
OEP: Peer review done by some other public review process by external experts
ENP: Peer review done by external group in a non-public manner
II: Independent internal EPA review

Exhibit 7

EPA Science Advisor Comments

The full text of the comments follows.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

August 19, 2002

OFFICE OF
RESEARCH AND DEVELOPMENT

MEMORANDUM

SUBJECT: Response to OIG Draft Audit Report - Science to Support Rulemaking

FROM: Paul Gilman *__/s/ Paul Gilman__*
Science Advisor to the Agency (8101R)

TO: Nikki Tinsley
Inspector General (2410T)

This memorandum transmits comments on the Office of Inspector General's (OIG) Draft Report, *Science to Support Rulemaking*, dated July 19, 2002. Briefly, I concur with the suggestions made to improve the transparency and consistency with which science is applied to Agency rulemaking.

In early spring of 2001, the Administrator recognized the need to improve the scientific and economic basis of Agency decisions and commissioned a task force to develop recommendations for improving the rulemaking process. The task force made many recommendations, and the Agency is well along the way towards implementing them.

One key outcome of the Administrator's Task Force is to increase the Office of Research and Development (ORD) involvement in the Agency's decision-making process. Another outcome is that the Administrator named me to serve as the Agency's Science Advisor. I take this role very seriously and plan to make important strides in ensuring that Agency decisions are based on sound science, and that science is presented and characterized properly in our rules and other important documents.

I am concerned about the OIG's finding (discussed on pages 17-18 of the draft report) that critical science supporting the rules often was not peer reviewed. I plan to review the Agency's progress in implementing its Peer Review Policy during the coming year.

In addition to implementing the recommendations to improve the scientific basis of our decisions, the Agency is working to finalize Information Quality Guidelines that will apply to all information that it disseminates. These guidelines, which will be effective in October 2002, present the Agency's procedures for ensuring the quality of information that we disseminate, and

provide an opportunity for the public to request correction of information that does not comply with the guidelines. These guidelines will help to improve the quality and transparency of our decision-making.

ORD would like to offer three related comments to sharpen the accuracy of the report. First, the draft report uses the term "primary document" to refer to the documents considered to have most critically influenced a regulatory decision. In the draft report, primary documents are described as those that "embodied the final process of gathering together the science and other information to support the rule," with examples being background support documents, regulatory impact analyses, and economic impact analyses (page 6). A different term should be used to refer to these documents (perhaps "critical document"), because in the scientific community a primary document generally refers to original scientific research, rather than gathering, reviewing and analyzing data collected by others.

Second, the draft report indicates an effort was made to determine which organizations performed and funded the science work embodied in the critical document (page 7). While it should be possible to determine who prepared and funded the critical document, the value of doing so is not clear, because the scientific research embodied in what OIG refers to as the primary documents was likely performed by many individuals and organizations whose work was being summarized. For example, all of the critical scientific research could have been performed by EPA scientists, but the critical document summarizing it was prepared by a contractor. This might present an inaccurate picture about the contribution of EPA scientists. The ambiguity inherent in this situation should be acknowledged.

Finally, while Agency preambles should effectively communicate the scientific underpinnings of the rules, the description of the professional norms for such communication (page11) is not accurate. The norms as described accurately reflect how scientists communicate in their primary documents, but not how science is communicated in what is described as critical primary documents. The key issue is that the preamble should present a clear summary of the science supporting the regulatory decision, including properly characterizing risks and the supporting science for risk management. The preamble should list the documents from which its science-based statements are made and the docket should contain the complete record. This would allow readers to refer to the source material, including the original primary science documents referenced in the critical documents (using "primary document" as traditionally used in the science community).

I appreciate the opportunity to review and respond to the draft report. Science must play a more prominent role in Agency decision-making. As Science Advisor to the Agency, one of my objectives is to ensure that the critical scientific information used in our decisions meets the highest standards of quality and transparency.

cc: ORD Executive Council
ORD Management Council
ORD Science Council
R. Dyer (8104R)
C. Bosma (8104R)
C. Varkalis (8102R)

Exhibit 8

Office of Water Comments

The full text of the comments follows.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
WATER

September 10, 2002

MEMORANDUM

SUBJECT: OIG Report: Science to Support Rulemaking

FROM: G. Tracy Mehan /s/
Assistant Administrator for Water

TO: Jeffrey Harris, Director for Program Evaluations
Cross-Media Issues
Office of Inspector General

Thank you for the opportunity to review the suggestions in the subject report for improving the use of science in EPA rulemaking. This is an issue of critical importance to the Agency's credibility.

We believe there is merit in the proposal to improve the consistency of the presentation of scientific data and conclusions in regulatory preambles. However, more work is needed to determine how to implement such a proposal given the wide variety of types of regulations the Agency develops. We also need to consider the impact on the cost of developing rules and on the length of preambles. OW will be happy to work with your staff, OPEI, and other offices to develop these proposals further.

The proposal to use information technology to hot-link various elements of the rulemaking package and Agency databases is intriguing and should be developed further. We also support reinforcement of EPA's peer review policy.

We are less positive about the proposal to "focus more attention in the development phase of regulations on collecting data and doing research to close "blind spots" to support rulemakings. For major rulemakings, there may be many years of data gathering and research available, but gaps in knowledge always remain. A decision to defer action while research is done is as much a risk-management decision as any other and implies the continuation of the status-quo for an additional period of time.

Comments by our staff are attached for your consideration.

Attachment

cc: Jay Messer
Thomas Gibson
Al McGartland

Comments

OIG Draft Pilot Study: Science to Support Rulemaking

The Pilot Study was undertaken to assess the use of science in EPA rulemaking. Predictably, many methodological issues were encountered, exacerbated by the difficulty of assessing efforts that occurred as much as a decade ago. The OIG is proposing not to undertake a more comprehensive study at this time. We support this conclusion.

The Pilot Study did lead, however, to some interesting suggestions. These comments center on the suggestions, which were:

1. Consider presenting the scientific findings that support a rule in specific sections of the preambles. These findings should be organized according to the norms of science, in summary form, and indicate:

    - Why the science is required to support the rule, and how the results will be used.
    - The methods used.
    - The important results (showing key data and their uncertainty).
    - Interpretation of the findings, and comparison with other studies that appear to support or contradict the results.
    - Scientific referencing of underlying scientific and technical documents.
    - A separate section of the preamble that would bring in issues of law, policy, economics, and administrative discretion that *do not depend on* the scientific findings.

2. Focus more attention in the development phase of regulations on collecting data and doing research to close "blind spots" to support rulemakings.

3. Take advantage of EPA's information technology capabilities to:

    - Hotlink references in preambles to documents in the docket.
    - Link scientific and technical documents in the docket to the Science Peer Review Database.
    - Link RAPIDS to the Science Peer Review Database.
    - Maintain through RAPIDS an inventory of all rules proposed and finalized each year.

4. Reinforce EPA's current peer review policy, ensuring that *all* EPA-generated documents critical to significant and substantive rulemakings are independently peer reviewed, and that the responses to the significant comments appear in the documents.

1. Consider presenting the scientific findings that support a rule in specific sections of the preambles.

The study team found an absence of consistency in reporting and using scientific findings in the rules which made them difficult to compare. The goal of fostering consistency in this area is a desirable one and will make things easier for our stakeholders. At the same time, it must be recognized that EPA develops a wide variety of types of regulations based on a variety of statutory mandates: for example, some are technology based, some based on individual risk targets, some on balancing costs and risks. Some are directed at human health risks, others at ecological risks, others at both.

It is not clear how one would formulate a structure that would accommodate this variety. The suggestions in the report, the so-called "norms of science", are really a model for reporting research results from a particular investigation. What we have in rulemaking preambles and supporting documents is generally a summary of knowledge in a particular area leading to a conclusion that contributes to the decision. In terms of scientific literature, this is more like a review article than a research report.

Further, requirements in this area have the potential of increasing the costs of rulemaking and increasing the length of preambles. These undesirable effects should be minimized as we develop ways of fostering greater consistency in the presentation of scientific findings.

In summary, this proposal has merit but needs further development before it can be adopted. OW will be happy to work with OIG, OPEI, and other offices on these issues.

2. Focus more attention in the development phase of regulations on collecting data and doing research to close "blind spots" to support rulemakings.

Many EPA regulations are based on years of research and data gathering by EPA, other Federal agencies, academia, and industry. For example, we have been working on the arsenic drinking water standard steadily since the 1970s. OW and other programs have extensive processes of joint planning with ORD and outside stakeholders to anticipate information needs as much as possible.

Yet, there are always data gaps and uncertainties which we must grapple with. This is in the nature of the rulemaking enterprise. While the Pilot Study cited respondents who said they would have liked to have had more data, it did not identify any particular ways of obtaining it without increasing costs or slowing down action. Allocating resources to closing "blind spots" means something else will not be done, and delaying action means the status quo will continue.

3. Take advantage of EPA's information technology capabilities.

There are some intriguing possibilities here. We would support an effort to identify and implement ways to improve the information the Agency makes available on rulemaking.

4. Reinforce EPA's current peer review policy.

EPA's Peer Review Policy was first issued in 1992, after some of the rules considered in the Pilot Study. Full implementation has taken time and continuous effort. Thus, it would not be surprising that compliance was limited in the earlier period, but we would hope that it had been improving as we approach the present time. Unfortunately, the report does not present information on peer review performance over time, so we cannot tell whether this has happened. We also note that, in many cases, the investigators could not determine whether documents were peer reviewed.

It is not clear whether the investigators are proposing a change in the Agency's Peer Review Policy. The recommendation (quoted above) does not appear to be any different from the current policy. If a change is being suggested, this should be made clear.

OGWDW Comments

OIG Draft Pilot Study: Science to Support Rulemaking

Factual Accuracy of Report

1) Exhibit 1 incorrectly lists the following rules as significant (by EO12866): Filter Backwash Recycling, Consumer Confidence report. The Exhibit incorrectly lists the Radon Rule as finalized in 1999; the Radon rule has not yet been finalized.

Exhibit 1 also incorrectly records the Arsenic rule as being withdrawn, which is not accurate. The original Arsenic rule promulgated on January 22, 2001. EPA temporarily delayed the effective date for this rule for 60 days, rom March 23, 2001 until May 22, 2001 (66 FR 16134), in accordance with the memo from Andrew Card entitled "Regulatory Review Plan". The effective date was again delayed to Februrary 22, 2002 (66 FR 28342) to conduct reviews of the science and cost analysis.

2) Different numbers for total critical documents are given for Exhibits 3 (471), 4 (469), 5 (443), and 6 (436) and on page 18 of main text (2940). Also the number of critical documents listed for individual rules are inconsistent across exhibits. It appears that these numbers should be the same - check these numbers and correct or otherwise provide an explanation for differences.

3) Page 18 of the main report states that EPA's Peer Review Product Tracking System data base should be the primary means for tracking present, past, and future peer review status of critical science documents identified in the pilot. It further states that, since the tracking system was developed, only 4 of 364 critical documents identified in the case studies, were found listed in this data base. This appears to be an inappropriate suggestion as EPA's tracking system is designed for EPA generated documents whereas only a fraction of the critical documents (116/471 -Exhibit 3) are generated by EPA.

Report Content

1) The discussion of critical science source and funding did not discuss the significance of the information or how it relates to the report's recommendations. The report does not discuss the linkage between source of funding and peer review status, and these data are important. The report should clarify how the two relate.

2) It is important to recognize, at least with regard to drinking water rules (largely due to the 1996 SDWA amendments), that the science discussion in preambles has evolved significantly in the last 10 years. Thus, the analysis of case study 2 is very outdated and does not reflect practices since 1996.

3) Please define the RAPIDS system and explain its purpose for the benefit of readers unfamiliar with the database.

Report Recommendations

1) The report's first recommendation to separate the discussion of science versus non-science influences into different preamble sections does not appear efficient as there would be significant redundancy in the discussion of rule criteria in each section. If this recommendation is implemented, it could result in doubling the preamble discussion, while not necessarily facilitating a better understanding of the basis for the rule.

Depending on statutory requirements for a given rule, the optimal preamble structure for communicating the role of science may be quite different. Any recommendations to revise the format for rule preambles across the Agency should be flexible and take this consideration into account. To achieve the same objectives of the report, we recommend modifying the recommendation to suggest that norms of science be applied consistently throughout current preamble formats where science is discussed, in order to improve the understanding of the scientific basis for rules.

2) We support the report's second recommendation to reduce "blind spots." However, if more greater data collection is mandated, this recommendation has major resource implications if additional funding is not provided. It could also negatively impact the ability to meet statutory deadlines.

The 1996 SDWA Amendments require EPA to use "the best available, peer-reviewed science and supporting studies conducted in accordance with sound and objective scientific practices" when setting drinking water standards (sec. 1412 (b)(3)(A)). The US Court of Appeals for the District of Columbia Circuit determined that Congress's intent was best available evidence at the time of rulemaking. EPA agrees with this assessment.

3) We support the report's third recommendation to make better use of the Agency's information technology capabilities. Consistent use of these tools throughout the rulemaking process will improve communication and access to the critical scientific support documents.

4) We support the report's fourth suggestion to reinforce the Agency's peer review policy. Because the current policy does not explicitly require peer review (http://www.epa.gov/osp/spc/perevmem.htm), it may be appropriate to recommend updating the policy to require peer review in certain situations to ensure it is applied more consistently across the Agency. A more consistent means of tracking peer reviewed documents will be very beneficial, and should help clarify the fact that many of the studies listed as having unknown peer review status in the draft report were actually peer reviewed.

Factual Accuracy of Case Study Discussions

Synthetic Chemicals Monitoring - Case Study 2

(1) Page A-6: the last paragraph beginning discussion of Category I, II and III pollutants.

This whole discussion needs some work - some statements are not quite accurate. We suggest the following replacement paragraph :

"Category I contaminants are those which EPA has determined there is strong evidence of carcinogenicity from drinking water ingestion and the MCLG is set at zero. Category II contaminants are those which EPA has determined that there is limited evidence for carcinogenicity from drinking water ingestion. The MCLG for Category II contaminants is calculated using the RfD/DWEL with an added margin of safety to account for cancer effects or are based on a risk range of 10^{-4} to 10^{-6} when data are inadequate to derive an RfD. Category III contaminants are those which there is inadequate evidence of carcinogenicity by drinking water ingestion. For Category III contaminants, the MCLG is established using the RfD. The science issues with respect to the MCLGs thus involve health risk assessments that deal with all the above aspects for each of the pollutants."

(2) Page A-8: third paragraph.

We suggest striking the first sentence that reads "Compliance with the MCL is determined by analysis with approved analytical techniques." While this is a true statement, this is not an appropriate lead into the discussion on PQLs and analytical feasibility limitations in setting of an MCL. We suggest replacing it with the following sentence: "The feasibility of setting an MCL at a precise level is also influenced by laboratory ability to reliably measure the contaminant in drinking water." Also, there is a typo toward the end of this paragraph ... instead of PCLs - this should be PQLs.

(3) Page A-9: first full paragraph that begins with "EPA proposed monitoring requirements ...."

Unfortunately, this paragraph does not provide complete information regarding the final decision for unregulated contaminants and may be a little misleading. The report cites the January 30, 1991 Final NPDWR for SOCs, IOCs, and unregulated contaminants. This paragraph discusses that EPA proposed monitoring requirements for ~110 unregulated contaminants and notes that EPA adopted a scheme requiring all systems to monitor for the highest priority organics, unless a vulnerability assessment determined that a system was not vulnerable to contamination, but it fails to specifically state that the final rule settled on a one time monitoring requirement for 30 unregulated organic and inorganic contaminants. The report does note this on the first page but we think this should be restated here as well.

(4) Page A-9: second full paragraph on SMCLs.

Tthe next to the last sentence is missing a parentheses to close out "discoloration of water." Also, we suggest breaking the second to the last sentence into two so that the following phrase for the aluminum SMCL can be included:

"EPA dropped the proposed organics SMCLs but retained the existing odor SMCL of 3 Total Odor Number (TON). The Agency finalized an SMCL range for aluminum (due to discoloration of water) with the precise level for each system being determined by the State. Furthermore, the Agency deleted an MCL for silver and finalized an SMCL to protect against skin dicoloration or argyria from a lifetime exposure."

(5) Page A-9: third full paragraph, five lines down - this should be 1,2-dichloropropane not 1,2-dichloropropanol.

(6) A couple places - chromium is capitalized (and it does not begin a sentence) - change to small case.

(7) Page A-16 - Last paragraph .... we suggest rewording the last two sentences as follows:

" Just as we were finishing the study, OGWDW announced its preliminary decision not to revise NPDWRs for 68 chemical contaminants. The Agency stated that the 68 chemical NPDWRs should not be revised at this time for one of the following reasons:

- 36 NPDWRs were undergoing Agency health risk assessments. These assessments are not expected to be complete in time for EPA to make its final revise/not revise decisions.
- 17 NPDWRs remained appropriate and any new information available to the Agency supports retaining the current regulatory requirements
- 12 NPDWRs had new health, technological, or other information that indicated a potential revision to MCLG and/or MCL; however, the Agency believed any potential revision would result in a minimal gain in the level of public health protection and/or provide negligible opportunity for significant cost-savings.
- 3 NPDWRs had data gaps or research needs that needed to be addressed before EPA could make definitive regulatory decisions. When the data gaps have been resolved, EPA plans to consider the results in the next review cycle.

Stage 1 DBPR - Case Study 11

(1) Page A - 80 : "Brief description of science input to the rule"

The last two sentences are incomplete in their intended coverage and should be revised. We suggest replacing the last two sentences with the following: "In addition, EPA needed to assess risks associated with DBP occurrence levels and to evaluate best available technologies for reducing such risks to feasible levels (while not compromising microbial protection). Using scientific and technological information gathered, EPA defined best available technologies, criteria by which total organic carbon (naturally occurring organic precursors to DBP formation)

should be removed, and how various DBPs and disinfectants should be measured and monitored.."

2) Many of the critical documents cited in the "Table of Critical Documents" as having unknown peer review status are actually published in journals that require peer review (e.g., JAWWA, Epidemiology). This may be true for other case studies. It will be worthwhile to reassess and re-tally these classifications with consideration of studies published in peer-reviewed journals–the report's conclusion's may be influenced by such an exercise.

3) The following documents should be listed as primary (Ref #46, 47, 48) to be consistent with the text describing "primary" documents in the main report.

Exhibit 9

Office of Prevention, Pesticides and Toxic Substances Comments

The full text of the comments follows.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON D.C., 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

September 13, 2002

MEMORANDUM

SUBJECT: Review of the Office of Inspector General's Pilot Study on Science to Support Rulemaking – OPPTS Comments

FROM: Angela F. Hofmann //s/ Angela F. Hofmann
Director of Regulatory Coordination
Office of the Assistant Administrator (7101M)

TO: Jeffrey Harris, Director for Program Evaluations on Cross-Media Issues
Office of Inspector General (OIG) (2460T)

Thank you for the opportunity to review the Office of Inspector General's (OIG's) draft report entitled: "Science to Support Rulemaking", a pilot study which evaluated the Agency's use of science to support EPA rulemaking. We coordinated the review for OPPTS, and respectfully submit the attached comments and suggestions for your consideration.

The pilot team sought to identify the role that science played in supporting 14 EPA rules promulgated between 1994 and 2001, represented by 15 case studies. Of the 15 case studies, three were related to rulemakings promulgated by OPPTS, i.e., case studies 8, 12 and 15. We have specific comments on two of the case studies, i.e., case studies 8 and 15, and do not have any comments on case study 12, which involved the PCB Disposal Amendments.

We discussed our specific comments on Case Study 15, the Plant Incorporated Protectants Rule, with Chris Baughman, and she has addressed our comments with the changes that we identify in the attachment. We discussed our comments on Case Study 8, the TSCA Biotechnology Rule, with Jay Messer, and he has indicated that he will consider our specific suggestions contained in the attachment. In addition, we have provided some general comments and suggestions that we believe will help improve the report.

If you have any questions about our comments, please contact Sandy Evalenko on my staff at 564-0264. Thank you.

Attachment

cc: IO: Steve Johnson; Susan Hazen; Sandy Evalenko
OSCP: Joseph Merenda; Tom McClintock; Elizabeth Milewski
OIG: Chris Baughman; Jay Messer

Attachment

OPPTS Comments on the OIG Pilot Study "Science to Support Rulemaking"

A. Comments Specific to the OPPTS Rulemakings

1. Text Changes Requested on Case Study 15 - Plant Incorporated Protectants

a. On page 13 of the draft report, the statement identified is contradicted by the finding on page A-108. The statement on page 13 should be revised as follows:

"The biotechnology rule (Case 8) and the plant-incorporated protectant rule (Case 15) both cited references by number, which corresponded to a reference section in the preamble~~, but many of these references were to dictionaries or general textbooks and did not support scientific statements~~."

b. On page A-107 under brief description of the rule, the following statement should be corrected as follows:

"In addition, the rule establishes a new part in the Code of Federal Regulations (CFR) specifically for plant-incorporated protectants, i.e., 40 CFR 174. Procedures are also set forth for Confidential Business Information (CBI); any claim of confidentiality must be substantiated when the claim is made. The rule also requires, for **exempted** plant-incorporated protectants ~~not registered~~, that any person who produces, for ..."

c. On page A-108, under the brief description of science input to the rule, the following statement should be corrected as follows:

"The rule was a legal mechanism to confirm that plant-incorporated protectants were covered by FIFRA. The science aspects concerned the ~~exception~~ **exemption** for protectants derived through conventional breeding from sexually compatible plants. To comply with FIFRA, such protectants ~~could~~ **may** not generally cause unreasonable adverse effects on the environment."

2. Text Changes Requested on Case Study 8 - TSCA Biotechnology

a. On page A-60, under the brief description of science input to the rule, the following statements should be corrected as indicated:

"The intent of the rule was to **establish EPA's regulatory program for microorganisms, with the goal of** ~~provide regulatory relief to those wishing to use certain products of microbial biotechnology, while~~ ensuring that EPA could adequately identify and regulate ..."

b. On page A-61, the characterization in the first bullet appears inconsistent with the discussion below it, which acknowledges that EPA's decision under the rule centered on whether the product is "new," i.e., not whether the 2 classes present

different levels or types of risks but whether one class is more likely to be "new." The first bullet needs to be corrected as indicated below:

"The science inputs to the rule ~~should~~ involve three key issues:

- Requirement for an MCAN - Is **the intergeneric microorganism more likely to be "new"** ~~there significantly less risk associated with intrageneric transfers than with intergeneric transfers? Is there a significant risk associated with transfer of non-coding DNA~~?

c. On page A-61, the following paragraph does not explain why these issues "clouded" or adversely affected the science considered in this rulemaking. An explanation is need to support the statements in the paragraph below or it needs to be revised and clarified. This rulemaking was more of a procedural rule, with the science used to determine the process and informational requirements that would be applied when these microorganisms were reviewed by EPA as part of the new chemical premanufacture notification requirements under TSCA.

"**Identifying the exact role of science in this rulemaking is clouded by several issues**. First, the the Biotechnology Science Coordinating Committee (BSCC) of the Domestic Policy Council Working Group on Biotechnology in the 1980s was developing a coordinated policy for dealing with biotechnology across the various agencies with a regulatory role (e.g., FDA, USDA, and EPA). Each of the Agencies and Departments then had to adapt the BSCC guidance to the particular statutory requirements under which the organization had regulatory authority. Under TSCA, EPA had to regulate microorganisms as "chemicals," because Congress had not specifically anticipated that genetically engineered microorganisms would themselves act as "products." This combination of restrictions brought about by the desire of the Federal government to have an integrated approach, and the need to stay within statutory boundaries that were somewhat artificial, greatly constrained the way new science could be applied to the rule."

d. On page A-62, the purpose of this paragraph needs to be better explained. What is the basis for the conclusion (highlighted below) that the articles didn't appear to be critical to support the final rule? This information was indeed important in supporting the specific requirements and reviews established in the rulemaking for these new microorganisms under the premanufacture notification provisions of TSCA.

"ORD also had a substantial research program in biotechnology in the 1980s. In a presentation to the BSAC in April, 1987, the AA for ORD indicated that ORD had a budget of $7 million for R&D in biotech, approximately 80% of which was in external research grants, primarily directed at developing "widely accepted methods in ... microbial ecology." ORD projects aimed at evaluating monitoring strategies for planned field releases were presented to the BSAC at the JULY 1987 and January 1988 meetings. ORD reported on several biotechnology workshops at the January 1989 meeting, and at the December 1989 meeting, ORD presented a progress report on 53 projects that had been conducted under the program, the "primary foci of these studies [were] on detection and

enumeration, survival and colonization, and genetic exchange." The following excerpt from one of the BSAC members is telling, however. After noting that although he did not totally agree that the program was a success, but was "one of the most important efforts in the area of environmental science," he noted that "much progress had been made in the considering genetic, ecologic, and evolutionary issues, ... the information was still insufficient to give a definitive answer on what merited review." **Although several journal articles funded by ORD are included in the docket, none appears critical to support of the final rule (nor do papers funded by other organizations).**"

e. On page A-67, the following conclusion (the last sentence in the paragraph under methodology - see highlighted text) is not supported by this paragraph. This statement requires additional explanation or it needs to be revised.

"OIG had no response from any of the respondents. The information was developed by reading the rule and preamble, the primary technical support documents, the ESA report (Tiedje 1989), the RIA, the response to comments report, and the reports and minutes from the BSAC meetings in the docket. The reference lists for the primary documents, as well as research papers cited in the docket table of contents were identified, and scanned for content, funding sources, etc. Research funded by ORD and identified by acquisition number were tracked back to the original decision memos in the GAD files (most turned out to be competitively awarded). **It became obvious during this exercise that the research cited, while broadly relevant to the survival of artificially introduced microorganisms in the field and mechanisms of gene transfer, did not specifically support (nor specifically not support) the positions to which they were referenced, and thus they are not included in the list of critical documents**."

B. General Comments

The following are general comments, observations and suggestions for your consideration.

1. Scope of the Pilot Study.

Please clarify early in the report whether the pilot team considered economic analyses when they evaluated "science" for the purposes of the pilot study. At times it appears that the team's consideration was limited to what is traditionally thought of as "science," i.e., scientific research and analyses of risks and effects. For example, in the first paragraph of the Executive Summary and in the detailed discussion of methodology. Since many consider economic analysis to be a scientific discipline, it would be helpful to describe what the team included as "science" in the context of their evaluation of science in support of rulemaking.

2. Understanding Rulemaking at EPA.

We would like to make a few comments and suggest several improvements to the discussion on this topic that appears on page 2.

a. Rulemakings are not just triggered by a statute, court order or executive initiative as stated in the first sentence of the first paragraph. Rulemakings may also be triggered by a citizen who petitions the Agency to take a specific regulatory action or to issue a rulemaking to address a particular concern, i.e., in addition to the Administrative Procedures Act, several statutes contain specific provisions that require the Agency to consider these petitions (e.g., TSCA section 21, EPCRA section 313, etc.). Licensing actions may also use rulemakings as the mechanism for implementing the licensing action. To avoid the potential for the reader to conclude that rulemakings are only triggered as described, we suggest that you preference the statement by inserting "Typically," or "In general," at the beginning of the first sentence.

b. As you know, rulemaking dockets for the major program offices are maintained in a specific facilities, which were recently consolidated to create the new EPA Docket Center located in the basement of EPA West. The parenthetical description should be revised to explain that these "drawers of paper files" can easily be accessed by the public, and are not files that are only maintained by the individual rule leads. Although opened to the public only this past April, it should be noted that the Agency now makes these files publicly available in its new online electronic docket and comment system, EPA Dockets. For future rulemakings, the public will have easier and online access to non-copyrighted and non-confidential references that are used to support a rulemaking.

c. The process summary that is provided does not include one of the most significant steps required for any significant or economically significant rulemaking, i.e., review by the Office or Management and Budget (OMB) and other interested federal agencies and offices pursuant to E.O. 12866. This review may often play a critical role in shaping the final rule that publishes in the Federal Register, and can impact on how the science is presented in the preamble. We suggest that you add a new sentence to recognize this critical step in the rulemaking process for both the proposed and final rule stages.

d. Although the public comment period may typically be 60 days, the Agency often provides for 90 days or longer for economically significant rulemakings, and, on occasion, may also provide just 30 days for public comment. We suggest that you reflect this be revising the following sentence as indicated:

"After allowing ~~at least 60 days~~ for public comment **(typically 60 days)**, EPA finalizes the rule by publishing it in the Federal Register, with a new preamble..."

e. In the second paragraph, please clarify whether the 20 rules were categorized as "significant" or "economically significant" under E.O. 12866. Although the criteria for "significant" rulemakings that appear in section 3(f) of E.O. 12866 are identified, there is no explanation of here for "economically significant," although that phrase is not used until the next page. Although the EO itself does not define this term, OMB's implementing guidance for EO 12866 defines this term as rulemakings that meet the criteria in section 3(f)(1) of the EO. Please note that the economic trigger here is not the only one. It can also be cost savings or

a non-cost related reason as indicated by the second part of the criteria in section 3(f)(1).

In addition to clarifying these terms, we suggest that the report clarify which criteria were used in selecting the rules evaluated. It is also important to clarify what is meant by "substantive rules," because that was a specific term of art that was used under the previous E.O. (EO 12291), which was replaced by E.O. 12866. Today rulemakers use this term to distinguish a non-substantive rule (e.g., something more technical in nature that does not impact the scope or requirements of the rule - like a rule that changes how a form should be sent to EPA) from a substantive rule that changes requirements or behavior, takes an action, implements a decision, etc..

f. For OPPTS, the remaining rules do not "primarily impact individual States, Tribes or sites, or involve minor modification and corrections to significant or substantive rules." The remaining rulemakings in OPPTS are substantive rules that OMB specifically exempted from E.O. 12866 that are categorized as exempt and not as "non-significant" (i.e., rulemakings that establish pesticide tolerances), or the are otherwise substantive rules that are categorized as non-significant under E.O. 12866. Only a few of the remaining rules involve corrections or minor modifications, or are otherwise limited to individuals.

g. The determination of whether a rule that was categorized as significant at proposal can be categorized as non-significant at final is one that is based on the criteria in section 3(f), and OMB's implementing guidance for EO 12866. If, for example, the agency does not receive adverse comments and the final rule is substantively similar to the proposal, OMB may determine that the final rule is not significant. The last sentence of the second paragraph implies that the only time the categorization for the rule might change at the final rule is if the estimated costs decrease or the rule is determined to modify existing significant rules. This statement should be corrected.

3. Significant Rules Identified

We would like to make a few comments and suggest several improvements to the discussion on this topic that appears on page 3.

a. RAPIDS is an internal agency tracking database that was first used by programs around 1995 primarily to help facilitate the development and review of the Regulatory Agenda. Active use of the system by the program offices was phased in across the Agency, which meant that some offices were entering their information directly, while others had their information entered by OPEI staff. In addition to standard reports that any user can access, a special report may be generated, as long as the information sought is maintained in the system. We do not believe that the criticism of OPEI and RAPIDS in this discussion is accurate. We suggest that you discuss these details with OPEI and revise this discussion accordingly.

b. With regard to searches for rules promulgated before 1994, it is important to note that pilot team did not have easy access to the information on these rules because the electronic reference sources that were used by the team, i.e., the website, and the electronic Federal Register access systems, were under development and only contain limited information for rules issued in 1994, or earlier. For this reason, the team was uncertain that the information on these earlier rules was complete. Searches using commercial electronic referencing or indexing sources might have identified rules for these earlier periods, as a manual search of the Federal Register indexes would have. To avoid a reader interpreting this discussion incorrectly as an indication that there isn't a way to generate such a list for this earlier time period, we believe that this discussion should be revised.

c. Correct the reference to why a rule might be "economically significant," as discussed above.

d. Clarify whether the 14 rules were taken from the economically significant group or both. For example:

On page 2 of the draft Report, it indicates that OPEI estimated that the Agency publishes 1,000 to 3,000 rules each year, and that "approximately 20 of these rules are "significant" according to E.O. 12866." Is that 20 a year, or 20 total for the period of the evaluation?

On page 3, it continues with the team having "identified 88 "significant rules" that were finalized in 1990 through 2001" then later that the team settled on "74 rules from 1994 on." And eventually explains that the pilot study focused on 14 of these rules.

The criteria the team used to select only 14 rules out of the potentially over 12,000 rules that EPA promulgated in that time are not clear. No criteria for selection are described in the study other than the attempt to ensure that the rules evaluated would provide a wide range of statutes, and that the rules were not intended to be a representative sample.

The report needs to further explain the selection criteria to provide credibility for the pilot study using only these 14 rules to serve as the basis for supporting the general conclusions regarding the Agency's use of science in rulemaking and the related recommendations.

4. Rulemaking Expertise

Rules written by the EPA serve a number of purposes, not all of them strictly scientific. Factors affecting the form and content of a rule include statutory, scientific, economic, political and enforcement/compliance considerations. Rules are first and foremost legal documents written to meet several legal goals. They must also communicate information clearly to the lay public, particularly information on how individuals may comply with the rules. Any team undertaking a study along the lines of this pilot should include the perspective of these other disciplines.

For example, although the report notes that the rulemaking process is governed by specific requirements contained in various statutes and Executive Orders (these are in addition to any in the environmental laws referenced), there isn't a discussion about what those requirements are, or how they may impact the development of, the analysis performed, or the information considered as part of the rulemaking. In addition, during the period covered by the study, many of these requirements were either newly imposed, or recently revised. For example, the only executive order related to these requirements that is mentioned, EO 12866, was issued in October 1994 as a revision to a previous EO. Since then, over 10 more executive orders or statues were issued that directly impact not only when an Agency must consider certain factors in rulemaking, but how the Agency must perform specific analyses. To be complete, any study about the use of science in rulemaking must also consider the rulemaking context, and all of the factors that must be considered by the Agency in making a decision.

Along these lines, we believe that any future studies should also consider how new requirements, whether procedural or policy related, that are intended to increase or make improvements, end up impacting the use of science in support of rulemakings. For example, on October 1 the Information Quality Guidelines are supposed to take effect. It would be interesting to see, when and how those requirements might impact our current activities with regard to science and rulemaking. The new electronic docket, which will substantially increase access to critical documents that are used to support rulemaking, will also impact this issue.

5. Method of Selecting "Critical" Documents

The methodology of selecting "contacts" is not clear. Of most concern is that, of the 83 identified contacts, no helpful responses were received from 58 of these contacts. A response from so few identified contacts, with a response rate of 33%, can introduce a strong bias into the study. To their credit, the authors recognize this potential for bias in their report. They nonetheless offer strong recommendations on how preambles of rules should be written. The team also ignored for the purposes of their study documents that they could not find in the rule dockets. Dockets do not necessarily contain a hardcopy of all documents associated with a rulemaking. Documents need not actually be physically in the docket for the Agency to have relied on them.

6. Rulemaking Preambles

The preamble to the rulemaking is not, nor has it ever been, considered the proper vehicle for communicating the science in the manner prescribed on page 11. The proper vehicle for communicating the science in that detail is in separate documents that are made available to the public as part of the rulemaking docket, with a general description description provided in the preamble. The preamble must provide a layman's explanation of the basis for the rulemaking, including the science, economic and technical analyses and other considerations that informed the decisions represented in the rulemaking.

The suggested addition of these science discussions in the preamble is cost prohibitive and impractical. For example, the suggested inclusion of the scientific

charts, graphs, and tables in the preamble would not only significantly increase the publication costs only, it would require additional resources and overly complicate the Agency's ability to ensure that the Federal Register document complies with accessibility provisions in section 508 of the American Disabilities Act because tables, charts and graphs require special programing to be electronically accessible for 508 readers.

In addition, most stakeholders consulted in 1994, when we evaluated the level of detail, format, and function of the preamble as part of the government wide streamlining initiative, indicated that they prefer for the preamble to contain a succinct summary of the science, economic and technical analyses and other considerations that went into the rulemaking. This allowed those responsible for or interested in the different disciplines to obtain a general understanding of all of these considerations, as well as the details of the one of most interest to them. Since the primary audience for the rulemaking is not the scientists, including the detailed scientific information in the preamble would not serve as an effective way to communicate the scientific information to the primary audience.

Exhibit 10

Office of Policy, Economics, and Innovation Comments

The full text of the comments follows.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF POLICY,
ECONOMICS, AND INNOVATION

September 22, 2002

MEMORANDUM

SUBJECT: Review of Draft Report "Science to Support Rulemaking"

FROM: Thomas J. Gibson
Associate Administrator

TO: Nikki Tinsley, Inspector General
Office of the Inspector General

Thank you for the opportunity to review the draft report "Science to Support Rulemaking." This report is important since it explicitly describes the role of science in achieving the Agency's mission. It is especially relevant in light of the Administrator's efforts to improve the Agency's decision making by promoting the full integration of science, including economics, into the regulatory process. In addition, the report's suggestions support many areas for improvement that are targeted in the Agency's new Information Quality Guidelines.

Having carefully reviewed the report, we offer the attached comments and suggestions on ways in which we believe the report could be improved, as well as our reactions to each enumerated suggestion made in the report. We hope that our suggestions will help strengthen the study's findings and the conclusions you draw from them.

Our general comments on the report can be found in Attachment 1. Attachment 2 contains our reactions to the report's suggestions, and Attachment 3 is detailed comments organized by page number.

Again, thank you for the opportunity to review the Draft Pilot Study. My congratulations on a well-written report that clearly articulates the need to explicitly define the role of science in the rule making process. I look forward to seeing your revised report.

Attachments

GENERAL COMMENTS

Recognizing Institutional Mechanisms

The report does an excellent job of recognizing Agency institutional mechanisms which ensure that regulations are based on sound science. The role of peer review and the peer review process in the development of credible science is discussed in depth, and the Office of Policy, Economics and Innovation (OPEI) agrees with the heavy emphasis the report places on the utility and importance of independent peer review. Not emphasized are two other key "good science" processes: Analytic Blueprints and the Risk Characterization Policy. The former was designed, in part, to ensure that critical science needs are identified early in the process and developed in time to inform regulatory decisions, and the latter requires that both the risk assessment process and risk the analyses are transparent, clear, reasonable and consistent. Taken together, these three existing mechanisms can assure that:

12. Critical science is identified early, and developed in time to inform decisions (Analytic Blueprint),

13. Critical science is of sufficient quality for regulatory decision making (Peer Review Process),

14: The quality of the science and the associated uncertainty is clearly described (Risk Characterization Policy).

Further, these three mechanisms appear to directly address three of the four findings of your report, i.e., that critical science supporting the rules often was not independently peer reviewed, that more data and fewer "blind spots" could reduce assumptions, and that the role of science (was) not made clear. Your report "determined that the oversight of peer review of the critical science documents to support the pilot rules was limited and ineffective." Applying the same logic suggests that shortfalls in identifying critical data needs, and the lack of transparency and clarity in science is due to inefficiencies or limitations in the two Agency processes intended to identify, develop and make critical science transparent.

Defining the Scope of the Science

The report refers to "science" quite broadly without ever offering a clear definition of what specifically was considered. The report would benefit from a clearer discussion of what categories of science were addressed and on which categories primary contacts were asked to comment. Page 5 of the report simply states: "We asked that [the contacts] consider several categories of science that may be relevant to the rules..." but does not disclose what these categories were. Presumably, such categories included risk assessment, exposure modeling, and

epidemiology. It is not clear from the text, however, whether engineering or any social sciences were included in this discussion.

The extent to which economics and other social sciences were addressed in this report is an important point to make especially in light of the renewed importance the Administrator and the General Accounting Office have placed on the conduct of quality economic analyses in the Agency. While the review of economic analyses may be beyond the scope of this particular report, the importance of this type of analysis as an input into the decision-making process should not be overlooked.

Characterizing the Role of Economics in the Decision Making Process

The report mis-characterizes the role of economics in the decision-making process in some places. The final point under suggestion number one lumps economics, a social science, together with non-scientific aspects of rule making such as law and administrative discretion. This should not be the case. Economics should be separated from other non-scientific considerations. Under some statutes, such as the Safe Drinking Water Act (amended 1996) findings from economic science may be the basis for the standard, and therefore merit separate, detailed treatment analogous to that given to other science. Also, under the Federal Insecticide, Fungicide and Rodenticide Act, the Agency must balance the risk posed by the use of pesticides against the economic impacts on crop production of restricting pesticide use. Even in cases where a standard may not be driven by economic findings, data on benefits, costs and impacts should be presented with the same clarity and detail as "scientific findings."

Use of Risk Characterization Policy as a Framework for Presenting Results and Suggestions

Some of the science supporting rulemaking deals with health and environmental risks. EPA adopted its policy on "Risk Characterization" in February 1992, via a memorandum from Henry Habicht, Deputy Administrator, and an accompanying document, prepared by a cross-office work group. The policy was reiterated and elaborated in the mid 1990s. At its core, the policy states that significant risk assessments should:

- Describe how the estimated risk is expected to **vary** across population groups, geographic areas, or other relevant break-outs,
- Describe the sources of **uncertainties** in the risk estimates, and quantify them, to the extent possible, and
- Explicitly identify the impact of **science and data, as opposed to policy choices**, as the source of various elements of the risk assessment.

We have found that this standard has been followed in an incomplete fashion in documents supporting regulations, as well as other EPA risk assessments. The draft Office of the Inspector General (OIG) report refers repeatedly to the second and third elements of EPA's Risk Characterization Policy, both in describing its findings and in its recommendations. We recommend that OIG examine this policy (in effect during most of the time period covered by the pilot study), and use it as a framework for presenting its results and suggestions.

A Call for the Development of "Principals of Analytic Integrity"

Recently, the Administrator reaffirmed the "Principals of Scientific Integrity" establishing clear and ethical standards that should govern the conduct of scientific studies within the Agency. To date, there is no parallel document establishing standards for the use of research in a policy analytic setting. OIG may wish to recommend that such a document be developed expanding on its recommendations for clarity of presentation, etc. and drawing on other Agency guidelines such as *The Guidelines for Preparing Economic Analyses.*

Characterization of the RAPIDS Data Base and its Capabilities

RAPIDS tracks all substantive rulemakings appearing in the *Semi-Annual Regulatory Agenda* as well as a number of actions not in the Agenda, such as Reports to Congress, Policy Plans, etc. RAPIDS does not track every non-substantive rulemaking (SIPs, SNURs, FIPs, State Approvals, etc.), but a sister database to RAPIDS (Federal Register Tracking Database - FR Dailies), also maintained by OPEI's Regulatory Management Staff (RMS), tracks *every* EPA action sent to and published in the Federal Register. These rules are not economically significant or normally reviewed by OMB and therefore are classified as "not significant."

RAPIDS records go back a number of years (1996 forward) with some rulemaking records from earlier years available. RAPIDS also tracks NPRMs published in many of those same years. The Regulatory Management Staff (RMS) has built numerous views in RAPIDS and has a view (list) of rules finalized each year.

The report seems to confuse or not clearly differentiate between "significant" rulemakings (those OMB reviews) and "economically significant rulemakings" (economic impact of greater than $100 million per year). RAPIDS separates out those rules identified as "economically significant." This designation has only been in effect for rules in the *Semi-annual Regulatory Agenda* as Priority "A" (Economically Significant) since 1995. Although for years before 1995, it is more difficult to clearly identify economically significant rules, RAPIDS identifies 50 final rules as economically significant for the years 1994-2001 and can produce lists of economically significant rules published final for the years 1990 to the present.

For additional information regarding the capabilities and content of the RAPIDS database or its sister database, OIG staff may wish to contact RMS staff directly (Darryl Adams is the contact for RAPIDS).

REACTIONS TO SUGGESTIONS

1) Consider presenting the scientific findings that support a rule in specific sections of the preambles. These findings should be organized according to the norms of science...

This suggestion is consistent with the Agency's efforts related to the use of and dissemination of information covered by the new Information Quality Guidelines (IQ Guidelines). These Guidelines have been developed in response to Section 515 of the Treasury and General Government Appropriations Act for FY 2001 (often referred to as the Data Quality Act) that directs the Office of Management and Budget (OMB) to issue guidelines that provide policy and procedural guidance to Federal agencies and direct Federal agencies to:

- adopt a basic standard of quality as a performance goal and take appropriate steps to incorporate information quality criteria into agency information dissemination practices;
- issue guidance for ensuring and maximizing the *quality, objectivity, utility,* and *integrity* of information disseminated by the agency; establish administrative mechanisms allowing affected persons to obtain correction of information that does not comply with the guidelines; and
- submit an annual report, beginning January 1, 2004, to OMB on the number and disposition of complaints received.

OMB published its guidelines to Agencies on October 1, 2001, and required agencies, including EPA, to develop and publish their own information quality guidelines by October 1, 2002. The Office of Environmental Information has led development of the IQ Guidelines within EPA. These Guidelines were developed as a Tier 1 rulemaking, with broad participation across the Agency and included briefings with the Deputy Administrator. EPA submitted its draft final IQ Guidelines to OMB on August 1 and the new Guidelines become effective October 1, 2002. Per OMB requirements, EPA published draft guidance and received public comment on the draft document.

The guidelines are consistent with many existing Agency practices and policies (e.g., EPA considered its peer review and risk characterization policies while developing its guidelines). However, the statutory basis and underlying OMB guidelines provide additional emphasis on EPA's implementation of these information quality practices and policies. The complaint resolution process will further intensify accountability for Agency staff, line managers, and senior managers to ensure quality information products. Pre-dissemination review processes need to be reviewed and there is a plan to develop minimum standards for pre-dissemination review (product review) consistent with the Guidelines. OEI is developing a communication strategy as well as the details and procedures necessary to implement the complaint resolution

process, including appeals and the appeals panel. OEI is responsible for ensuring that sufficient information is available to report complaint resolution in conformance with OMB deadlines. Each program office and region are responsible for implementing the guidelines when they are finalized and implemented on October 1, 2002.

OPEI believes that a full implementation of the IQ Guidelines will improve the Agency's performance related to its discussion regarding the use of science in rulemakings.
This is also an area where OPEI and ORD together can develop more complete recommendations regarding the presentation of scientific findings in preamble discussions. OPEI and ORD are both increasing their presence in Agency rulemakings as a result of last year's Task Force on Improving Regulation Development. OPEI believes that this increased participation by ORD and OPEI analysts will improve the attention to and discussion of the results of the underlying analysis, including but not limited to science, used to support EPA regulations could be improved. This discussion would be consistent with the IQ Guidelines, existing policies such as the risk characterization policy, and some of the key findings of your report.

2) **Focus more attention in the development phase of regulations on collecting data and doing research to close "blind spots" to support rulemakings.**

The purpose of an analytic blueprint is to identify research needs and guide data collection and research studies during the development phase of regulations. While a requirement for developing, updating, and following an "analytic blueprint" has been a formal part of EPA's rule-making process for more than a decade, it has been OPEI's experience that most analytic blueprints are treated as little more than formalities. As a result of last year's review and reassessment of EPA's rule-making process, OPEI and the program offices are taking steps to make the blueprints more central and relevant to actual rule-making decisions. We suggest that the OIG report consider referring to the analytic blueprints as one means to achieve the results desired in Suggestion 2.

3) **Take advantage of EPA's information technology...**

OPEI is currently evaluating and enhancing RAPIDS in order to improve the management information that is available or potentially obtainable. To date, RAPIDS has focused on tracking regulation development progress and facilitating EPA 's submission of its portion of the *Semi-Annual Regulatory Agenda* to OMB. OPEI is interested in adding features that enhance management accountability and improved performance metrics. RAPIDS currently links to relevant guidance and policy documents. OPEI will continue to improve RAPIDS and seek to take advantage of other information technology capabilities over the next year. Much of this work will be coordinated through the Regulatory Steering Committee or Regulatory Policy Council. We will follow up with you over the next several months to more fully understand these recommendations and identify what specific changes or opportunities we can adopt.

4) **Reinforce EPA's current peer review policy ensuring that *all* EPA-generated documents critical to significant and substantive rulemakings are independently peer reviewed, and that the responses to the significant comments appear in the documents.**

OPEI fully supports this recommendation on peer-review of critical documents and in fact has recently extended this peer-review policy to include economic analyses. OPEI is working closely with the Agency's Program Offices to ensure that a full review of supporting economic analyses for all economically significant rules occurs prior to the rule's submission to OMB. In this way, the application of sound and consistent economic practices is ensured and the Agency's position on the use of sound science strengthened.

DETAILED COMMENTS

Page 1 ("What We Did and Why")

It is unfortunate that economic analysis was not included in the pilot study, especially given the importance the Administrator has recently placed on the role of economics in rule making. It may be worth mentioning that although economics is important to the rule making process, you chose to focus on chemistry, biology, health sciences, etc. for the purposes of the pilot study.

In the last paragraph, consider elaborating a bit more regarding what was presented to the Research Strategies Advisory Committee and the Regulatory Steering Committee as well as the comments you received from them.

Page 2

In the first full paragraph, more exposition would be useful for those not familiar with the Government's Auditing standards. Do the standards recommend the testing of controls?

A short summary of the methodology employed would also be helpful for the reader if provided early in the report. We recommend the following:

> "The pilot study was conducted in steps. Once we learned more about the rule-making process, we began our pilot study by identifying all significant rules that were eligible for the study and then selected a small sample to pursue in case studies. For each selected rule, we identified primary contacts involved in the rule making and contacted each individual via email for assistance in identifying the critical science documents. We then attempted to locate each primary and secondary science document underlying the rule-making process for each selected rule. For each located document, we established who conducted the study, how the study was funded, and the level of peer-review the study received. Each step is discussed in more detail below and the findings for each selected rule are summarized in the case studies located in the appendix."

In the second paragraph consider changing the wording so the sentence reads:

> "The remaining notices *are for rules that* primarily impact individual States, Tribes, or sites...."

Page 3 ("We Identified Significant Rules Since 1990 and Selected 15 Case Studies")

For the title consider inserting "as" so that the title reads "We identified significant rules since 1990 and selected 15 as case studies"

The second paragraph could be made clearer by making the following changes (shown in italics):

> "Therefore, we used the Federal Register and EPA website to identify 88 significant rules finalized in 1990 through 2001. They are listed in Exhibit 1. *The list of rule promulgated before 1994 may be incomplete since* EPA's web-based materials tended to be dated 1994 and later. *Focusing on the 74 rules finalized from 1994 on, we show in Figure 1 that* more than half (38) of these rules were issued under the Clean Air Act...."

Page 4 ("We Sought to Identify the Critical Science Behind Each Rule")

Footnote 2: The composition of the pilot team is an important factor in how the study was conducted and by whom. This footnote should perhaps be moved to the text.

Page 5

Top of page: Is it the case that all primary contacts for the 15 rules responded? Were all primary contacts still at EPA? Presumably the 83 contacts mentioned at the end of the paragraph were those identified by the primary contacts. Are the primary contacts for each rule included in the 83? Did the pilot study team identify the contacts or did the primary contacts identify the contacts, or were the 83 contacts all primary contacts identified by the pilot study team? What proportion of the 83 contacts were at EPA?

Second paragraph: In the email sent to contacts, was a description of the project included in the email? Was any official endorsement of the study by a manager included to help gain cooperation?

Third paragraph (first full paragraph): In this paragraph you mention that follow-up contacts were made with those individuals who had not responded. What kinds of follow-ups were made? Were the follow-ups by email? Telephone? Did the follow-ups yield any additional cooperation? What was the breakdown of the 83 contacts by role (EPA execs, peer reviewers, etc.)? When stating, "We then turned to a combination of interviews and reading materials in the dockets," who was interviewed? Presumably, the report refers to those individuals who responded to the initial inquiries. Was a standard set of questions asked in each interview? How many attempts were made to contact stakeholders and peer-reviewers? Was accurate contact information available for each individual or was it the case that the contact information had changed and the person could not be found?

Page 6

First paragraph: The example of "think of laying a brick wall" was not as helpful as it could be and does not match the situation entirely. Perhaps if the example were reworded to read "think of a brick wall comprised of many individual pieces...."

Second paragraph: The second paragraph mentions an advisory from the Research Strategies Advisory committee. Does this refer to the recommendations received from the committee as a result of the briefing they received about the study? The suggestions they made should be summarized earlier in the report as noted above.

The first sentence is not as clear as it could be. Consider rewording it so that it reads: "Identifying the critical science inputs to the various rules proved to be a much more difficult task than expected given that the pilot study team members carrying out the identification process were not involved in the original rulemaking. As a result, for some rules, the data are likely to be incomplete. We encountered a particular problem as we traced...."

Readers of this paragraph may get get the health criteria documents and the critical documents confused. Are the underlying studies primary or secondary critical documents? According to the text box, it appears they should be secondary. A few wording changes might clarify this. Consider making the following changes:

> "These underlying studies then become critical *secondary* documents (there are usually more than one per *health* criteria document)".

Rewording the next few sentences may also help clarify the discussion here (changes noted in italics):

> *"Thirty-three of these underlying criteria documents were identified for Cases 2, 9 and 11 alone.* Because the number of critical *secondary* documents increases exponentially as one goes backward through the citation chain, *locating these documents becomes a very time-consuming process.*"

Page 7 ("We Identified the Sources of the Critical Science")

First full paragraph: Add comma and remove "or" so that the sentence reads, "Who performed the research was often identified on the title page of reports, the by-lines in journal articles, or in the acknowledgements...."

Second paragraph: Again, the report should establish who the respondents are. Are these the 7 people who responded to the initial inquiry?

Third paragraph: ("We asked the respondents about science gaps and science quality")
Last sentence: the rating scale should be defined (what does one mean? What does five mean?)

Last paragraph: ("We identified the type of peer review undergone by the critical science")
This section may read better with some reordering: cut the first paragraph in this section and move the OMB quote and the sentence preceding it so that they follow the now second to last paragraph in this section (before the paragraph starting "Some documents indicated...").

Page 9 ("Science Played a Critical Role in the Rules, but That Role May Not Be Clear")

Title: Consider changing the title wording so that it reads " ...but that role was not always clear" The wording change should be carried over to the last sentence in the first paragraph.

Page 10

Second bullet: "We also identified critical science documents without which it is reasonable to believe the section authorizing the rule might not have been included in the Clean Air Act?" This seems to mean that you reviewed Congress' use of science, which is interesting, but seems beyond the scope of the report. Did you undertake similar efforts to review the science underlying other relevant statutes passed during the study period?

Page 11 ("Role of Science Not Made Clear")

Second full paragraph: Consider changing "science" to "scientific" so that the sentence reads "However, we saw little evidence of any of these conventions in communicating the scientific underpinnings of the rules in the preambles..."

Last sentence of the second full paragraph: consider adding "described below" so that the sentence reads "Two of the preambles *described below* provided examples of food practices in the presentation of the data."

Page 12

The last paragraph on page 12 says that "only six [preambles] were well-referenced to the science underpinnings." Five bullets follow, and most of them illustrate inadequate referencing, although the second bullet seems to offer no criticism of the preamble of Case 14. This list is confusing, and contrasts to the two illustrative bullets on pages 11 and 12, which unambiguously detail examples of "good practices in the presentation of data".

Page 15 ("Who <u>Funded</u> the Critical Work")

"Intrastate" should be "interstate"

Table 3. It is not clear from the text how the count for ORD critical science documents came to 75. The text states that ORD funded 74 of the secondary documents and that EPA program offices funded all but one of the primary documents. Did ORD fund a primary document? If so, this should be stated clearly in the text. Also, it would be useful to break the "Other" category into its constituent parts (primarily State governments and industry, according to the text).

The text states on page 9 that 436 critical scientific studies were identified and classified in various ways, in Tables 2, 3, 4, and 5. Although footnote 5 on page 14 notes that some

categories can be counted more than once (so the totals for Tables 2, 3, and 4 are greater than 436), it would be clearer if each of those three tables contained a note to that effect.

Page 17 ("More Data and Fewer "Blind Spots" Could Reduce Assumptions")

The finding that more data and fewer 'blind spots' could reduce assumptions seems reasonable, but the text does not say that a great number of conservative assumptions were made where there were "blind spots." Was this, in fact, the case? It seems the text should support the finding more clearly.

Consider refraining from referring to the rules as "pilot rules." The rules themselves have been finalized and are therefore not "pilot." Perhaps you could refer to them as "the rules included in this pilot study" or "the selected rules" or simply "the rules."

Second full paragraph, first sentence: Consider changing the wording order so that the sentence reads "Based on the responses, we concluded that having more data would have resulted in *even more efficient* rules, because...."

Second full paragraph, second sentence: Remove the extra period at the end of the sentence.

Last paragraph ("Critical science supporting the rules was not always independently peer reviewed"): Be consistent on the relative merits of peer review and public comment. This paragraph states that public comment does not substitute for peer review, which seems sound and reasonable. However, page A-75 of the appendix provides an extended editorial on the relative merits of peer review and public comment that suggests otherwise. The text in the appendix even seems to question the validity of Agency peer review policy through the use of scare quotes:

> ...This rulemaking process must be substantially more rigorous than the Agency's "peer review" process...

Last paragraph, last sentence: Consider giving an indication of how many total staff members were in the sample. Add wording so that the sentence reads "Nonetheless, we were told by six of the X EPA staff members..." where X = total number of EPA staff members with which you were in contact.

Page 18

First sentence: Consider changing the wording so that sentence reads "A large number (290) of the critical documents supporting the rules either were not peer reviewed (138) or their peer-review status was indeterminate (152)." The "large number of the critical documents supporting the pilot rules – 2,940" should apparently be the number "290."

Table 5: Consider changing last "Action" entry so that it reads, depending on the intended meaning, either "Independent internal EPA review done through the risk assessment forum, ORD

or a program office" or "Independent internal EPA review done of a program office document, such as through the risk assessment forum or ORD."

Page 21 ("Pilot Lessons Learned")

Third bullet: The meaning in this bullet is not entirely clear. Consider rewording as follows:

> "A clear determination of a rule's relevant history should be made prior to the commencement of future studies, where "relevant history" is defined as the length of time preceding a rule's finalization during which review team members can be confident that identified science documents meeting the requirements of "critical documents", can in fact, be defined as such. Any future studies of this sort should plan to conduct reviews over the rule's relevant history.

Fifth bullet: Consider rewording as follows:

> "Interviews should be conducted with as many people connected to the rulemaking as possible. Special effort should be made to interview peer-reviewers and stakeholders. Email is not an effective mechanism to elicit this kind of information."

Seventh bullet: The bullet should lead with the recommendation. Consider rewording as follows:

> "There should be at least one research scientist on the team in spite of the fact that a science background is not necessary to identify critical science documents. A science background increases the efficiency of the identification process."

Exhibits

The Exhibits would be more informative if they were reorganized. Specifically, Exhibit 1 should highlight the rules that are part of the study sample. For the other exhibits, so long as the name and case number accompanies each study there is no need to present each list in chronological order. Exhibits 2-6 can be reordered to highlight completeness, aggregate numbers or other interesting findings along the dimensions displayed.

Appendices

Confirm coding on "who performed" the work. Are EPA contracted reports 'private sector' or 'program office'? The body of the report suggests that EPA-contracted reports are performed by the 'private sector,' but at least one the appendix indicates otherwise. See specifically A-45, reference #2. This may be an isolated error; each reference was not reviewed in detail.

Confirm coding for peer review: on pages A-78 and A-79, the peer review status of several journal articles are coded as "unknown" although they appear to be from peer-reviewed journals (including Fundamental and Applied Toxicology - now published as Toxicological Sciences:

Epidemiology, which is peer-reviewed; Toxicologic Pathology, which is peer-reviewed; and others). These are simply examples. Each reference was not reviewed in detail.

There are a number of typographical errors and minor editorial errors that need to be addressed, particularly in the appendices.

Exhibit 11

Report Distribution

Headquarters Officials
Associate Administrator for Policy, Economics, and Innovation (1804A) (paper copy)
Agency Followup Official (2710A) (paper copy)
Agency Audit Followup Coordinator (2724A) (paper copy)
Associate Administrator for Congressional and Intergovernmental Relations (1301A)
Associate Administrator for Communications, Education, and Media Relations (1701A)
Inspector General (2410)

Audit Liaisons
Pat Gilchriest, OA (1104A)
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