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THE ROLE OF REGULATORY ANALYSIS IN REGULATORY DECISIONMAKING

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CHAPTER THREE

THE USE OF REGULATORY ANALYSIS IN THE DECISIONMAKING PROCESS

I. Introduction

The Regulatory Impact Assessment, in one form or another, has been a fact of life for most executive agencies for almost a decade. In the last two presidential administrations, regulatory analysis has held a sufficiently high priority that it has become part of the standard operating procedures of most departments and executive agencies. It has been much less relevant to the day-to-day business of the independent agencies, because a lesser proportion of their business consists of rulemaking and because they have not felt bound by the Executive Orders that have required the non-independent agencies to use regulatory analysis.

This chapter will examine in detail the role that regulatory analysis has played in the rulemaking efforts of three departments (the Departments of Labor, Transportation, and Agriculture) and one executive agency (the Environmental Protection Agency). The chapter will describe in detail the rulemaking process in these institutions and point out the formal and real-world roles of the entities that have responsibility for preparing and evaluating regulatory analysis documents. The chapter will also attempt to probe the impact of these institutional units on the substantive outcome of agency decisions. It will pay particular attention to the interaction between two organizational units that usually become involved in the rulemaking process -- the "program office" and the "regulatory analysis office."

The "program office" is defined for purposes of this chapter as the office (or offices) that houses the technical staff who have expertise in the primary subject matter of the regulations that the agency issues. The inhabitants of the program office are usually professionals; the nature of their training depends upon the subject matter of the regulations that the office produces. For example, the "program office" that produces Occupational Safety and Health Standards may consist of industrial hygienists, toxicologists, biostatisticians, and engineers; the "program office" that produces quarantine regulations for protecting plants and animals might consist primarily of veterinarians and plant pathologists; and the "program office" that produces automobile safety standards might be composed of engineers, statisticians, and other auto safety experts. The personnel in the "program office" typically, but not always, adopt the "techno-bureaucratic" view of the world described in Chapter 1.

The "regulatory analysis office" is not as easily characterized. In theory, it is a separate office of independent professionals with training in economics and/or policy analysis who carefully examine the technical and policy predicates for rules, identify additional regulatory options, and prepare or review the regulatory analysis documents. In many cases a brief scan of the agency's organizational chart quickly reveals the "regulatory analysis office." It may be named the "Regulatory Impact Section" of the "Economic Analysis Branch." In other cases, names can be deceiving. The "Policy Analysis" office of a regulatory agency may have nothing to do with the regulatory impact assessment process, devoting itself instead to analysis of broad legislative policy options. The "Regulatory Impact Staff" may do little more than shepherd documents through the rulemaking process.

Finally, the department or agency may create two or more regulatory analysis staffs, providing each program office with a small regulatory analysis "suboffice" and maintaining a large department- or agency-wide staff as well.

As the following description of the regulatory analysis process reveals, the "regulatory analysis" office comes in many sizes and shapes and is used in many different ways throughout the federal government. For each of the agencies studied in this chapter, the author has made an attempt to isolate an office that could appropriately be labeled the "regulatory analysis office." In most cases the attempt was successful. In some cases, the concept of "regulatory analysis" had to be strained somewhat to find any institutional entity that deserved the label. Each department or agency that promulgates rules that may invoke the regulatory analysis requirements of Executive Order 12291 or the Regulatory Flexibility Act must have a staff to prepare such documents. But it is not always true that this staff consists of independent analysts with training in economics and/or policy analysis. In some cases professionals in the program office without training in economics or policy analysis draft the regulatory analysis documents.

An office that is assigned the task of assembling data on the economic impact of regulations is not necessarily a "regulatory analysis office" any more than an economist is automatically a "regulatory analyst." A "regulatory analyst" to be worthy of the title should do more than assemble cost data. He or she should in addition analyze that data, identify regulatory options, evaluate the potential benefits of the options as well as the costs, and display this information in a format that is

comprehensible to an upper level decisionmaker. The regulatory analyst takes a broader perspective on a regulation than an economist who generates economic impact data. The regulatory analyst fits cost information into the agency's broader policy goals and attempts to measure regulatory options against all of those goals.

Nor does it take a degree in economics or policy analysis to be a legitimate regulatory analyst. Many scientists and engineers in the program offices of agencies that contained separate regulatory analysis offices legitimately considered themselves just as deserving of the label "analyst" as the personnel of the separate regulatory analysis office.

Ultimately, whether or not an individual was considered to be a "regulatory analyst" for purposes of this Report depended upon a consideration of that person's professional training, his or her day-to-day activities, and the role that he or she occupied in the institution's formal organizational hierarchy. In most cases a quasi-independent staff of policy analysts who devoted a significant proportion of their time to analyzing agency regulations could be located. The extent to which these diverse offices share the "comprehensive analytical rationality" perspective of the policy analyst described in Chapter 1, however, varies considerably across the agencies and even within a single department.

In addition to describing the formal process for generating rules in the agencies, this chapter will assess the extent to which the "comprehensive analytic rationality" of the regulatory analysis office has combined with the "techno-bureaucratic rationality" of the program office to affect agency rulemaking decisions. This evaluation will lead to some suggestions for reducing or eliminating some of the more troublesome

impediments to analysis that have arisen in early attempts to incorporate comprehensive analytic rationality into the agency decisionmaking process. It will also suggest some limits on the extent to which comprehensive analytic rationality can effectively play a role in complex technical agency decisionmaking.

II. The Use of Regulatory Analysis in the Department of Agriculture.

The United States Department of Agriculture is not widely known as a regulatory body. Yet while the bulk of its activities consists of distributing public monies and managing federally owned natural resources, the Department does play a significant role in regulating private conduct. For example, the four Services examined in connection with this Report perform the following regulatory functions: the Food Safety and Inspection Service inspects the slaughtering and processing of livestock, poultry, and their products and sets standards and labeling requirements to prevent the preparation and distribution of adulterated or misbranded food in commerce;[1] the Agricultural Marketing Service administers several regulatory programs to protect consumers of agricultural products from financial loss or personal injury resulting from careless, deceptive, or fraudulent marketing practices;[2] the Animal and Plant Health Inspection Service regulates private conduct in connection with programs to control or

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1 See, 21 U.S.C. §§ 451 et seq. and 601 et seq. (1982); United States Government Manual 107 (1983) [hereinafter cited as Gov't. Manual].

2 See, Gov't. Manual, supra note 1, at 104.

eradicate animal and plant diseases or pests;[3] and the Agricultural Stabilization and Conservation Service administers commodity and land use programs designed to stabilize prices, markets and farm income.[4] USDA's regulatory programs have a very substantial impact on the agricultural economy; indeed, USDA has historically produced more RIAs for major regulatory actions than any other department or agency.

A. Departmental Structure and Heirarchy.

USDA is a highly decentralized organization.[5] Although the Secretary of Agriculture is ultimately responsible for all of the regulations that the services within the Department promulgate, as a practical matter for most nonmajor actions Departmental oversight is not especially stringent, and the services are relatively autonomous. Oversight at the Secretarial level is more prevalent for major actions, especially in the commodity program area.[6]

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3 See, Gov't Manual, supra note 1, at 105.

4 See, Gov't. Manual, supra note 1, at 111.

5 In the words of one USDA employee, the Department is "like a supermarket." Telephone Interview with Mr. Daniel Vitiello, Policy and Program Planning Staff, Food Safety and Inspection Service, USDA, May 3, 1983 [hereinafter cited as Vitiello Interview].

6 The author of this Report submitted early drafts to interviewees in the Department of Agriculture for comment and correction. Many of the interviewees communicated directly with the author. Others communicated indirectly through the Departmental Office of Budget and Program Analysis in the Office of the Secretary. Comments from many agencies were incorporated into a single communication to the author along with the comments of that Office. Letter to the author from Mr. Sid Clemans, Chief, Legislative, Regulatory, and Automated Systems, Office of Budget and Program Analysis, USDA, dated August 10, 1984 [hereinafter cited as OBPA Communication].

Table 3-1 sets out the organizational structure of the Department. The Secretary and Deputy Secretary are the ultimate decisionmakers for the Department. Below these two officials are two Undersecretaries and seven Assistant Secretaries. Also serving the Secretary directly are the Office of General Counsel, the Judicial Officer, the Office of the Inspector General, and the Office of Budget and Program Analysis. Almost all of the Department's regulatory functions are lodged under the Assistant Secretary for Marketing and Inspection Services. Many of the programs that USDA operates, however, are grant and loan programs and are not regulatory in nature. For example, Agricultural Stabilization and Conservation Service programs are largely voluntary, and regulations are issued to define the conditions of program participation.

Although the Under and Assistant Secretaries have "signature" responsibility for all major rules, they have delegated authority to issue many nonmajor rules to the Administrators of the Services. All documents that are published in the Federal Register, however, must receive clearance for legal sufficiency from the Office of the General Counsel, which serves directly under the Secretary.[7]

The Department has always had a large staff of agricultural economists. Although this staff has been located at various places in the Department, it currently operates under the Assistant Secretary for Economics. The primary duties of this staff are to assemble data relevant to the agricultural economy and to make projections about future crop yields, prices, and

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7 Departmental Regulation No. 1512-1, USDA Regulatory Decisionmaking Requirements, December 15, 1983 at 4 [hereinafter cited as Departmental Regulation 1512-1].

exports. In the early and mid 1970s the staff of the Economics, Statistics and Cooperatives Service (now incorporated in relevant part in the Economic Research Service)[8] played a fairly large role in preparing regulatory analyses for the regulatory services within the Department.[9] While the various regulatory agencies within the Department of Agriculture have historically made some attempt to assess the economic impact of their rules, they did not begin to acquire a capacity to perform independent analyses until the late 1970s and early 1980s. As the agencies committed more resources to the regulatory analysis function, the Economic Research Service (ERS) staff has performed a much less prominent role in regulatory analysis.[10] The Assistant Secretary for Economics has a formal review role over RIA preparation for major rules,[11] but the ERS staff rarely feels that it is necessary to make significant changes in an agency's analysis. This is true in part because the development of a regulatory analysis generally involves much direct and indirect discussion between individuals in many different offices in the Department including those in

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8 The Economic Research Service, like the Assistant Secretary for Economics, is a relatively recent creation of the present Administration. The Economics, Statistics and Cooperatives Service was established in 1978 and reported to the Departmental Director of Economics, Policy Analysis, and Budget.

9 Telephone Interview with Mr. Loren Lange, Deputy Director, Policy and Program Planning Staff, Food Safety and Inspection Service, USDA, March 13, 1984 [hereinafter cited as Lange Interview]; Telephone Interview with Ms. Judith Neibrief, Special Assistant to the Administrator, Food Safety and Inspection Service, USDA, April 19, 1984 [hereinafter cited as Neibrief Interview III].

10 Telephone Interview with Mr. Terry N. Barr, Office of the Assistant Secretary for Economics, USDA, May 3, 1983; Lange Interview, supra note 9.

11 Departmental Regulation No. 1512-1, supra note 7, at 4.

the Economic Research Service and in the Office of the Assistant Secretary for Economics. The persons charged with regulatory analysis responsibilities in some of the regulatory agencies within the Department also rely heavily on the data that the bureaus under the Assistant Secretary for Economics generate.[12]

On rare occasions a regulatory agency will request that personnel in ERS with particular expertise in a subject matter relevant to a pending rulemaking be assigned to aid the service in preparing an RIA or in assessing the validity of an economic study submitted by an outside party.[13] For example, in the "Mechanically Separated (Species)" rulemaking in the Food Safety and Inspection Service, the American Meat Institute and the Pacific Coast Meat Association submitted a detailed economic study of the economic effects of the agency's previously issued rule with their petition to amend the rule. The Policy and Program Planning Staff of the Food Safety and Inspection Service asked personnel in the Economics, Statistics and Cooperatives Service (ESCS -- now ERS) to evaluate the petitioners' study. The ESCS staff critically examined the petitioners' study and designed an independent model that took into account a larger number of relevant factors.[14] However, ERS only very rarely becomes this

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12 See, text accompanying notes 182-184, infra.

13 Lange Interview, supra note 9.

14 See, Mechanically Separated Meat Case Study [hereinafter cited as MSM Case Study] [Case Study submitted as Appendix A to this Report]. Interestingly, the economists in the Policy and Program Planning Office of the Food Safety and Inspection Service decided to use the industry-submitted study in preparing the RIA for the proposed rule, rather than the ESCS's more detailed study. The agency did so because the industry-submitted study was less complicated and because the

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actively involved in an individual rulemaking proceeding.[15] For the most part, the regulatory agencies rely upon their own economic expertise in preparing regulatory analysis documents and evaluating outside economic studies.

The Office of Budget and Program Analysis (OBPA) in the Office of the Secretary is another Department-wide office that has historically played a role in regulatory analysis. That office was established in 1921 to perform a budgetary review function.[16] Since the mid-1970s, however, it has also had a role in preparing and reviewing many regulatory analyses. OBPA has approximately 20 individuals with program expertise who focus on regulatory concerns in many contexts, including budget proposals, legislative proposals, and specific regulations.[17] Since regulatory issues take up only a portion of any of the OBPA analyst's time, however, it is difficult to determine exactly how many staff years are dedicated to regulatory policy in OBPA.[18]

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14 predictions of both studies did not vary by more than five percent. Lange Interview, supra note 9.

15 Barr Interview, supra note 10.

16 History on the Office of Budget and Program Analysis (undated document on file with author).

17 Telephone Interview with Mr. Jon Meyerson, Office of Budget and Policy Analysis, USDA, May 2, 1984 [hereinafter cited as Meyerson Interview]; Telephone Interview with Mr. Wayne Bjorlie, Office of Budget and Program Analysis, USDA, May 1, 1984 [hereinafter cited as Bjorlie Interview II]. See generally, Hearings on Regulatory Reform Act Before the Subcomm. on Administrative Law and Governmental Relations of the House Comm. on the Judiciary, 98th Cong., 1st Sess. 526 (1983) (testimony of Mr. Steven Dewhurst, Director, Budget and Policy Analysis Office, USDA) [hereinafter cited as Hall Hearings].

18 OBPA Communication, supra note 6.

OBPA performs a centralized clearance function for all important agency rules, and it reviews the regulatory analysis documents for all major and many nonmajor rules. USDA's implementation of Executive Order 12291 modified OBPA's role by placing greater emphasis upon Under and Assistant Secretary and agency responsibility for regulatory analysis. While OBPA must review RIA's for major rules, it is also a resource that Under and Assistant Secretaries may use if they wish on any nonmajor rule.

The extent to which OBPA personnel become involved in day-to-day regulatory activities depends a great deal on the importance that top USDA policymaking officials attach to an issue. This, in turn, is sometimes determined by an issue's program and budget implications.[19] Occasionally, OBPA personnel have become actively involved in the individual agencies' decisionmaking process, but this has become increasingly rare.[20] OBPA has seldom been involved in agency decisionmaking with respect to "minor" rules, unless such rules have a large budget impact.[21] Following the implementation of Executive Order 12291, OBPA personnel have taken a more active interest in budget and program issues than in regulatory issues.[22]

In 1978 OBPA prepared a suggested outline and analytical guidelines for regulatory analyses. With some modest revisions, these documents are still

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19 Telephone Interview with Mr. Sid Clemans, Chief, Legislative, Regulatory, and Automated Systems, Office of Budget and Program Analysis, USDA, May 4, 1984 [hereinafter cited as Clemans Interview I].

20 Clemans Interview I, supra note 19.

21 Meyerson Interview, supra note 17.

22 Telephone Interview with Mr. Gail Updegraff, formerly Deputy Director, Policy and Program Planning Staff, Food Safety and Inspection Service, USDA, March 13, 1984.

in effect.[23] Unlike the Department of Transportation, USDA has not prepared extensive written operating procedures for preparing regulatory analysis documents and threshold analyses; nor has it attempted to coordinate the regulatory analysis efforts of the many services with regulatory functions.[24] The OMB procedures were transmitted to all USDA agencies, and procedures developed by other governmental entities have been studied in OBPA. OBPA management, however, does not believe that extensive written guidelines would be very helpful to the regulatory agencies within the Department. OBPA believes that there are generally so many complexities involved in a regulatory decisionmaking that detailed, "cookbook" type instructions for use throughout the Department would impede effective analysis for those who are good analysts. Further, such instructions are likely to be of little assistance in helping an individual with insufficient analytic training to complete an effective analysis.

During the last five years the individual regulatory agencies within the Department have gradually acquired independent capacities to prepare regulatory analysis documents.[25] As regulatory analysis has become a more important function in agencies with regulatory responsibility, some services have become more proficient with regulatory analysis and have developed a credibility that has given them a degree of independence from OBPA and the

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23 OBPA Communication, supra note 6.

24 Vitiello Interview, supra note 5.

25 See, Hall Hearings, supra note 17, at 526 (testimony of Mr. Steven Dewhurst, Director, OBPA).

other bureaus in USDA with economic expertise.[26] This trend is consistent with the Department's general tendency toward decentralized decisionmaking.

Each of the Services studied in connection with this Report prepares its own regulatory analysis documents. The Food Safety and Inspection Service has independent staffs who prepare regulatory analysis documents, while the Agricultural Stabilization and Conservation Service and the Agricultural Marketing Service assign the task of drafting regulatory analysis documents to the same person who is responsible for drafting the rulemaking documents for publication in the Federal Register. The Animal and Plant Health Inspection Service fits between these two extremes. It has an independent staff of policy analysts who do some regulatory analysis and draft some, but not all, of the agency's regulatory analysis documents. The Services that do not have separate offices to prepare regulatory analysis documents have small staffs composed of persons with training in economics who review those documents.[27]

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26 Telephone Interview with Ms. Miriam Bender, formerly Office of General Counsel, USDA (currently St. Louis University School of Law), March 15, 1984 [hereinafter cited as Bender Interview].

27 Telephone Interview with Mr. James Toomey, Regulation Review Staff Officer, Market Research and Development Division, Marketing Program Operations, Agricultural Marketing Service, USDA, May 6, 1983 [hereinafter cited as Toomey Interview I]; Telephone Interviews with Mr. Larry Walker, formerly Group Leader, Regulatory Impact and Conservation and Program Evaluation Group, Analysis Division, presently Director, Regulatory Impact and Executive Correspondence Staff, Program Planning and Development, Agricultural Stabilization and Conservation Service, USDA, May 5, 1983 [hereinafter cited as Walker Interview I] and May 1, 1984 [hereinafter cited as Walker Interview II].

1. The Food Safety and Inspection Service.

The Food Safety and Inspection Service (FSIS) is located under the Assistant Secretary for Marketing and Inspection Services. It has an Administrator, an Associate Administrator, and Deputy Administrators for five functional offices -- Administrative Management, International Programs, Meat and Poultry Inspection Operation, Meat and Poultry Inspection Technical Services, and Science. The agency has a separate Policy and Program Planning Staff that serves the Administrator directly. This staff devotes approximately 25 professionals to regulatory analysis.[28] The agency undertakes an informal pre-decisional analysis for all of its rules, whether or not they cross the RIA and RFA thresholds.[29] The Meat and Poultry Inspection Technical Services staff usually manages rulemaking dockets, and the Policy and Program Planning Staff makes threshold recommendations and prepares all of the regulatory analysis documents.

2. The Agricultural Marketing Service.

The Agricultural Marketing Service (AMS) also serves under the Assistant Secretary for Marketing and Inspection Services. AMS has an Administrator, a Deputy Administrator for Management, and a Deputy Administrator for Marketing Program Operations. All of the agency's rulemaking activities are carried out under the Deputy Administrator for Marketing Program Operations. The staff under the Deputy Administrator is

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28 Telephone Interview with Ms. Judith Segal, Director, Policy and Program Planning Staff, Food Safety and Inspection Service, USDA, March 15, 1984 [hereinafter cited as Segal Interview I].

29 Segal Interview I, supra note 28.

divided into six divisions, each of which regulates a separate activity or commodity.[30] A seventh division, the Marketing Research and Development Division, houses the three-person Regulation Review Staff.[31] The various commodity divisions generate agency rules, and the staffs of those divisions draft both the rulemaking documents and the regulatory analysis documents. The Regulation Review staff in the Marketing Research and Development Division reviews regulatory analysis documents for sufficiency.

3. The Animal and Plant Health Inspection Service.

The Animal and Plant Health Inspection Service (APHIS) is also located under the Assistant Secretary for Agricultural Marketing and Inspection Services. It has an Administrator, a Deputy Administrator for Management and Budget, a Deputy Administrator for Plant Protection and Quarantine, and a Deputy Administrator for Veterinary Services. The Policy Analysis and Program Evaluation Staff consists of four policy analysts and serves under the Budget and Accounting Division Director, who in turn serves under the Deputy Administrator for Management and Budget.[32] The Policy Analysis and Program Evaluation Staff was originally intended to look at major regulatory

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30 The six divisions are: the Cotton Division, the Dairy Division, the Fruit and Vegetable Division, the Livestock, Meat, Grain, and Seed Division, the Tobacco Division, and the Warehouse Division.

31 Telephone Interview with Mr. James Toomey, Regulation Review Staff Officer, Market Research and Development Division, Marketing Program Operations, Agricultural Marketing Service, USDA, May 1, 1984 [hereinafter cited as Toomey Interview II].

32 Telephone Interview with Ms. Rita Anselmo, Policy Analyst, Policy Analysis and Program Evaluation Staff, Animal and Plant Health Inspection Service, USDA, May 5, 1983 [hereinafter cited as Anselmo Interview I].

efforts in the context of overall agency policy goals. When the agency began to prepare regulatory analysis documents in the late 1970s and early 1980s, this office was asked to participate in the drafting of regulatory analysis and rulemaking documents. The office, however, has become actively involved in document drafting in only a very small percentage (less than 5%) of the agency's rulemaking efforts.[33]

A separate Regulatory Coordination Staff, composed almost entirely of lawyers, is part of the Administrator's staff.[34] The Plant Protection and Quarantine and Veterinary Services Staff generates rules and prepares most regulatory analysis documents; the Policy and Analysis and Program Evaluation Staff prepares some regulatory analysis documents and reviews some others;[35] and the Regulatory Coordination Staff coordinates the rulemaking efforts and drafts the Federal Register documents.

4. The Agricultural Stabilization and Conservation Service.

The Agricultural Stabilization and Conservation Service is located under the Under Secretary for International Affairs and Commodity Programs. It has an Administrator and Deputy Administrators for Management, Program Planning and Development, Commodity Operations, and State and County Operations. Most regulatory analysis documents are drafted by the Analysis

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33 Telephone Interview with Mr. Thomas Gessel, Director, Regulatory Coordination Staff, Animal and Plant Health Inspection Service, USDA, August 17, 1984 [hereinafter cited as Gessel Interview III].

34 The Regulatory Coordination Staff consists of five attorneys, two writer-editors, one administrative person, and three secretaries.

35 The same staff also performs a large program evaluation function. Both tasks are performed by a staff of four professionals.

Division under the Deputy Administrator for Program Planning and Development. Rule are typically drafted by staff in the relevant program area. The three-person Regulatory Impact and Executive Correspondence Staff, under the same Deputy Administrator, performs a review function.[36]

B. The Formal Regulatory Process.

The rulemaking process in all of the services is governed by a general Departmental regulation.[37] In addition, individual agencies have established procedures to govern matters not addressed in the general Departmental regulation.

1. Origin and Threshold Analysis.

In all of the regulatory agencies in the Department, proposals for rulemaking can come from at least four sources: (1) a statutory requirement that the agency enact rules; (2) outside petitions for rulemaking; (3) decisions by upper level decisionmakers that a rule is needed; and (4) recommendations by lower level staff employees who identify particular problems.

Departmental regulations require each agency to advise its Under or Assistant Secretary of the fact that it is considering promulgating a rule early in the developmental process. The regulations suggest that the agency draft a "work plan" for this purpose.[38] This requirement provides upper

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36 Walker Interview I, supra note 27.

37 Departmental Regulation Number 1512-1, supra note 7.

38 See, Departmental Regulation 1512-1, supra note 7, at 2-3.

level agency decisionmakers and Departmental officials an opportunity to review the objectives of and need for the contemplated regulation, preliminary estimates of the regulation's costs and the costs of likely alternatives, and a preliminary timetable for the regulation's development. The work plan is a single-page form that allocates approximately three inches to a description of the objectives of and need for the rule. The standard form suggests that the preparer attach a one page outline of the alternatives and their expected effects. Whether or not a full-fledged "work plan" is drafted, this early warning system is intended to be a vehicle for identifying at an early stage regulations that are likely to be "major," those that are likely to require a Regulatory Flexibility Analysis, and those that will receive special treatment at the request of the Under or Assistant Secretary. Finally, the work plan is a vehicle for involving the Office of Budget and Program Analysis in the decisionmaking at an early stage, providing some of the Assistant and Under Secretaries with background information, and assisting in making threshold determinations.[39] Even in the absence of a written work plan, OBPA usually becomes aware of any major regulatory changes through its involvement in budget decisions and legislative proposals.

The Under or Assistant Secretary must review the work plan and designate it "major," "nonmajor," or "reserved nonmajor." The distinction between "major" and "nonmajor" is simply the distinction drawn in Executive Order 12291. The "reserved nonmajor" category is a special category established by the Department that includes important rules that do not meet

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39 Meyerson Interview, supra note 17; Clemans Interview I, supra note 19.

the Executive Order's threshold criteria, but which are of sufficient programmatic importance to demand closer scrutiny within the agency and the Department. The hybrid category "reserved nonmajor" is applicable to rules that would:

(1) Establish new policies or substantially modify existing policies or programs; or

(2) Affect budget outlays substantially; or

(3) Affect more than one agency; or

(4) Be likely to be controversial.[40]

The staff of OBPA is available to assist Assistant and Under Secretaries in making the threshold determination.

There is a strong perception among many of those who regularly work with regulatory analysis documents that the "reserved nonmajor" category is the more important category. In this view, the most important aspect of a "majorness" designation is that it gives OMB sixty days for its review, rather than the ten days allotted for nonmajor rules. Since most agency personnel are not especially eager to seek out OMB comment on their regulatory analyses and in fact seem positively antithetical to the prospect, the "major" characterization is one that they would prefer to avoid.

Staffers are generally very interested, on the other hand, in knowing which rules are deemed important by upper level decisionmakers. The "reserved nonmajor" category tends to be the repository of rules that do not obviously cross the $100 million threshold but are important enough to merit special upper-level consideration. The agencies may well undertake the same

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40 Departmental Regulation number 1512-1, supra note 7, at 2.

intensive analysis for "reserved nonmajor" rules that they prepare for "major" rules. In the mind of at least one regulatory analyst in the Department, this separate category has been very useful in bringing about acceptance of the regulatory analysis office among line officials in the program office.[41] In this view, if program office staffers thought that the only reason for regulatory analysis was to satisfy an OMB paperwork requirement, they would have been much less receptive to the input of the agency's regulatory analysis office.[42]

Within the individual agencies in the Department, the pattern of rule development varies. The following discussion will focus briefly on the typical origin of rules in each of the four Services studied here and follow the rule through the threshold determination whether an RIA or RFA should be prepared.

a. Food Safety and Inspection Service.

In the Food Safety and Inspection Service (FSIS) most rules originate in the program offices under the Deputy Administrator for Meat and Poultry Inspection Technical Services. The need for a regulation might become apparent to an inspector in the field or it might come about through a new innovation in food processing technology. A petition from the regulated industry often initiates rulemaking efforts. If an industry organization

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41 Segal Interview I, supra note 28.

42 Segal Interview I, supra note 28.

petitions in a plausible and uncontroversial way, the agency is often inclined to adopt the industry proposal as its own.[43] .

Over a period of seventy-five years the relationship between the agency and the regulated industry has evolved into one in which there is a great deal of information sharing. For example, the agency secures the assistance of regulated companies when it seeks to test new inspection procedures. Consequently, proposed changes in inspection procedures seldom come as a surprise to regulated entities. Industry trade associations have technical committees that discuss ideas with agency personnel and agency staff frequently speak at association meetings. The net effect of these informal interactions is a relatively free flow of information.[44] The agency and the industry can usually agree that a new rule is necessary, and the contents of a rule usually become controversial only when the industry itself is split on an issue. It is not unusual, however, for the industry to split on an issue.

Typically, a staff employee in the Office of Meat and Poultry Inspection Technical Services drafts a proposed rule and supporting documents.[45] Although most rules originate in the Office of Meat and Poultry Inspection Technical Services, a few come from the Office of

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43 Telephone Interview with Mr. Robert Hibbert, Director, Standards and Labeling Division, Meat and Poultry Inspection Technical Services, Food Safety and Inspection Service, USDA, April 5, 1984 [hereinafter cited as Hibbert Interview I]

44 Comments of Mr. Loren Lange, Deputy Director, Policy and Program Planning Staff, Food Safety and Inspection Service, USDA on an earlier draft of this report, August, 1984 [hereinafter cited as Lange Comments].

45 Hibbert Interview I, supra note 43.

Science, the Office of Meat and Poultry Inspection Field Operations, the Office of International Programs, and the Agency's administrative management.[46] On occasion, however, the Administrator considers a rulemaking sufficiently important that he has designated his Special Assistant to draft the primary rulemaking documents and coordinate rulemaking activities. These specially designated rules usually involve complex issues that cut across the entire agency and that require a significant resource commitment. In the one rulemaking, for example, the Administrator's Special Assistant drafted the Federal Register notices, arranged working group meetings, and directed questions to various staff members with particular expertise.[47] The Administrator's Special Assistant has many roles in these rulemakings. In addition to managing particular issues and rulemaking projects, he or she also functions as an executive secretary and docket manager.

In normal cases, the agency follows a different and more systematic review process. The staff person from the program office with responsibility for an issue forwards a tentative proposal to the Deputy Administrator for Meat and Poultry Technical Services, who might question the staff employee about the need for and content of the regulation. After the program staffer has defined a proposal and secured the Deputy Administrator's approval,[48] he or she prepares a brief (usually one-page)

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46 Lange Comments, supra note 44.

47 See, MSM Case Study, supra note 14.

48 The Administrator must approve any new regulatory action before significant Agency resources are expended in pursuit of such action. Interview with Mr. Donald Houston, Administrator, Food Safety and

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entry for the agency's Index of Pending Regulatory Actions (IPRA entry). This entry gives a descriptive title to the regulatory action and provides a brief summary. The initiating staff will also work together with an employee from the Policy and Program Planning Staff (the regulatory analysis office) to prepare a threshold analysis.[49] In the threshold analysis, the staff professionals make an initial recommendation as to whether an RIA or Regulatory Flexibility Analysis is required. Although the Departmental Regulation requires that options be identified at the work plan stage, not much effort is made to identify options at this early stage in the rulemaking process.[50]

The staff effort at the work plan stage is devoted almost exclusively to identifying the likely impacts of the proposed rule for purposes of the threshold analysis.[51] In making the threshold determination, the staff uses the criteria set out in the Departmental Regulation, which mimic the criteria in the Regulatory Flexibility Act and Executive Order 12291. The Policy and Program Planning Staff uses in-house information for this initial

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48 Inspection Service, USDA, April 23, 1984 [hereinafter cited as Houston Interview].

49 Lange Interview, supra note 9; Telephone Interview with Mr. John McCutcheon, Former Director, Policy and Program Planning Staff, Food Safety and Inspection Service, USDA, March 1984 [hereinafter cited as McCutcheon Interview]. FSIS does not follow Departmental procedures to the extent of preparing a formal "work plan." Rather, the initiating staff prepares an IPRA entry and a "threshold analysis," which serve as vehicles for obtaining upper level approval for new regulatory projects and for obtaining a determination from the Administrator on the "majorness" issue and the need for a Regulatory Flexibility Analysis. Lange Comments, supra note 44.

50 Lange Interview, supra note 9.

51 Lange Interview, supra note 9.

determination.[52] Although the Departmental Regulation states that personnel from the Office of Budget, Planning and Program Analysis are available to aid individual agencies in making threshold determinations,[53] the FSIS Policy and Program Planning Staff never relies on OBPA for advice.[54] The staff only very rarely (less than one time per year) makes a recommendation that a regulation be classified as "major," and it only slightly more often recommends that a Regulatory Flexibility Analysis be prepared for a rule.[55]

The Policy and Program Planning Staff forwards the IPRA entry and the threshold analysis to the Administrator, who makes a decision whether or not to pursue the rule. The current Administrator of FSIS is especially interested in being informed about all rulemaking initiatives early on in the pre-proposal process so that he can terminate poorly conceived efforts and guide the selection of options for efforts that he allows to go forward.[56] The Administrator has some concern about the natural tendency of lower level staffers to feel that they have failed if a rule that they have generated does not go forward. He feels that it is his responsibility

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52 Vitiello Interview, supra note 5.

53 Departmental Regulation 1512-1, supra note 7, at 2.

54 Telephone Interview with Ms. Judith Segal, Director, Policy and Program Planning Staff, Food Safety and Inspection Service, USDA, May 2, 1984 [hereinafter cited as Segal Interview II]; Lange Interview, supra note 9 ("No one from OBPA has asked for a threshold analysis recently.);" Meyerson Interview, supra note 18.

55 Vitiello Interview, supra note 5.

56 Houston Interview, supra note 48. On the other hand, the Administrator usually does not get involved in the development of minor rules until the decisionmaking process is almost completed.

to resist this tendency and to ensure that poorly conceived rules do not receive his initial approval.[57] It is therefore not unusual for the Administrator to meet informally with the Deputy Administrator for Meat and Poultry Inspection Technical Services prior to receiving the IPRA entry and threshold analysis. After the Administrator gives his initial approval to the IPRA entry and threshold analysis, he monitors the periodic docket development reports to determine the extent to which he will involve himself in the actual decisionmaking process.[58]

Pursuant to the Departmental Regulation, the IPRA entry is forwarded to the Assistant Secretary for Marketing and Inspection Services along with the staff threshold recommendation for a final threshold determination.[59] A copy is later forwarded to OBPA for review and inclusion in the regulatory agenda. OBPA has never believed that a threshold determination was so groundless that it has been motivated to disagree with the Assistant Secretary's determination.[60] Similarly, the Assistant Secretary never rejects the staff recommendation on whether an RIA or Regulatory Flexibility Analysis should be prepared.

This general deference to the FSIS's threshold efforts is largely attributable to the reputation that the agency has acquired within the Department for high quality analytical work.[61] In addition, the Assistant

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57 Houston Interview, supra note 48; Hibbert Interview I, supra note 43.

58 Houston Interview, supra note 48.

59 Departmental Regulation 1512-1, supra note 7, at 5.

60 Lange Interview, supra note 9; Meyerson Interview, supra note 17.

61 OBPA Communication, supra note 6.

Secretary does not have his or her own staff of experts qualified to perform this oversight function. The Assistant Secretary can, however, independently modify the agency's threshold recommendation based on internal Departmental policy or the controversial nature of the rule. Reserved nonmajor rules receive more attention at high Departmental levels than other nonmajor rules, but they do not generally follow the mandatory departmental procedures for major rules, such as routing through the Assistant Secretary for Economics and OBPA. In addition, while the agency generally prepares some kind of regulatory analysis document for reserved nonmajor rules,[62] the document need not fit the narrow confines of Executive Order 12291 and the OMB guidance documents. While the Policy and Program Planning Staff prepares a regulatory analysis document for virtually all FSIS rules, it rarely drafts a detailed document for nonmajor rules that have not been specially designated by the Administrator or the Assistant Secretary.

b. The Agricultural Marketing Service.

The Agricultural Marketing Service promulgates two kinds of rules. By far the most common rules address general marketing orders for commodities subject to such orders. Although styled "orders," these actions are by statute formal rules that require the formal rulemaking procedures of sections 556 and 557 of the Administrative Procedure Act.[63] The agency

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62 USDA, Secretary's Memorandum 1512-1, Reduction of Regulatory Burdens and Simplification of USDA's Decisionmaking Procedure, June 1, 1985, at 4.

63 5 U.S.C. §§ 556, 557 (1982).

must therefore make its decision on a formal record built through adversarial procedures.

Occasionally, however, the agency is empowered by statute to promulgate informal rules using informal rulemaking procedures. These two types of rules are treated quite differently from the perspective of regulatory analysis. The agency prepares RIAs and RFAs for all rules meeting the relevant thresholds, but the regulatory analysis documents for formal rules are submitted as formal testimony in the formal rulemaking hearings. As such, they are subject to cross-examination and rebuttal.[64] The agency ignores the Regulatory Flexibility Act and Executive Order 12291 in promulgating final formal rules.[65] Since the agency makes a special effort to encourage the participation of small businesses in the formal hearings, it takes the position that the formal opinion that concludes the formal rulemaking process is the equivalent to a final RIA and RFA.[66] In addition, a recent amendment to the appropriation of the Office of Information and Regulatory Affairs prohibits OMB from involving itself in the review of marketing orders.[67] The Office of Budget and Program Analysis, the Departmental "mini-OMB," does play a relatively active role in promulgating marketing orders compared to its role in other Departmental

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64 Toomey Interview I, supra note 27.

65 Regulatory Flexibility Act, 5 U.S.C. § 601(z) (1982); Exec. Order No. 12,291, 3 C.F.R. 127 (1982), at § 1(a)(1).

66 Telephone Interview with Mr. John Borovies, Dairy Division, Agricultural Marketing Service, USDA, May 4, 1984 [hereinafter cited as Borovies Interview].

67 Inside the Administration, Sept. 7, 1984, at 3.

regulatory programs.[68] The agency follows the Departmental procedures for the much rarer informal rules.

The origin of most rules in AMS is a new statutory enactment or a petition from the regulated industry. A staff employee in the Division dealing with the commodity that is the subject of the rule drafts the work plan for the rule and identifies options. Because the origin of many of the rules is a detailed statute, the options available to the agency are often limited. For example, the origin of a recent major rule on advertising and promotion of dairy products was a statute that explicitly told the agency what the rule should be and set out a narrow time frame for promulgating the rule. The staff of the Dairy Division had very little leeway in devising options.[69]

A draft of the work plan is forwarded to Regulation Review Staff under the Deputy Administrator for Marketing Program Operations. The Regulation Review Staff reviews the work plan, but rarely suggests additional options. The primary concern of the Regulation Review Staff is to ensure that the work plan is readable. This three-person Staff also makes a recommendation to the Administrator and the Assistant Secretary on whether the rule crosses the thresholds for preparing a formal RIA or RFA. The agency does no analysis for rules that do not require an RIA or RFA. The regulation then goes up to the Assistant Secretary for a threshold determination. Although OBPA receives a copy of the threshold recommendation, it has never found the

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68 Meyerson Interview, supra note 17.

69 Borovies Interview, supra note 66.

Assistant Secretary's threshold determination to be so far "off base" that it has recommended a change.[70]

c. The Animal and Plant Health Inspection Service.

A rule in APHIS typically comes from one or more of three sources. A staff employee in one of the two operating divisions[71] may identify the need for a rule, and the proposal flows upward.[72] Alternatively, a large pest outbreak may generate requests for action from the regulated farming and ranching community, and a staff person in one of the divisions is directed to work with the Regulatory Coordination Staff to initiate the rulemaking process.[73] Finally, members of the affected industries may petition the agency to initiate a rulemaking effort. Generally, the agency's rules are not very controversial, because they are designed to protect the regulated industries from pest and disease outbreaks. One controversial aspect of the agency's rules concerns the amount that the agency will pay for animals and crops that the agency destroys in quarantine programs.[74] Another unique aspect of APHIS rules is that they are often

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70 Meyerson Interview, supra note 17; OBPA Communication, supra note 6.

71 The operating services are divided along functional lines. The staff under the Deputy Administrator for Plant Protection and Quarantine deals with plant protection, and the staff under the Deputy Administrator for Veterinary Services deals with animal protection.

72 Anselmo Interview I, supra note 32.

73 Telephone Interview with Ms. Rita Anselmo, Policy Analyst, Policy Analysis and Program Evaluation Staff, Animal and Plant Health Inspection Service, USDA, May 3, 1984 [hereinafter cited as Anselmo Interview II].

74 Anselmo Interview II, supra note 73.

promulgated on an emergency basis, so that the regulatory analysis document, if any, must be prepared either on an expedited basis or after the fact.[75]

When an employee of one of the two divisions has identified the need for a rule or responded to instructions that a rule be considered, he or she will coordinate his or her activities with the Regulatory Coordination Staff in the Administrator's Office. The Regulatory Coordination Staff is charged with drafting the regulations for the agency.[76] The responsible staffer from the program office first drafts a work plan. The Regulatory Coordination Staff then reviews the work plan and presents it to the Assistant Secretary for Marketing and Inspection Services. The APHIS Policy Analysis and Program Evaluation Staff and the Departmental Office of Budget and Program Analysis do not participate in drafting the work plan.[77] Few efforts are made to identify options at the work plan stage;[78] rather, the plans usually consist of a broad articulation of a single proposal. The work plan is meant to present the essence of the idea that the staff is considering, and to give upper level decisionmakers a basis for determining the extent to which they will be interested in following the rule's development.[79] With this limited purpose, the plans are rarely specific,

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75 Telephone Interview with Mr. Thomas Gessel, Director, Regulatory Coordination Staff, Animal and Plant Health Inspection Service, USDA, May 4, 1983 [hereinafter cited as Gessel Interview I].

76 Telephone Interview with Mr. Thomas Gessel, Director, Regulatory Coordination Staff, Animal and Plant Health Inspection Service, USDA, May 21, 1984 [hereinafter cited as Gessel Interview II]; Anselmo Interview II, supra note 73.

77 Anselmo Interview I, supra note 32; Meyerson Interview, supra note 17.

78 Anselmo Interview II, supra note 73.

79 Gessel Interview III, supra note 33.

and they almost never include analysis or regulatory impact data.[80] The work plans do, however, contain a place for the staff to indicate its recommendation on whether the rule should be designated "major."

The Regulatory Coordination Staff forwards the agency's threshold recommendation through agency channels to the Assistant Secretary.[81] The technical officials in the two divisions usually provide the estimates of the impact that the regulation will have on the industry.[82] Occasionally, a staff official from the program division consults with a person on the Policy Analysis and Program Evaluation Staff concerning the threshold question.[83] This consultation usually consists of a meeting in which the two officials discuss preliminary impact data that the program staffer has assembled.[84]

Although the agency has prepared general guidelines that elaborate somewhat on the Executive Order's threshold criteria,[85] the determinations are still largely ad hoc.[86] The agency does not base its threshold

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80 Anselmo Interview II, supra note 73.

81 The Assistant Secretary may already be aware of the agency's preliminary rulemaking efforts prior to receiving the work plan. Because he or she receives status reports from the agency on a weekly basis, the Assistant Secretary can be closely associated with a regulation from its very inception. Gessel Interview III, supra note 33.

82 Gessel Interview II, supra note 76.

83 Anselmo Interview I, supra note 32; Gessel Interview I, supra note 75.

84 Anselmo Interview I, supra note 32.

85 Animal and Plant Health Inspection Service, APHIS Directive 114.3, October 19, 1982.

86 Anselmo Interview I, supra note 32.

determination on the amount that the regulation will benefit the agricultural industry or consumers.[87] According to the Director of the Regulatory Coordination Staff, if the agency used this measure for the threshold analysis, then a large number of programs that the agency undertook would be "major," because nearly every program provides domestic agriculture with more than $100 million worth of protection.[88]

The Assistant Secretary ostensibly makes the threshold designation on the basis of a recommendation from the agency. However, the work plans do not always include sufficient information for an intelligent threshold determination. Therefore the program staff and regulatory analysis staff often meet after the Assistant Secretary has signed the work plan to make an independent threshold recommendation.[89] The Assistant Secretary's formal determination rarely conflicts with their recommendation.[90] Although the standard form for the work plan has a place for the Assistant Secretary to make a Regulatory Flexibility Act determination, he or she usually does not do so at this early stage of a rule's development.[91]

The Departmental Office of Budget and Program Analysis is not involved in the agency's threshold recommendation or the review thereof.[92] The

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87 Gessel Interview I, supra note 75; Anselmo Interview I, supra note 32.

88 Gessel Interview I, supra note 75 ("From the standpoint of the consumer almost everything we do is a major rule."); Anselmo Interview I, supra note 32.

89 Anselmo Interview II, supra note 73.

90 OBPA Communication, supra note 6.

91 Anselmo Interview II, supra note 73.

92 Meyerson Interview, supra note 17.

agency analysts, however, do not operate in a vacuum. They generally consult with knowledgeable officials who might have an interest in their recommendations.

Part of the abbreviated nature of this process is attributable to the emergency nature of many of the agency's functions. When a pest outbreak threatens crops, the agency attempts to minimize its response time. Executive Order 12291 recognizes that agencies may have to respond to emergencies, and it exempts any major regulation that responds to an emergency situation, provided that the agency reports to OMB as soon as practicable, publishes an explanation for its failure to prepare an RIA in the Federal Register, and prepares an RIA as soon thereafter as practicable.[93] This can, however, put the agency in the anomalous position of publishing the RIA for its response to an outbreak long after

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93 Exec. Order No. 12,291, supra note 65, at § 8(a)(1). OMB has specifically exempted the following actions from OMB review:

1. Premises quarantined or released from quarantine based on presence of disease.
2. Change in domestic areas regulated because of the presence of animal pests or diseases.
3. Changes in lists of States meeting criteria for receiving animals imported from disease-affected countries.
4. Changes in the lists of ports-of-entry approved for importation or exportation.
5. Declaring foreign countries to be affected by certain animal diseases.
6. Extensions of regulated areas due to the detection of infestation of exotic plant pests.
7. Changes in domestic areas regulated because of the presence of plant pests or diseases.
8. Revisions to lists of hosts of plant pests or diseases.
9. Affirmation of final rules if an interim rule is published and there are no comments or all comments are favorable.

APHIS Directive 114.3, supra note 85, at 3. These actions have not, however, been exempted from the Regulatory Flexibility Act's requirements.

the pest has been brought under control.[94] Given the foregoing constraints on the agency's threshold analysis, it is perhaps not surprising that the agency has never prepared a formal RIA for a "major" rule. The program staff is, however, responsible for preparing regulatory analysis documents for rules that the Assistant Secretary designates "reserved nonmajor" and for rules for which the attorneys on the Regulatory Coordination Staff request additional information on regulatory impacts.

d. The Agricultural Stabilization and Conservation Service.

A rule in the Agricultural Stabilization and Conservation Service follows a route very similar to the route that a rule takes in the Agricultural Marketing Service. The most common impetus for a rule in ASCS is newly enacted legislation.[95] When Congress enacts a new Farm Bill, the Director of the Regulatory Impact and Executive Correspondence Staff (the regulatory analysis office) sends a reminder to personnel in the commodity divisions that they must submit work plans to his office.[96] Specialists serving under the relevant Deputy Administrator will then examine the new Farm Bill and identify the places in each program area where the agency must

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94 The Director of the Regulatory Coordination Staff, however, can remember no instance in which the agency has used the emergency nature of a regulation as an excuse to avoid preparing an RIA for a major rule. Gessel Interview III, supra note 33.

95 Another less frequently invoked source for ASCS rules is a petition from a farmer organization to amend the agency's operating procedures. Telephone Interview with Mr. Gene Rosera, Commodity Analysis Division, Commodity Operations, Agricultural Stabilization and Conservation Service, USDA, May 1, 1984 [hereinafter cited as Rosera Interview].

96 Walker Interview II, supra note 27; Rosera Interview, supra note 95.

promulgate regulations to implement the statute.[97] Most of the mandated changes have impacts on the agricultural sector of greater than $100 million and therefore require the agency to prepare an RIA. Moreover, since many of the programs that the agency administers have significant impacts on farmers, and since most farmers are small businesses, the concerns of small producers are also important to the agency.[98]

After a program office specialist has identified the need for a regulation, he or she fills out the work plan and forwards it to the Regulatory Impact and Executive Correspondence Staff.[99] The commodity specialist in the program office provides all of the regulatory impact information and analysis for the work plan. Normally, very little data gathering and analysis precedes the work plan. The work plan sometimes makes no attempt to identify and discuss options. In all cases, OBPA provides a memorandum to the Under Secretary providing background information and options, if needed, to permit appropriate designation.

The three-person Regulatory Analysis and Executive Correspondence Staff plays a largely review and advisory role. All members of that staff must have training in economics, but an employee from that staff will actually participate in the preparation of a work plan or regulatory analysis

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97 Specialists in the program office specialize in particular commodities. A single specialist will have responsibility for drafting all regulations and regulatory analysis documents pertinent to his or her special commodity.

98 Rosera Interview, supra note 95. Because most ASCS activities are not strictly regulatory actions (the programs are largely voluntary), the Regulatory Flexibility Act does not by its terms apply to most agency actions. OBPA Communication, supra note 6.

99 Rosera Interview, supra note 95; Walker Interview II, supra note 27.

document only when the program specialist assigned to prepare the RIA is overburdened with other responsibilities.[100]

The Director of the Regulatory Analysis and Executive Correspondence Staff next collects the work plans and places them on a semi-annual agenda. The agenda specifies a date for a policy guidance session, a date for publishing the proposed rule in the Federal Register, a date for a final policy guidance session to select from among the options in light of the public comments, and a date for publication of the final rule.[101] At the same time, the Director sorts through the work plans and makes threshold recommendations to the Under Secretary for International Affairs and Commodity Programs.[102] The Director does not make a separate attempt to gather data for this function, but over the years he or she becomes familiar with the programs that the agency administers and can make fairly accurate estimates about how the Under Secretary will want to designate work plans. The Director's recommendations are forwarded to the Under Secretary through the Departmental Office of Budget and Program Analysis (OBPA). A representative from OBPA then meets with the Under Secretary to make the threshold designations.[103] The specialists in the commodity programs

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100 Walker Interview II, supra note 27.

101 Walker Interview II, supra note 27.

102 For purely administrative changes to regulations that are clearly nonmajor, the Administrator is empowered to make the threshold designation without referring the rule to OBPA or the Under Secretary.

103 Telephone Interview with Mr. Wayne Bjorlie, Office of Budget and Program Analysis, USDA, May 5, 1983 [hereinafter cited as Bjorlie Interview I]; Walker Interview I, supra note 27.

divisions play no role whatsoever in the threshold designations.[104] The Under Secretary then designates the rule "major," "nonmajor," or "reserved nonmajor." Normally, a regulatory analysis document is prepared for reserved nonmajor regulations as well as major rules.

In making the threshold determination, potential government outlays and costs to the relevant agricultural sector are considered. Another important factor influencing the threshold designation is the "sensitivity" of the regulation. The effects of the regulation on consumers and political considerations play a role in determining sensitivity, as do practical considerations such as the threat of litigation. The agency will nearly always prepare a regulatory analysis document for nonmajor rules if the agency suspects that the rule may wind up in litigation.[105]

The next stage in the process, the first policy guidance session, is the most important step in the genesis of a rule at ASCS. The policy guidance session is usually attended by the program specialist and his or her Division Director and his or her Deputy Assistant Administrator. Others who usually attend policy guidance sessions generally include the Administrator or someone from his or her staff, one or two Deputy Administrators, one or two members of the Regulatory Impact and Executive Correspondence Staff, group leaders for other commodities, a representative from the Office of General Counsel, a person from the staff of the Under

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104 Walker Interview II, supra note 27.

105 Walker Interview I, supra note 27.

Secretary, a person from OBPA,[106] and a representative from ASCS state and county operations. A total of 10-20 people generally attend policy guidance sessions.

Prior to the meeting, the specialist prepares a lengthy agenda that explains the reasons for the regulation, identifies several options, relates the information and analysis supporting each of the options, and suggests a calendar for promulgating the rule.[107] In preparing the agenda the commodity specialist is careful to consult with persons with expertise in many areas within the Department. Representatives from virtually all of the entities that are represented in the policy guidance session are approached informally prior to the formal meeting for input and analysis. The commodity specialist maintains particularly close contacts with experts on the Departmental Interagency Commodity Estimates Committee that provides the numbers for the agency's economic analyses.[108] In addition, representatives from the various offices with the agency meet with the Administrator regularly to discuss regulatory projects and plan regulatory agendas. The Administrator in turn meets regularly with the Under Secretary. Through these informal mechanisms, the Administrator, the Under

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106 OBPA representatives regularly attend policy guidance sessions, and they sometimes offer options in addition to those that the commodity specialist has already identified. Bjorlie Interview II, supra note 17.

107 According to one of the program specialists, the agenda says in effect, "Here is what we have to accomplish. Here are the options that the law provides. Here are our constraints. Here is a review of the situation." Rosera Interview, supra note 95.

108 See, text accompanying notes 181-182, infra.

Secretary, and their staffs are kept abreast of important issues that arise in the rulemaking process.[109]

The purpose of the policy guidance session, which usually lasts about two hours, is to decide what options the agency will identify in its published proposal. The group attempts to identify a very broad range of options that "cover the waterfront."[110] For example, the agency believes that analyzing regulatory options beyond the scope of its current legislative authority may be useful in surfacing issues that might be appropriate for future legislative initiatives. Although any member of the group is encouraged to contribute options, the program specialist, who is the most familiar with the commodity and the statute, provides nearly all of the options in the agenda that he or she prepares in advance of the meeting.[111] The analyst, however, has usually discussed issues and options with other meeting participants prior to preparing the meeting agenda, and some additional options may arise during these discussions. Additional options usually arise out of the give and take of ideas and opinions during the policy guidance session.[112]

A second purpose of the policy guidance session, as its name implies, is to communicate policy preferences from upper level policymakers to the

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109 Telephone Interview with Mr. Larry Walker, formerly Group Leader, Regulatory Impact and Conservation and Program Evaluation Group, Analysis Division, presently Director, Regulatory Impact and Executive Correspondence Staff, Program Planning and Development, Agricultural Stabilization and Conservation Service, USDA, August 15, 1984 [hereinafter cited as Walker Interview III].

110 Rosera Interview, supra note 95.

111 Rosera Interview, supra note 95.

112 Walker Interview III, supra note 109.

program specialists. High level decisionmakers, including the Under Secretary, become intimately involved in the options identification process at the policy guidance sessions and in the informal communications that precede the policy guidance sessions. While upper level input helps to narrow the range of options somewhat, the policymakers do not dictate choices among options at this point.

The policy guidance sessions rarely give rise to disputes, because at this point the focus is primarily upon identifying options. Additional options can always be added to avoid disputes. Usually the participants' questions can be answered by reference to the newly enacted statute or prior administrative practice. Things can get more contentious later, when the Federal Register document and the regulatory analysis document are being circulated for review prior to being published and released.

After the policy guidance session, the program specialist writes a memorandum for the Assistant Secretary for Economics and the Under Secretary for International Affairs and Commodity Programs summarizing the need for the regulation, the options, and the advantages and disadvantages of the options. This gives the upper level decisionmaker (the Under Secretary) and the Department's chief economic advisor (the Assistant Secretary for Economics) a final opportunity to inquire about the direction that the agency is taking prior to the preparation of the proposal for the Federal Register. Occasionally, the Under Secretary's staff will call the specialist with questions or suggestions for additional options. If, however, the members of the policy guidance session have adequately

performed their options-identification function, the options listed in the memorandum should satisfy the Under Secretary.[113]

2. The Proposed Rule and the Preliminary Regulatory Analysis Document.

After the appropriate upper level policymakers approve a work plan, the agency initiates the process of drafting any regulatory analysis documents that must be prepared in conjunction with the rulemaking effort. If the proposed rule has been designated "major," or if the agency Administrator or other higher level decisionmaker has determined that a preliminary regulatory flexibility analysis or other regulatory analysis document should accompany the proposal, the agency will also begin the process of drafting that document. The locus of responsibility for drafting these documents varies from agency to agency within the Department. The Departmental Office of Budget and Program Analysis (OBPA) does not usually participate in drafting regulatory analysis documents,[114] but it does review the finished products for major and some nonmajor regulations. OBPA analysts are often queried for suggestions informally prior to the formal clearance process.[115] OBPA's primary role with respect to regulatory activities is to ensure that any major regulations that agencies propose are based upon adequate analyses and are consistent with broad Departmental policies. OBPA

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113 Rosera Interview, supra note 95.

114 Meyerson Interview, supra note 17.

115 Meyerson Interview, supra note 17.

also flags any inconsistencies with the Department's legislative positions.[116]

a. The Food Safety and Inspection Service.

A rule can take one of two paths within FSIS. A few important, complex and/or resource-intensive rules are developed by a working group of high level employees and lower level staff that is chaired by the Administrator or the Deputy Administrator for Technical Services. Most regulations, however, follow a different and more hierarchical path through the agency. In neither case does the Departmental Office of Budget and Program Analysis play a significant role in the decisionmaking or regulatory document drafting processes. In the late 1970s that office monitored the decisionmaking process relatively closely, but that role diminished to a minimal review role as FSIS acquired its own in-house analytical capability.[117] Regardless of which path the rule follows, the Policy and Program Planning Staff will undertake an informal analysis of the rule to contribute relevant information to the rule's preamble.[118] On some occasions this analysis is committed to writing in a separate internal document for upper level staff.

i. Rules Receiving Special High Level Treatment.

When the Administrator identifies a rulemaking that is certain to

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116 Meyerson Interview, supra note 17.

117 Segal Interview II, supra note 54.

118 Segal Interview II, supra note 54.

involve controversial and complex issues and significant agency resources, he has often designated that rulemaking for special high level management. In these rare cases,[119] the Administrator has formed a working group composed of his Special Assistant (who acts as the docket manager), the Deputy Administrator for Meat and Poultry Inspection Technical Services and one or more of his Division Directors, the Director of the Policy and Program Planning Staff and/or the Director of the Policy Analysis Office, the Deputy Administrator for Science and one or more of his staff, an occasional representative from OBPA,[120] and the Administrator himself. The Special Assistant has been responsible for drafting and reviewing rulemaking documents and coordinating the rulemaking efforts. She directs questions to persons with expertise in particular areas asking for their input, develops and circulates information, and works with staff members to resolve outstanding issues. Numerous drafts of the rulemaking documents are reviewed during lengthy working group meetings. The members of the working group attempt to achieve consensus on the contents of the contents of the regulatory provisions, the preamble, and other documents. Any disputes that cannot be resolved prior to the working group meetings are usually resolved by the Administrator on the spot after the discussion has reached an impasse.[121]

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119 Lange Interview, supra note 9; Telephone Interview with Ms. Judith Neibrief, Special Assistant to the Administrator, Food Safety and Inspection Service, USDA, March 12, 1984 [hereinafter cited as Neibrief Interview II].

120 The OBPA representative has been an irregular attender of these high level work group meetings, and he or she has always played a very
(Continued on page 44)

121 Houston Interview, supra note 48.

Since rules that receive special treatment have already been singled out for special treatment, they invariably require a regulatory analysis document. The Policy and Program Planning Staff is responsible for drafting this document. In preparing these documents, for both special and ordinary rules, the analysts on the Policy and Program Planning Staff rely almost exclusively on data from existing sources. Even for rules receiving special treatment, the agency only very rarely commissions original empirical research. The Policy and Program Planning Staff will search the relevant economic literature and request information from the relevant personnel in the Economic Research Service (formerly the Economics, Statistics and Cooperatives Services). On very rare occasions a group in the Economics Research Service has studied the agency's regulatory problem and suggested an economic model to aid the agency.[122]

The most common source of information on the costs of compliance with agency regulations is the regulated industry. Occasionally a company or trade association prepares a regulatory impact study for a particular rulemaking.[123] More often, the agency simply asks industry

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120 minor role in the decisionmaking process. See MSM Case Study, Appendix A; Lange Interview, supra note 9; Meyerson Interview, supra note 17.

122 For example, in the "Mechanically Separated (Species)" rulemaking (detailed in the Appendix to this Report), the staff of the Economics, Statistics and Cooperatives Services developed a model for assessing the impact of various options. The agency in that case, however, elected not to use the model. See, MSM Case Study, supra note 14.

123 In the "Mechanically Separated (Species)" rulemaking, for example, the agency relied almost exclusively on the analysis of two industry-submitted studies. The regulatory analysis office did, however, contract for an independent analysis of one of the studies

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representatives to estimate the projected compliance costs for a particular regulatory proposal. The agency, however, has generally found this to be an unsatisfying source of information. In addition to the obvious distortions resulting from the data submitter's incentive to inflate cost estimates, analysts within the agency have discovered that most of the companies that the agency regulates do not have cost accounting systems that allow them to calculate compliance costs with any accuracy. This absence of an adequate cost accounting device has lead the Director of the Policy and Program Planning Staff to conclude that the agency has no verifiable method to "get to the bottom of how much regulations cost the industry."[124]

Finally, the agency does on rare occasions conduct its own empirical research.[125] For example, the agency can undertake an independent survey of meat packing plants. While the presence of an FSIS inspector in every meat packing plant can facilitate such a survey, it is still very expensive, and the agency is generally reluctant to undertake such studies on its own.[126]

The regulatory analysis document typically evolves as the high level working group deliberates, and it is usually completed at about the same time that the working group has finished with the rulemaking documents. Options and analyses change as the working group identifies new options and

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123 and had the other evaluated by personnel in the Economics, Statistics and Cooperative Services. See, MSM Case Study, supra note 14.

124 Segal Interview II, supra note 54.

125 The agency has only very recently begun gathering cost data in a systematic way. Segal Interview II, supra note 54.

126 Segal Interview I, supra note 28.

suggests different rationales for choosing one or another option. The Policy and Program Planning staffer's chief function at the working group meetings is to provide information to the working group on the costs of various options. Occasionally he or she identifies options for the working group that the group did not see, but these instances are relatively rare.

Because regulatory analysis documents evolve as the rulemaking documents evolve, the time consumed in preparing them does not delay the decisionmaking process. For the same reason, however, the regulatory analysis document itself plays no real role in the high level decisionmaking process. While the information that is ultimately contained in the regulatory analysis document is usually available to the working group through the participation of the Policy and Program Planning Staff, the document itself is not completed until after the working group's decisions are made.[127]

The document drafter therefore has an opportunity to construct the document in a way that reflects the decisions reached by the working group as conflicts are resolved throughout the evolution of the project.[128] Members of the Policy and Program Planning Staff feel that within broad limits their duty is to draft a document that makes the best analytical argument for what the agency proposes. The analyst does not draft a document that represents his or her individual position on the issues.[129]

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127 See, MSM Case Study, supra note 14; McCutcheon Interview, supra note 49; Lange Interview, supra note 9.

128 Lange Interview, supra note 9. ("The analysis that we do will always support the document that comes out at the end.")

129 Lange Interview, supra note 9.

The final regulatory analysis documents that the agency makes public therefore represent a "blend of analysis and advocacy."[130] The Policy and Program Planning Staff perceives that at least part of its effort is for the benefit of OMB rather than the agency's Administrator.[131] The Administrator will usually read the regulatory analysis document for "special" rules prior to forwarding the proposal to the Assistant Secretary.[132]

ii. Ordinary Rules.

Once the Administrator has approved an IPRA entry and threshold analysis,[133] ordinary rules generally work their way from the bottom up through the institutional hierarchy. After the Administrator approves a rulemaking project in concept, one or more staff employees in the Meat and Poultry Inspection Technical Service Division (program office) is responsible for gathering data, performing the technical analyses, and drafting the rulemaking documents. At present, the standard operating procedures for ordinary rules in the agency do not provide for assembling a working group to develop rulemaking proposals, though this may change in the very near future. The program office staff member, however, has generally met informally with other persons in the agency, including the Policy and

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130 Lange Interview, supra note 9.

131 Lange Interview, supra note 9.

132 Houston Interview, supra note 56.

133 The Administrator terminates some rulemaking initiatives at the IPRA entry/threshold analysis stage, which is intended to allow the Administrator to give some "top-down" direction before substantial Agency resources are committed.

Program Planning Staff, who might be affected by or have expertise on the rule.

After the program office employee has drafted the rulemaking documents and the decision package, he or she forwards it to his or her Division Director for review.[134] Whether this process is accomplished with or without any significant input from the analysts in the Policy and Program Planning Staff depends on the origin of the rule. If the rule originates within the program office (a "bottom up" rule),[135] then the program office is as a practical matter obliged to "sell" the rule to the other offices in the agency. The program office will take pains to coordinate its ideas with the Policy and Program Planning Staff at a relatively low staff level to ensure that no major objections arise later on in the process when that office has formal input.[136] If, however, the Administrator has already indicated his or her desire to promulgate a rule (a "top down" rule), the program office often feels less constrained to secure the advance agreement of the Policy and Program Planning Staff.[137]

After the decision package has received the Division Director's approval, he or she forwards it across to the Regulations Developmental Unit

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134 Hibbert Interview I, supra note 43.

135 I use the term "bottom up" rule here to describe rules that the program offices have generated and which would probably die without a commitment from low level employees in the program office. The term is not meant to imply that high level officials in the agency have not approved of them. The Administrator of FSIS approves every rulemaking effort that goes forward in the agency at a very early stage in the rule's evolution.

136 Hibbert Interview I, supra note 43; Lange Interview, supra note 9.

137 Hibbert Interview I, supra note 43.

in the Policy and Program Planning Staff. The Regulations Developmental Unit is a separate unit from the analytical staff of the Policy and Program Planning Staff, and it performs the functions of coordinating rules and ensuring that they contain all of the information required for Federal Register publication. The package is also forwarded to the analytical staff of the Policy and Program Planning Staff for a determination whether the regulation should undergo further analysis. For routine regulations, the program office tends to assume that an elaborate regulatory impact analysis is unnecessary and perhaps undesirable.[138] In the program office's perception, its job is to get the regulations up through the chain of command as rapidly as possible so that their superiors see them as efficient case managers. Since the Policy and Program Planning Staff is not in their chain of command, program office officials do not see much value in burdening the process with a lot of external analysis.[139] Still, if the Policy and Program Planning Staff decides that further analysis is necessary, the program office will usually acquiesce, even though this means that the regulation will inevitably suffer some delay.[140]

If the Policy and Program Planning Staff elects to perform a regulatory analysis, the intensity of the analysis will vary with the importance of the rule. The Policy and Program Planning Staff's chief concern is that the program office explicitly place the proposal within the agency's existing

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138 Hibbert Interview I, supra note 43.

139 Hibbert Interview I, supra note 43.

140 For those rules that have been coordinated earlier in the regulation development process, the analysis may have already begun, and delay is thereby avoided.

policy framework. Either the rulemaking documents or the regulatory analysis documents prepared by the Policy and Program Planning Staff should state how the proposal will advance particular policy objectives of the agency.[141] Policy and Program Planning Staff officials feel that relating proposals to specific policy objectives helps make the agency accountable for its decisions.[142] In the opinion of the Director of the Office of Policy and Program Planning, the agency lacks a tradition of "going back to zero and explaining why we are doing what we are doing."[143] The Policy and Program Planning Staff feels that this intellectual exercise ultimately generates better decisions.

The two different perspectives of the regulatory analysis office and the program office inevitably breeds tension between the two staffs. The program office adopts a "production type" mentality that abhors "paralysis by analysis." Once the program office is satisfied with the substance of a rule and its explanation for that rule, it would prefer that the Policy and Program Planning Staff "roll over" and acquiesce in the work that the program office has done.[144] The goal of the Policy and Program Planning Staff, on the other hand, is to have the program office adequately explain itself and identify and discuss all of the relevant options. In the minds of some Policy and Program Planning Staff employees, regulatory programs become "management-oriented," and managers are reluctant to re-examine old

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141 Segal Interview I, supra note 28.

142 Segal Interview I, supra note 28.

143 Segal Interview I, supra note 28.

144 Hibbert Interview I, supra note 43.

assumptions. In this view, the program staffers are inclined over time to lose track of the reasons for why they do things, and they fail to relate the rules to the policy framework defined by the agency's statute.[145] As a result, past and present directors of the Policy and Program Planning Staff have urged staff analysts to play an aggressive policy development role.[146] Additionally, they have attempted to push the program office in the direction of the goals of Executive Order 12291, a direction that the program office might not otherwise pursue.[147]

Since the program office has already decided upon a preferred option by the time that the Regulations Development Unit of the Policy and Program Planning Staff sees the rulemaking documents, the tension becomes most acute when the Policy and Program Planning Staff suggests that the program consider additional options. Whether the program office is likely to acquiesce in the Policy and Program Planning Staff's suggestions depends once again on the origin of the rule. If the idea for the rule originated in the program office, that office must attempt to build a consensus for the rule throughout the agency. The program office may therefore be more receptive to suggestions and delay the process while the Policy and Program Planning Staff prepares a regulatory analysis document. If the rule originated at higher levels in the agency and the program office perceives that the Administrator would like to see the proposal published rapidly, it is likely to press forward with the rule through the chain of command to the

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145 Segal Interview I, supra note 28.

146 McCutcheon Interview, supra note 49; Segal Interview I, supra note 28.

147 McCutcheon Interview, supra note 49.

Administrator, irrespective of the Policy and Program Staff's wishes. Of course, if a regulatory analysis is required by the Regulatory Flexibility Act or Executive Order 12291 or if the Assistant Secretary has determined that a regulatory analysis document should be prepared, the program office has no choice; it must await the preparation of a regulatory analysis document by the Policy and Program Planning Staff. However, only one rule in the history of FSIS has been a "major" rule, and that rule received the special treatment of a high level work group.

If the program office decides to wait for the Policy and Program Planning Staff to prepare a regulatory analysis document, there is still a potential for conflict after that document is completed. The regulatory analysis effort may raise concerns in the Policy and Program Planning Staff about the advisability of promulgating the rule as drafted by the program office. If the Policy and Program Planning Staff's concern is minor, the program office will redraft the rulemaking documents to reflect this concern. If the Policy and Program Planning Staff's concern is more substantial and the program office agrees, the program office will redraft the rulemaking documents, and it may amend the proposal itself. If the program office disagrees with the Policy and Program Planning Staff's concerns or if those concerns suggest a major overhaul of the rule, the program office is generally fairly inflexible. That office regards the rule as ultimately within its baliwick, and it is reluctant to make major changes if it is not convinced that they are necessary.[148] Ultimately, the Administrator may be called upon to resolve the substantive dispute. The

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148 Hibbert Interview I, supra note 43.

Policy and Program Planning Staff, however, has rarely escalated matters to the Administrator, preferring instead to adopt a less confrontational role.[149] In the past, the fact that the Deputy Administrator in charge of the program office was a very strong and highly regarded administrator meant that most disputes were resolved in favor of the program office.[150]

During the last several years the rulemaking process in FSIS has gradually evolved away from the hierarchical model toward the team model that the agency uses for rules that receive special high level treatment. The agency is seriously experimenting with the idea of assigning the task of preparing the rulemaking documents to a team of agency officials from the relevant agency offices chaired, in most cases, by the program office. The Policy and Program Planning Staff would, under this scheme, become involved in the rulemaking effort at an earlier stage, before the program office has solidified behind a particular option. The documents would result from a consensus-building effort that would possibly eliminate much of the friction that has sometimes characterized the relationship between the two offices in the past.[151]

b. The Agricultural Marketing Service.

In the Agricultural Marketing Service, an employee in the commodity

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149 Lange Comments, supra note 44. ("We recognize that in other agencies . . . the economic analysis group frequently takes a position opposing a program's proposal. They fight it out at the top. We simply don't do that.")

150 Hibbert Interview I, supra note 43.

151 Segal Interview I, supra note 28; Hibbert Interview I, supra note 43; McCutcheon Interview, supra note 49.

division drafts both the rulemaking documents and the regulatory analysis documents. This person will generally introduce both documents and any studies that support those documents in formal testimony in the formal rulemaking hearings. He or she is then subject to such cross-examination as the Administrative Law Judge allows. Regulatory analyses are performed only very rarely for major informal rules that do not go through the formal hearing process. Indeed, in the last 12 months AMS has promulgated no major informal rules.[152] The agency has prepared formal RIAs only for its controversial proposals for amending its beef grading standard (which was later withdrawn) and its Dairy Promotion Program. AMS rulemaking efforts do not utilize formal working groups. The commodity division employee forwards the documents that he or she drafts to the regulation review staff, which performs the ministerial function of ensuring that the documents are suitable for publication in the Federal Register.[153] The regulation review staff then forwards major rules and accompanying RIAs to the Administrator for review. From there they go to OBPA for review of the economic analysis. OBPA, however, plays only a very minor review role.[154]

For formal rules, the agency relies heavily upon data from the Bureaus under the Assistant Secretary for Economics. An additional source of data is the regulated industry. All of this information is closely scrutinized in the formal hearings, and this is the chief mechanism that the agency

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152 OBPA Communication, supra note 6.

153 Toomey Interview I, supra note 27.

154 Toomey Interview II, supra note 31. Interestingly, the commodity division employee interviewed in connection with this report who prepared the Regulatory Impact Analysis for the Dairy Promotion Program had never heard of OBPA. Borovies Interview, supra note 66.

employs in screening data for bias. The agency has no systematic sources of data for its rare regulatory analysis documents for informal rules.[155]

c. The Animal and Plant Health Inspection Service.

An attorney on the Regulatory Coordination Staff has the primary responsibility for drafting most rulemaking documents in APHIS with the aid of staff from the program office. After he or she drafts the documents, the attorney meets with the program staffer and representatives from any other programs that the rule may affect. A representative of the Policy Analysis and Program Evaluation Staff (the regulatory analysis office) will meet with this working group only if the program office or the regulatory coordination staff explicitly requests that Staff's input.[156] At these working group meetings the participants critique and edit the rulemaking documents.

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155 The Preliminary RIA for the proposed amendments to the beef grading standards was prepared by the Policy and Program Planning Staff of the FSIS, before the beef grading function was transferred to AMS.

The Final RIA for the Dairy Promotion Program does not rely on any data. Instead, it makes several predictions about the possible impact of a 15 cents per hundredweight assessment on milk to be spent for advertising dairy products. It predicts that the advertising may increase demand for milk, which will cause more to be purchased at the administratively supported price, which might allow the government to purchase less milk at the artificially high support price and thereby save taxpayers the cost of purchasing excess supplies of milk at supported prices. While this is a sensible prediction of the general effects of the rule, it is obviously not an especially sophisticated economic analysis. In particular, the analysis does not attempt to explain why it makes economic sense to force consumers to bear the cost of advertising aimed at increasing demand for a product that sells at artificially high administered prices. On the other hand, it may be unfair to expect any analyst to attempt to justify a

(Continued on page 56)

156 Telephone Interview with Ms. Rita Anselmo, Policy Analyst, Policy Analysis and Program Evaluation Staff, Animal and Plant Health

(Continued on page 56)

Since it proposes so few "major" rules and since the few "major" rules that it does propose usually obtain "emergency" waivers, the agency as a practical matter does not have to prepare formal regulatory analysis documents. Nevertheless, the agency has promulgated a Directive on Regulatory Analysis[157] and it maintains a small Policy Analysis and Program Evaluation Staff that is charged, inter alia, with drafting regulatory analysis documents. The staff in the program offices prepare nearly all regulatory analysis documents. These documents are then reviewed by the Regulatory Coordination Staff. When the Regulatory Coordination Staff identifies analytical gaps in the rationale for proposed regulations, they generally return the document to the program office staff for further work. For rules requiring an RIA or RFA, the Regulatory Coordination Staff may call upon the Policy Analysis and Program Evaluation Staff for aid in preparing the economics sections of the regulatory analysis documents.[158]

The fact that the Policy Analysis and Program Evaluation Staff only becomes involved in the development of a regulation upon request means that when it does enter the process, it does so after the program office has eliminated most alternatives to its proposal. This leaves some personnel on Policy Analysis and Program Evaluation Staff with the strong impression that

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(Continued from page 55)
155 congressionally mandated rule that has so little economic justification and bears such heavy political freight.

(Continued from page 55)
156 Inspection Service, USDA, May 21, 1984 [hereinafter cited as Anselmo Interview III].

157 APHIS Directive 114.3, supra note 85.

158 Gessel Interview III, supra note 33.

they are only invited to meetings when the Regulatory Coordination Staff believes that the regulations are in need of further justification.[159] The Policy Analysis and Program Evaluation Staff, however, has resisted the role of "justifier." On one occasion, when that staff was asked to participate in a rulemaking effort, it prepared a regulatory analysis document, even though a separate document was not requested. That document identified and examined alternatives to the program office's proposal and critiqued that proposal.[160] The Policy Analysis and Program Evaluation Staff are most concerned that the working group examine alternatives to the initial proposal.[161] If the regulatory analyst feels strongly enough about an alternative that the program office did not examine, the analyst may attempt to send his or her independent analysis through formal channels to the Deputy Administrator for Administration, thereby virtually ensuring that the document will find its way into the rulemaking record.[162] The

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159 Anselmo Interview II, supra note 73.

160 Anselmo Interview II, supra note 73. ("We do analyses. We do not justify rules.") The Director of the Regulatory Coordination Staff believes that the Policy Analysis and Program Evaluation Staff misconstrued its role in this instance. The Regulatory Coordination Staff had asked that staff to prepare a Regulatory Flexibility Analysis pointing out options for making the rule that the program office had drafted more flexible for small business. In the Directors' opinion, a Regulatory Flexibility Act does not require the agency to explore alternatives to the entire rulemaking effort; it merely requires the agency to explore options for making the rule more flexible. The Policy Analysis and Program Evaluation Staff, however, drafted a Regulatory Impact Analysis that explored nonregulatory options and suggested that the entire rule was unnecessary. The program office and the Regulatory Coordination Staff was not receptive to the RIA.

161 Anselmo Interview I, supra note 32. ("We affect decisions by developing alternatives.")

162 Anselmo Interview II, supra note 73.

Director of the Regulatory Coordination Staff, however, does not believe that the Policy Analysis and Program Evaluation Staff has the authority to elevate issues to higher levels within the agency.[163] The Policy Analysis and Program Evaluation Staff does not have any authority to veto a rule with which it disagrees.

The Departmental Office of Budget and Program Analysis, a potential ally to the regulatory analysis office in these matters, plays no role whatsoever in the internal agency decisionmaking process,[164] because the agency promulgates so few major rules. Another potential ally, the Office of Management and Budget, is more helpful. OMB occasionally asks the APHIS liaison why the Policy Analysis and Program Evaluation Staff did not prepare a regulatory analysis document on a rule when the OMB staffer has questions about the cost-effectiveness of a rule for which the agency has not prepared such a document.[165] More often, however, OMB questions the substance of the rule, rather than the analysis supporting it.[166]

In the opinion of the Director of the Regulatory Coordination Staff, it is almost always cheaper to stop a pest infestation or disease at the border or limit its spread through quarantine than it is to allow the infestation or disease to spread. In his opinion, "the benefit of our regulations so obviously outweigh the costs that it is not necessarily a good use of our

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163 Gessel Interview III, supra note 33.

164 Anselmo Interview II, supra note 73.

165 Anselmo Interview I, supra note 32.

166 Gessel Interview III, supra note 33.

resources to engage in detailed analysis."[167] He feels that the regulatory analysis requirement of Executive Order 12291 is therefore largely inappropriate for the agency's activities. While an important purpose of regulatory analysis is to force the agency to justify its rules by explicit reference to agency policy, the justification for most APHIS rules is, in his opinion, obvious.[168] Finally, he is of the opinion that the agency nearly always chooses the least-cost alternative for combating a pest or disease. There is, however, apparently little documented analysis of the costs to all economic sectors of the various regulatory options.[169]

At least one member of the Policy Analysis and Program Evaluation Staff, on the other hand, feels that agency decisions could be improved by a larger effort to identify less costly alternatives to current response mechanisms, citing the failure to search broadly for alternatives in the agency's response to the Mediterranean Fruit Fly outbreak in 1981 as an example of agency failure in this regard.[170] Conceding that regulatory analysis is rarely determinative of the big "yes-no" decisions, the regulatory analyst nevertheless argues that analysis can be very helpful in identifying minor cost-effective suboptions and in discovering instances in which rules impact intensely in unintended ways upon small entities.[171]

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167 Gessel Interview III, supra note 33.

168 Gessel Interview I, supra note 75.

169 OBPA Communication, supra note 6.

170 Anselmo Interview I, supra note 32.

171 Anselmo Interview III, supra note 156.

On the rare occasions when the Policy Analysis and Program Evaluation Staff does prepare a regulatory analysis document, it relies to a large extent on government-generated data. Information on small entities is obtained from census data. Projections on the prices of animals that must be destroyed are obtained from the Economic Research Service. Information on impacts on the farming industry is obtained by telephoning affected parties. The Policy Analysis and Program Evaluation Staff cooperates with regulated entities in seeking the most cost-effective ways to approaching problems.[172] The agency has no effective mechanism for checking for bias in this source of data. According to one analyst on the Policy Analysis and Program Evaluation Staff, it is difficult to get hard data in this area.[173] The agency has no funds to hire contractors to supply further information and analysis.[174]

d. The Agricultural Conservation and Stabilization Service.

The first "policy guidance session" is the "kickoff" for the regulatory analysis process. After that meeting, the ASCS commodity program specialist drafts the rulemaking documents and any necessary regulatory analysis documents. The agency prepares regulatory analysis documents for all "major" rules, nearly all "reserved nonmajor" rules, and many "minor" rules.[175] For other rules, the rulemaking documents that are published in

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172 Anselmo Interview I, supra note 32.

173 Anselmo Interview II, supra note 73.

174 Anselmo Interview I, supra note 32.

175 Walker Interview I, supra note 27.

the Federal Register contain a significant amount of economic impact information.[176] The commodity program specialist may draft rudimentary parts of the rulemaking documents first, because they must be approved by the Departmental Office of General Counsel. The Office of General Counsel has recently begun to require at least some analysis of the options in the rulemaking docket.[177] The review process is often brought to a relatively rapid conclusion by the statutory target date for the rule's promulgation.[178]

While the Office of General Counsel is reviewing the rulemaking documents, the program specialist drafts the regulatory analysis document and circulates it to persons who might be interested in its contents. Regulatory analysis documents vary from about ten to thirty pages in length, and they often contain 2-3 tables detailing economic impacts.[179] Since the regulatory analysis document and the rulemaking document address the same subject matter, there is generally a good deal of overlap and repetition.[180]

The analyst's roles are: to ensure that the relevant information is included in the regulatory analysis document; to analyze that information; to discuss the information and analysis with persons in the Department who may have a knowledgeable opinion about the relevant issues; and to draft the

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176 Walker Interview II, supra note 27.

177 OBPA Communication, supra note 6.

178 Rosera Interview, supra note 95.

179 Walker Interview I, supra note 27.

180 Walker Interview I, supra note 27.

document.[181] The program analysts depend heavily upon others for the information that goes into the regulatory analysis documents. Virtually all of this information comes from sources within the Department. The program specialists rely to a very large extent upon the estimates generated in monthly meetings of the Departmental Interagency Commodity Estimates Committee. This committee includes members from ASCS, the Economic Research Service, the Foreign Agricultural Service, the Agricultural Marketing Service, and the World Agricultural Outlook Board. The committee products are published as the official USDA commodity estimates, and individual agencies within the Department are not free to depart from these estimates in undertaking regulatory activities.[182] It would therefore be very difficult for anyone in ASCS to "fudge" the numbers to support a preconceived result.[183] The Committee estimates reflect the best collective judgment of some of the most highly qualified agricultural economists in the country, and they are generally regarded as objective and reasonably accurate. These estimates also form part of the basis for a good number of private investment decisions.

In addition to relying on Departmental economists for information, the program specialists in ASCS usually make a point of sending the tables that are at the core of the regulatory analysis documents to their counterparts in the Departmental Office of Budget and Program Analysis for review prior

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181 OBPA Communication, supra note 6.

182 Rosera Interview, supra note 95; Walker Interview II, supra note 27.

183 Walker Interview III, supra note 109.

to completing the full-blown RIA.[184] Program specialists and members of the Regulatory Impact and Executive Correspondence staff in ASCS have a great deal of respect for their counterparts in OBPA, and they do not hesitate to take advantage of their advice. This receptivity to OBPA input makes ASCS unique among the USDA agencies studied in connection with this Report.

After the commodity program analyst completes the proposed rule, which is really no more than a series of proposed options, and the regulatory analysis documents, he or she forwards them to the relevant group leader or branch chief for review. From there, the documents proceed to the Director and/or Deputy Director of that Division. They are then forwarded to the Regulatory Impact and Executive Correspondence Staff for review. That staff reviews the regulatory analysis document for completeness, and the staff may edit the analysis to include any aspect of the analysis that may have been omitted. Finally, the Regulatory Impact and Executive Correspondence Staff examines the regulatory analysis document to ensure that all of the options that it identifies are reasonable and feasible.[185] The Director of that staff has veto power, and the program specialist will generally accommodate any objections that the Regulatory Impact and Executive Correspondence Staff has with the proposal.

The members of the Regulatory Impact and Executive Correspondence Staff have training in economics, and one of their jobs is to find soft spots in the regulatory analysis documents. If someone on the Regulatory Impact and

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184 Rosera Interview, supra note 95.

185 Walker Interview III, supra note 109.

Executive Correspondence Staff has a problem with the program specialist's analysis, the two will meet informally to discuss the objection. Since not all of the program specialists are trained in economics, they usually accept the input of the Regulatory Impact and Executive Correspondence Staff. On occasion, however, the program specialist, who is intimately familiar with the particular commodity that he or she oversees, must educate the economists in the realities of the markets that the agency regulates.[186]

At the same time that the Regulatory Impact and Executive Correspondence Staff is reviewing the rulemaking and regulatory analysis documents, any Division Directors who have an interest in the rule may review those documents. Most of these reviewers likewise have training in economics, and many of them began as commodity program analysts themselves.

After the Director of the Regulatory Impact and Executive Correspondence Staff signs off on the rulemaking package, he forwards it to the Deputy Administrator for the appropriate program area and then to the Administrator's Office. From the Administrator's Office the package goes to the Office of General Counsel and OBPA for formal sign-off. Since the documents have already been reviewed by the General Counsel's Office and OBPA at the staff level, and since any suggestions of those offices have been incorporated, this is usually a pro forma undertaking. The package is then forwarded to the Under Secretary for approval, after which it is reviewed by OMB. Prior to this point, OMB has had no formal input into the rulemaking process.

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186 Walker Interview II, supra note 27.

3. Interagency Review of Proposed Rules and Preliminary Regulatory Analysis Documents.

Executive Order 12291 requires that all agencies forward copies of proposed rules to OMB prior to publishing them in the Federal Register. The Departmental Regulations state that the Office of Budget and Program Analysis is the agency within the Department with responsibility for coordinating the clearance of regulations through OMB, responding to OMB questions, maintaining records of transmittals to and from OMB, and notifying agencies of OMB actions.[187]

Personnel in the individual agencies forward documents to their counterparts in OMB and send "courtesy copies" to OBPA as required by OBPA regulations.[188] Agency and OBPA personnel will often contact OMB personnel apart from the formal clearance process to discuss problems that OMB may have with the agency's work product.[189] For example, in the MSM Rulemaking, personnel from the FSIS Policy and Program Planning Staff met twice with OMB officials to discuss problems that OMB had with the Preliminary RIA and the Final RIA for that rulemaking. Although several high level agency officials were present at meetings with OMB, the primary agency contact with OMB was in fact a mid-level management employee in the agency's Policy and Program Planning Staff who had worked on drafting the RIA. The discussions, which focused heavily on the substance of the regulations and the content of the RIA, did not include OBPA personnel.[190]

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187 Departmental Regulation 1512-1, supra note 7, at 5.

188 Clemans Interview I, supra note 19.

189 Clemans Interview I, supra note 19.

190 See, MSM Case Study, supra note 14.

Thus, while on paper OMB dialogues only with OBPA personnel, in reality much substantive communication between OMB and both OBPA and FSIS personnel has occurred outside of the formal Departmental clearance process.[191] Formal OMB clearances are, however, coordinated through OBPA.

The time consumed in OMB review has not been especially burdensome to two of the agencies studied here. Most APHIS regulations are exempt from OMB review, and those rare rules that do not receive total exemptions are emergency rules for which the agency can prepare RIAs after the fact. OMB examines the text of APHIS rules in advance, but it generally agrees with what the agency proposes.[192] The Food Safety and Inspection Service, which probably sends the most detailed analyses to OMB, has not experienced undue delay in receiving responses from OMB.

Both the Agricultural Marketing Service and the Agricultural Stabilization and Conservation Service have experienced some delays with OMB review.[193] Because the programs of both of these agencies are closely tied to growing cycles, they are especially sensitive to delays of even a few days. In addition, some of the complaints about delay may stem from the resentment that some program office employees feel at having to rewrite documents in response to OMB criticisms.

In ASCS these problems of delay are largely worked out informally. The program specialist can often avoid delay by "touching base" with his or her

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191 Clemans Interview I, supra note 19; Lange Interview, supra note 9. All participants in the informal review process believe that it is a valuable timesaving device.

192 Gessel Interview I, supra note 75.

193 Walker Interview II, supra note 27; Toomey Interview I, supra note 27.

counterpart in OMB prior to sending the documents to OMB for review.[194] ASCS personnel have generally found OMB personnel to be responsive to the agency's need to accomplish OMB review expeditiously.[195] This can have the practical effect of rendering irrelevant upper level Departmental review. In most cases, however, upper level Departmental officials keep abreast of a rule's progress in the agency, and they pass down their concerns and directions long before they see the full rulemaking package during the formal review process. Even though the formal review process is often pro forma, low level contact with OMB does not necessarily freeze out upper level policymaking officials. The extent of upper level input into the decision thus depends largely upon the informal interactions between upper level policymakers and the lower level personnel who are responsible for drafting the rulemaking and regulatory analysis documents.

In the case of AMS, the problems of delay have been more severe. Personnel in OMB have had a philosophical antipathy toward marketing orders, the promulgation of which is one of AMS's primary functions. OMB has on several occasions prolonged its review of these orders to such an extent that they never went into effect. Since OMB is generally prompt in responding to USDA-submitted regulations, there is a strong implication that the long delays in responding to AMS marketing orders has not been due to overwork or other resource considerations. The delay caused by OMB review has had a profound substantive impact on many of the programs that AMS

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194 Walker Interview II, supra note 27; Rosera Interview, supra note 95. OMB rarely makes substantive comments at the proposal stage. Rosera Interview, supra note 95.

195 Walker Interview III, supra note 109.

administers. Not surprisingly, the affected constituency groups petitioned Congress for relief, and Congress wrote a prohibition on interference with AMS marketing orders into OMB's appropriation.[196]

Although USDA agencies, with the notable exception of AMS, have not generally experienced undue problems of delay from OMB review, they still attempt to avoid it whenever possible. Part of this inclination is undoubtedly attributable to the natural desire of any institution to avoid review by another. Perhaps a more important factor, however, is the almost universal perception in all of the USDA agencies studied in connection with this Report that OMB personnel, while bright and articulate, often have too little time to obtain an appropriate level of sophistication in program complexities. Many employees have even stronger opinions on the apparent inability of OMB personnel to understand USDA programs in a sophisticated way. According to some USDA personnel, this impression of the quality of OMB staff, which is no doubt reciprocated, strongly colors the relationship between the two institutions. Other USDA personnel have the impression that OMB personnel are simply trying to manage USDA agencies from afar. Both of these impressions help explain the tendency of all agencies in the Department to avoid OMB review if at all possible.

4. Agency Response to Public Comment.

After the public has had an opportunity to comment on the agency's proposed rule and preliminary regulatory analysis documents, the agencies must take those comments into account in promulgating their final rules.

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196 Inside the Administration, Sept. 7, 1984, at 3.

The public comments can be directed toward the technical and legal analysis in the proposed rule's preamble, or they can address the analysis contained in the regulatory analysis documents. Since two of the goals of the regulatory impact analysis process are to expose the agency's data, analysis, and public policy choices to public scrutiny and to induce focused public comment, it is instructive to examine the public comment process. In addition, it is important to observe how the public comment on the regulatory analysis documents affects the ultimate decisions on the final rules.

Public comment in the USDA agencies studied here appears to address the substance of agency rules much more often than the analysis contained in the regulatory analysis documents. Most agency officials interviewed in connection with this Report believed that the regulatory analysis documents and/or the analytical material derived from those documents in the preambles to proposed rules have helped improve the quality of public comments. Most officials, however, indicated some measure of disappointment that the agencies' analytical efforts had not had a more positive impact upon the utility of public comments to the agencies.

a. The Food Safety and Inspection Service.

For those rules receiving special treatment by a high level agency work group, the Administrator's Special Assistant works with the program office staff to assemble and summarize the public comments. The Special Assistant also refers questions and information to persons within the agency with expertise to address particular issues. Since the agency does not generally

publish its regulatory analyses in the Federal Register,[197] there is rarely public comment on these analyses per se.[198] There may, however, be comment on the part of the rulemaking document that sets out the agency's economic analysis. In the only case since 1980 in which the agency has published a Preliminary RIA for a major rule (the "Mechanically Separated (Species)" proposal described in Appendix A), the Administrator's Special Assistant referred the comments on the PRIA to the Policy and Program Planning Staff and requested that that staff provide information in response to the comments.[199]

For run-of-the-mill regulations, the official in the program office responsible for the regulation refers comments addressed to the economic analysis in the preamble to the Policy and Program Planning staff for response.[200]

While comments on routine agency rules occasionally cause the agency to reconsider some substantive aspect of its proposal,[201] the public comments have rarely addressed the specific analysis and quantified cost assessments in the regulatory analysis documents. The only public comments on an FSIS economic analysis document occurred in the "Mechanically Separated

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197 Telephone Interview with Mr. Robert Hibbert, Director, Standards and Labeling Division, Meat and Poultry Inspection Technical Services, Food Safety and Inspection Service, USDA, May 24, 1984 [hereinafter cited as Hibbert Interview II].

198 The agency does not necessarily commit a regulatory analysis to writing for nonmajor rules.

199 MSM Case Study, supra note 14.

200 Hibbert Interview II, supra note 197.

201 Hibbert Interview I, supra note 43.

(Species)" rulemaking, where the agency had spent considerable resources drafting a full-blown RIA.[202] Even so, the comments were more in the nature of broadsides than detailed critiques of the data and analysis contained in the RIA.[203] They did not raise fundamental objections to the assumptions underlying agency's costs and benefits projections. It is very rare in any rulemaking for the agency to get a cogent comment directed at some particular defect in the agency's economic analysis.[204]

b. The Agricultural Marketing Service.

The Agricultural Marketing Service is unique among the agencies studied in this Report, because most of its proposed rules are carefully scrutinized in formal rulemaking proceedings. The parties are entitled to submit competing analyses and to cross-examine the agency economic experts. The primary focus of the hearing is upon the predicted economic impacts of the agency's action. At the conclusion of the hearing, the staff prepares a recommended decision, and the parties address this recommendation in their briefs to the Administrator.

For the very rare instances in which the agency acts by informal rule, the comments do not generally focus on the economic analysis that accompanies major rules. The comments are analyzed and considered by the commodity division official who drafted the proposed rule and preliminary

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202 Telephone Interview with Ms. Judith Segal, Director, Policy and Program Planning Staff, Food Safety and Inspection Service, USDA, May 21, 1984 [hereinafter cited as Segal Interview III].

203 See, MSM Case Study, supra note 14.

204 Hibbert Interview I, supra note 43.

RIA as he drafts the final rule. The same employee prepares the Final RIA, which has not in the past departed substantially from the Preliminary RIA. The final rule and Final RIA must then clear the same channels that the proposed rule cleared.[205]

c. The Animal and Plant Health Inspection Service.

The public rarely has anything to say about the regulatory analysis documents that APHIS publishes. No one interviewed in connection with this Report could remember an instance in which a public comment was directed to the analysis in a regulatory analysis document.[206] Almost all of the comments go to the technical analysis in the rulemaking documents.[207]

After the close of the comment period, the program officials meet with the Regulatory Coordination Staff to discuss the final rulemaking document.[208] The Regulatory Coordination Staff then drafts the final document. The Policy Analysis and Program Evaluation Staff can be called in to participate in the preparation of the final rule and final regulatory analysis document, but this is not required by memoranda or standard operating procedures, and it occurs only very rarely.

d. The Agricultural Stabilization and Conservation Service.

The extent to which public comment focuses on the regulatory impact

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205 See text accompanying notes 152-55, supra.

206 Gessel Interview I, supra note 75; Anselmo Interview I, supra note 32.

207 Anselmo Interview I, supra note 32; Gessel Interview III, supra note 33.

208 Gessel Interview III, supra note 33.

analysis documents in ASCS varies with the commodity.[209] Regulatory analysis documents frequently attract public comments that focus on the numbers in those documents and critique the analysis that derived those numbers. Regulatory analysis documents for the rice commodity program, on the other hand, attract almost no comment beyond the predictable supplications for less stingy programs.[210]

The commodity specialists analyze all of the public comments and incorporate them into a position paper. The position paper narrows down the numerous options in the proposed rule to two or three serious options and sets out the recommendations of the commodity specialists. The Regulatory Impact and Executive Correspondence Staff does not review the public comments; nor does it participate in drafting the position paper.

An internal agency policy guidance session is held after the position paper is finished.[211] At this point the members of the policy guidance group pay particular attention to the regulatory analysis documents, because it is at this point that the group must make hard choices among the options that the commodity specialist has identified in deciding upon its ultimate recommendations to the Under Secretary. After the relevant agency personnel have agreed upon a preferred option, the analysis is updated and transmitted with a decision memorandum to the Under Secretary for a decision. This

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209 Rosera Interview, supra note 95; Walker Interview I, supra note 27.

210 The commodity specialist for rice can recall only one instance in which detailed comments were addressed to a regulatory analysis document, and those comments were almost identical to prepared congressional testimony submitted while Congress was considering the Farm Bill. Rosera Interview, supra note 95.

211 Rosera Interview, supra note 95; Walker Interview II, supra note 27.

memorandum and attachments must clear channels within the Department. The documents then go forward to OMB with the agency's preference clearly identified.[212]

5. Interagency Review of the Final Rule and Final Regulatory Analysis Documents.

The impact of the second round of OMB comment varies with the agency and the nature of the rule. For ASCS rules, this stage in a rule's development is crucial, because it is at this stage that USDA and OMB negotiate out the program outlays and the stringency with which the agency will deal with producers. In recent years this has been a two party negotiation between two apparent equals. Thus, all that has gone before in terms of data-gathering and analysis and public comment is in a very real sense a prelude to these important negotiating sessions.

In the other three USDA agencies studied here, however, the OMB role at the final review stage is much less prominent. OMB does not often involve itself much with final APHIS rules, and its input usually goes to the substance of the rules, rather than to the quality or content of the regulatory analysis.[213] Once AMS has proposed a rule and the formal rulemaking process has begun, OMB historically played a very small role. Of course, now that OMB's role has been explicitly limited by statute, it plays no role at any stage of the decisionmaking process.

OMB input into FSIS final rulemaking and regulatory analysis documents has typically been more in the nature of political review than analytical

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212 Rosera Interview, supra note 95.

213 Gessel Interview III, supra note 33.

review. The agency almost never finds fault with the agency's analysis, but it has on several occasions provided ideological and/or political input. For example, in the MSM rulemaking, OMB was apparently concerned that the current administration by late 1982 was being branded "anti-consumer." The final MSM rulemaking and regulatory analysis documents, however, reflected the "regulatory relief" philosophy of the Administration's first year. Although it did not request that the agency change the substance of the rule, OMB asked the agency to change the tone of its documents to emphasize a "pro-consumer" perspective. At least one member of the agency's working group felt that the OMB request went more to how the rule should be "pitched" to the public than to the rule's substance or the agency's analysis.[214]

C. Level of Analysis in Regulatory Analysis Documents.

None of the USDA agencies studied here prepares a cost-benefit analysis as required by Executive Order 12291. Many analyses do, however, attempt to explore alternatives to the proposed or final actions and analyze which of the options could achieve the desired result at least cost. All of the agencies attempt to quantify the costs that their regulations impose. Only in rare cases, however, do the agencies attempt to quantify the benefits of the regulations. In many cases, such as safety regulations, this may reflect a general inability to quantify units of harm, such as disease or

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214 See, MSM Case Study, supra note 14.

death. In other cases, the failure to quantify benefits stems from a failure of the agency's predictive power.[215]

AMS and ASCS Regulatory Impact Analyses are very straightforward predictions of the impacts of the actions that the agency proposes to take on the prices and supplies of commodities. The heart of these analyses, which typically do not exceed twenty pages, are the tables that summarize the predicted economic impacts. Rarely do such analyses examine distributional impacts beyond the impacts on obvious winners and losers, including producers, consumers, and the federal government. Cross-elasticities, inter-industry distributional impacts, and distributional impacts on different classes of consumers are discussed in AMS and ASCS RIAs to the extent that they can be quantified, but this is rare.

In APHIS, the primary thrust of the analytical effort is devoted to examining less expensive minor alternatives to the program that the program office recommends. This usually consists of collecting available information on the costs of minor variations to those programs, analyzing those data, and displaying that analysis in a usable form. In the minds of program officials it is always cheaper to nip infestations in the bud through quarantine programs, once they have crossed a certain damage threshold, than it is to allow pests and diseases to spread to other areas. The program officials therefore rarely ask the Policy Analysis and Program Evaluation Staff to prepare a cost-benefit analysis of a program. When such analyses are undertaken, they are usually prepared by program office

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215 See e.g., MSM Case Study, supra note 14.

staff.[216] The assumption is that if the program is needed, its benefits must necessarily outweigh its costs.[217] The regulatory analyses therefore usually focus on cheaper ways to meet the objective of containing the pest or disease. Hence, the regulatory analyses may generally be characterized as cost-effectiveness analyses.[218]

FSIS has probably been the most conscientious of the agencies within USDA in implementing the spirit of the executive orders requiring regulatory analysis.[219] Still, that agency has been plagued by a general lack of usable information. This lack of accurate cost information is not as disconcerting to the agency as might be imagined, because the agency by statute cannot place a large emphasis on the costs of complying with its rules. Its statutes generally require it to elevate safety concerns above cost concerns. Cost considerations do, however, play a role in choosing the least cost route to a statutory safety goal. Thus, FSIS ordinarily undertakes a "cost-effectiveness" analysis.

Usually, the technological mechanisms available for compliance are not very numerous, and cost comparisons are obvious without quantitative cost analysis. For example, the difference in cost between requiring a warning label and requiring that a product be manufactured in a particular way is usually quite obvious. Hence, the Policy and Program Planning Staff can usually identify the least-cost option from an examination of institutional

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216 Gessel Interview III, supra note 33.

217 Gessel Interview I, supra note 75.

218 Anselmo Interview I, supra note 32.

219 Bender Interview, supra note 26.

variables.[220] The agency has rarely been forced to make regulatory decisions on the basis of close differences in cost. In any event, the costs that the agency's largely performance-oriented requirements impose on the regulated industry are usually quite small. For example, the agency almost never requires the installation of a particular technology until nearly all of the regulated concerns have already installed it. Likewise, the agency usually gives regulated concerns long lead times for compliance, thus allowing them to incorporate regulatory changes into normal process changes. The agency does not, in other words, attempt to "force technology" in the same way that agencies like EPA and OSHA do.[221]

The FSIS devotes even less effort to quantifying the benefits of its regulations. The regulatory analysts generally regard the benefits of its regulations, which by-and-large permit the use of new meat processing technologies, as fairly obvious. The agency can predict that the new technology will allow a new food product or more of an old food product to enter the market, but the agency does not attempt to predict quantitatively how much of the new product will in fact be desired and consumed.[222]

One of the agency's most extensive regulatory analysis documents was the RIA that it prepared for its "Mechanically Separated (Species)" rule. In that case, the agency had previously promulgated a rule requiring products containing mechanically separated meat products to indicate that fact in a phrase qualifying the product's name and, in a further qualifying

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220 Segal Interview II, supra note 54.

221 Segal Interview II, supra note 54.

222 Segal Interview I, supra note 28.

phrase, to state the minimum amount of powdered bone that the product might contain.[223] Meat processors were of the opinion that customers would never purchase products containing mechanically separated meat under the label that the rule required, and they did not attempt to market such products. The processors twice petitioned the agency to change the requirements, and the agency granted the second petition.

The agency prepared extensive Preliminary and Final RIAs to accompany the rulemaking documents.[224] Those documents relied very heavily upon an economic analysis that two industry trade associations had submitted to the agency with its petition. The agency's economic analysis estimated the value of the food that would have been produced but for the requirements of the existing regulations. Thus, the agency limited its attention to the benefits of amending the former rule (the costs of the former rule). The agency found the costs of the rule change to be very minor, consisting largely of the cost of printing labels. The agency did not, however, calculate the cost to consumers of taking the information about powdered bone off the label.[225] While this cost may have been difficult to

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223 See, MSM Case Study, supra note 14. The agency took this action primarily to protect "calcium hyperabsorbers," a small number of people who absorb much more calcium from their diets than most people. They are likely to be under medical supervision that may include dietary management to restrict their consumption of calcium-containing food. The expected extra calcium in products containing mechanically separated meat might pose a health hazard to them.

224 The Preliminary RIA was published in the Federal Register with the Proposed Rule. The Final RIA was not published, but its contents were summarized in the Federal Register, and copies were made available to the public.

225 The agency replaced the statement with a requirement for a calcium content declaration. The agency took the position that there were no

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quantify, a complete regulatory analysis would at least have identified it. Thus, while FSIS normally confines itself to a "costs only" analysis of the effectiveness of alternative means of approaching a safety goal, when it determined that its statutory goal of preventing adulteration and misbranding did not warrant an existing requirement, it analyzed only the benefits of changing the rule.

D. Impact of Regulatory Analysis on the Decisionmaking Process.

Since one of the primary purposes of the regulatory impact analysis process is to bring comprehensive analytical rationality to bear on agency decisions, one of the most important questions to ask about any regulatory impact analysis program is the extent to which it has an impact on real-world agency decisions. The regulatory analysis process can affect agency decisions in at least two ways. First, regulatory analysis can have an impact when the regulatory analysis documents that the agency generates to meet formal statutory and Executive Order requirements and informal Departmental guidelines are read by agency decisionmakers. In this context, "decisionmaker" should be read broadly to include program staffers who are responsible for drafting rules, persons who participate in working group meetings, and agency heads with formal decisionmaking authority. Second, regulatory analysis can have an impact on agency decisions through the

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225 costs to consumers, because the product was not being manufactured under the existing labeling regulations. But the primary reason that the product was not being manufactured under the existing regulations was industry's conclusion that consumers would not purchase the product if the fact that it contained powdered bone was featured prominently on the label.

participation of the regulatory analysts who draft the regulatory analysis documents in the rulemaking process. Even if no one on a working group actually reads a regulatory analysis document, the regulatory analyst can identify options, "cost out" various alternatives, point out gaps in logic, and otherwise contribute to the decisionmaking process. The very presence of a regulatory analyst on a working group, in other words, can affect the working group's output. And the working group's output usually has a profound impact on the final agency decision. Hence, an analysis of the impact of the regulatory analysis process must examine both the role of the formal regulatory analysis documents and the role of the personnel in the regulatory analysis office who might not be included in the decisionmaking process but for the fact that the documents must be drafted.

1. The Food Safety and Inspection Service.

a. The Impact of the Formal Regulatory Analysis Documents.

The Food Safety and Inspection Service probably makes more use of formal regulatory analysis documents than any other agency in USDA. But even in that agency the formal documents have little real impact on the decisionmaking process.

The Administrator reads the documents for the rules that receive special high level treatment.[226] Yet since the Administrator participates actively on the high level working group that drafts the proposed and final rules and is therefore quite familiar with the issues, reading the formal

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226 Houston Interview, supra note 48.

document would not generally be especially burdensome to him. The documents themselves do not affect the deliberations of the high level working group for specially designated rules, because the documents are not drafted until the working group has substantially completed its deliberations. The cost considerations that are raised at the meetings prior to the preparation of the formal document do, of course, affect the Administrator's thinking. It is probably more accurate to say that the content of a regulatory analysis document for a rule receiving special treatment reflects the input of the working group.

For ordinary rules, the impact of the regulatory analysis document is not much greater. Under the current procedural scheme, which may be changed in the near future, the program office frequently does not interact with a regulatory analyst from the Policy and Program Planning Staff until the program office has settled upon an option. The program office is ordinarily not especially receptive to advice and new options at this point. If the rule is a "bottom up" rule for which the Policy and Program Planning Staff's acquiescence is necessary, the program office will normally wait for the analyst to draft a document. For ordinary rules, however, this document is never a full-blown RIA; rather, it is generally an assessment of the costs of the program office's proposal and perhaps an analysis of the costs of some additional options. If the Policy and Program Planning Staff is insistent, the program office may amend its draft rulemaking document to reflect concerns raised in the Policy and Program Planning Staff's document.

For "top down" ordinary rules, the program office may perceive a high level desire to move the rulemaking process expeditiously. If so, the program office may bypass the regulatory analysis office altogether. Even

when the regulatory analysis office's input is requested or required, the program office has in the past been hesitant to amend its recommendations in light of the regulatory analysis office's input. Thus, the documents that the regulatory analysis office produces probably have little impact on the decisionmaking process for such rules.

b. The Impact of the Regulatory Analysis Office.

The Policy and Program Planning Staff in FSIS has a higher profile than its equivalents in other agencies within USDA. The Policy and Program Planning Staff had a real impact on the agency decision in the "Mechanically Separated (Species)" rulemaking detailed in the Appendix to this Report. In that case the staff did a preliminary investigation of the negative economic impact of the existing rule and prepared an options paper that gradually evolved through many high level working group meetings into the formal RIA. The Policy and Program Planning Staff was represented at all of the high level working group meetings, although recollections vary as to the prominence of its role in those meetings.[227] In addition, the Policy and Program Planning Staff played a quality control role in evaluating existing economic data and analyses and organizing that information into a comprehensible whole.

The agency's positive experience with the mechanically separated meat rulemaking persuaded the Administrator to commit additional resources to strengthen the agency's regulatory analysis effort.[228] For example, the

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227 See, MSM Case Study, supra note 14.

228 See, MSM Case Study, supra note 14; McCutcheon Interview, supra note 49.

Policy and Program Planning Staff was provided the resources necessary to hold a series of seminars on regulatory analysis that featured prominent analysts from academia and government.[229] The Administrator is convinced that because of the role that the agency regulatory analysts play in the decisionmaking process, the agency now makes better decisions than it did fifteen years ago.[230] Consequently, he has assigned the Policy and Program Planning Staff a large role in the decisionmaking process for specially designated rules.

For ordinary rules not receiving special high level treatment, the role of the regulatory analysis office is more equivocal. The agency does not have to prepare formal RIAs for such rules; Regulatory Flexibility Act analyses are almost never undertaken; and the Assistant Secretary and the Administrator rarely request a full-blown regulatory analysis document. Since there is no formal working group under the current rule-generation process, the Policy and Program Planning Staff normally becomes involved in the decisionmaking process only if the program office requests its input. For "bottom up" rules, the program office often needs the support of the regulatory analysis office, and it is therefore solicitous of the Policy and Program Planning Staff's advice. The program office is usually willing to amend its rulemaking documents to reflect the Policy and Program Planning Staff's concerns, but it is generally unwilling to reexamine fundamental assumption or to consider options that it has not already identified. For "top down" rules, the program office is even less apt to ask the Policy and

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229 McCutcheon Interview, supra note 49.

230 Houston Interview, supra note 48.

Program Planning Staff for analysis. Still, personnel in the Policy and Program Planning Staff are convinced that their presence in the agency has caused all employees to have a greater sensitivity to cost considerations, and that this sensitivity manifests itself in the regulation development process.[231]

The role of the Policy and Program Planning Staff may become more important under the new procedures that the agency is developing for rulemaking efforts. The new procedures may give the Policy and Program Planning Staff the role of representing "policy interests" on the agency's docket committee and ensuring that agency policy is adequately considered in developing new rules.

2. The Agricultural Marketing Service.

a. The Impact of the Formal Regulatory Analysis Documents.

Since the regulatory analysis documents that the Agricultural Marketing Service prepares for the formal rules that make up the bulk of its rulemaking activity are submitted as evidence in the formal hearing, it is difficult to assess the impact that they have on the recommended and final decisions of the Administrator. They are usually subject to rebuttal and cross-examination in the hearings, and they can play a fairly prominent role in that context. It is fair to say, however, that the agency would be required to prepare testimony on the economic issues covered in the regulatory analysis documents quite apart from any regulatory analysis

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231 McCutcheon Interview, supra note 49; Lange Interview, supra note 9.

requirements. It is therefore likely that the formal requirement that the agency prepare regulatory analysis documents has had no real impact on the process. At best, it has resulted in changing the name of the agency's submission to the formal hearing.

The agency's experience with regulatory analysis documents in informal rulemaking is so limited that it is impossible to make any assessment of the value of those documents to the decisionmaking process when the agency acts by informal rule.

b. The Impact of the Regulatory Analysis Office.

The regulatory analysis office in AMS plays virtually no role in the decisionmaking process. Indeed it is probably inappropriate to refer to the Regulation Review Staff as a "regulatory analysis office." That office merely coordinates the preparation of work plans and rulemaking and regulatory analysis documents. It does not participate in the drafting of those documents; nor does it participate in any working groups or otherwise advise agency decisionmakers. In a very real sense AMS does not have an office that is the equivalent of the Policy and Program Planning Staff in FSIS or the Policy Analysis and Program Evaluation Staff in APHIS.

3. The Animal and Plant Health Inspeciton Service.

a. The Impact of the Formal Regulatory Analysis Documents.

The Policy Analysis and Program Evaluation Staff in APHIS produced very few regulatory analysis documents. Because the agency has promulgated very few rules having large negative economic impacts, and because the emergency

nature of the rules that it does write allows the agency to avoid the formal regulatory analysis process, the agency has never written a formal RIA or RFA. The program staffs, however, do attempt to draft regulatory analysis documents analyzing their costs and benefits of most rules. The independent analysts in the Policy Analysis and Program Evaluation Staff on rare occasions will undertake regulatory analyses when the program office or the Regulatory Coordination Staff requests its input.

The Policy Analysis and Program Evaluation Staff has insisted upon preparing a regulatory analysis when its input is requested, and it has resisted perceived attempts to have it provide economic justifications for decisions previously reached. When the Policy Analysis and Program Evaluation Staff prepares a regulatory analysis document and the program staff seems unwilling to examine one or more of the options contained therein, the Policy Analysis and Program Evaluation Staff can send the analysis through formal channels, thereby ensuring higher level scrutiny of its document and guaranteeing that the document will be in the public rulemaking record. Yet as a practical matter, this almost never happens. Since the Policy Analysis and Regulatory Coordination Staff never prepares a regulatory analysis absent a specific request, and since the document may wind up in the rulemaking file, the program and regulatory coordination staffs have a strong incentive to read the rare documents that the Policy Analysis and Program Evaluation Staff produces and incorporate their contents into the decisionmaking process. For the same reason, however, those staffs have an equally strong incentive not to request the regulatory analysis office's input in the first place.

b. The Impact of the Regulatory Analysis Office.

The current agency decisionmaking procedures place the independent regulatory analysis office in the role of "outsiders looking in."[232] The Policy Analysis and Program Evaluation Staff can only have an impact on the decisionmaking process when the program office or Regulatory Coordination Staff requests its input, and this has happened on only a very few occasions in the last two years. The vast majority of regulatory analysis work in APHIS is done by the program office staff. In the opinion of the Director of the Regulatory Coordination Staff, this is largely attributable to the reluctance of the Policy Analysis and Program Evaluation Staff to involve itself in the regulatory analysis process.[233]

On those relatively rare occasions in which the Policy Analysis and Program Evaluation Staff becomes involved in the rulemaking process, an analyst from that staff becomes part of the working group that makes the preliminary regulatory decisions and the recommendations for final rules. However, the working group does not meet until after the program office has settled upon a single preferred alternative. Although the Policy Analysis and Program Evaluation Staff can suggest additional options and send its analysis through channels if the program office does not seriously consider those options, one is left with the impression that the regulatory analysis office has very little impact on the agency's decisions.[234]

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232 Anselmo Interview I, supra note 32.

233 Gessel Interview III, supra note 33. Other interviews tend to bear out this impression.

234 Anselmo Interview I, supra note 32.

The Policy Analysis and Program Evaluation Staff is most effective when it suggests minor alternatives to options that the program office has proposed.[235] This role can be important. For example, in the only case in which the Policy Analysis and Regulatory Coordination Staff was requested to prepare a Regulatory Flexibility Analysis, its Preliminary RFA identified several minor options capable of reducing the regulation's impact on small businesses. The program office adopted a sufficient number of these minor options that a Final RFA was unnecessary.[236]

It is fair to conclude that the Policy Analysis and Program Evaluation Staff in APHIS has had very little impact on the agency decisionmaking process. That staff can best be viewed as an independent consultant to the program and regulatory coordination staffs, who are the primary advisors to upper level agency decisionmakers. Personnel on that staff do not attempt to advocate any particular position in the context of individual rulemaking proceedings, and they do not attempt to influence agency decisionmakers. When their input is requested, they attempt to analyze the available options without taking a position on which option is preferable.[237] Its limited role may be inherent in the nature of the business that the agency conducts. This certainly seems to be the opinion of the other agency decisionmakers. When asked whether the regulatory analysis process has had an impact on the agency's decisionmaking process, the Director of the Regulatory Coordination

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235 Anselmo Interview I, supra note 32.

236 Anselmo Interview I, supra note 32.

237 Telephone Interview with Mr. David Gradick, Deputy Director, Budget and Accounting Division, Animal and Plant Health Inspection Service, USDA, January 8, 1984.

Staff referred to the emergency nature of the agency's primary functions and replied, "I don't think it could."[238] He believes that analyses need to be done, but they are not likely to affect the ultimate outcome of the rulemaking process.[239]

Similarly, the staffers in the program and regulatory coordination offices are convinced that the agency sufficiently considers the costs of their regulations, even without the regular input of the Policy Analysis and Program Evaluation staff.[240] Yet it is possible that the regulatory analysis office's limited impact is attributable to its institutional status of "outsider looking in." It is also possible that the limited role of the Policy Analysis and Program Evaluation Staff is due to its own reluctance to become involved in the rulemaking process. Whatever the reasons, it is clear that very few APHIS regulatory actions profit from independent analysis by regulatory analysts outside of the program offices.

4. The Agricultural Stabilization and Conservation Service.

a. The Impact of the Formal Regulatory Analysis Documents.

The formal regulatory analysis documents themselves have little impact on the options identified in ASCS's proposed rules. Since the commodity specialist drafts the formal document after the first policy guidance session, it is more a report of the considerations laid on the table at that

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238 Gessel Interview I, supra note 75.

239 Gessel Interview III, supra note 33.

240 Gessel Interview I, supra note 75.

meeting than an independent assessment of the costs and benefits of regulatory options. The preliminary regulatory analysis documents go forward with the proposed regulation package to the Under Secretary, but that office rarely objects to their content. The Under Secretary's office has often commented informally upon previous drafts of the rulemaking and regulatory analysis documents. Even though the Under Secretary's office rarely comments upon the formal documents, the Under Secretary relies upon them in making his or her final decisions.[241] The documents are also intended to inform OMB and the public about the basis for the agency's decision.

The formal documents may play a larger role in the agency decisionmaking process with respect to final rules. The preliminary regulatory analysis document and the commodity specialist's summary of the relevant public comments are available at the second policy guidance session. The high level members of that working group can rely upon that document in narrowing down the options that go forward to the Under Secretary. The commodity specialist prepares the final regulatory analysis document after a second internal agency policy guidance session. The document itself plays no role in the second session. It simply documents the issues considered at that session. It may, however, aid the Under Secretary in choosing a single option as the Departmental position in negotiations with OMB.[242] The final regulatory analysis document is available to the Administrator and the Under Secretary, but if their staffs

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241 OBPA Communication, supra note 6.

242 It may also provide useful information to OMB for those negotiations.

have been adequately briefing them on the policy guidance sessions, they would not necessarily need to read the actual documents.[243] Much of the intellectual process involved in narrowing options and firming explanations is accomplished at the policy guidance sessions, which are held before the regulatory analysis documents have been drafted.

b. The Impact of the Regulatory Analysis Office.

The Regulatory Impact and Executive Correspondence Staff plays a very minor role in the agency decisionmaking process. That office does not draft regulatory analysis documents; rather, it performs a coordination and review function. The Staff will occasionally make suggestions to the commodity specialists for improvements in regulatory analysis documents, and these suggestions are usually accepted by the commodity specialists, who may not have any training in economics. But that office rarely identifies additional useful options, and it never supplies additional data or analysis. The Regulatory Impact and Executive Correspondence Staff is not generally represented at policy guidance sessions where high level officials discuss and narrow options. What regulatory analysis is undertaken by ASCS personnel is generally done by the commodity specialists that draft the regulatory analysis documents. This analysis, however, is generally highly regarded within the Department.[244] To a large extent this is attributable to the fact that the commodity specialists in ASCS are careful to secure the

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243 Walker Interview II, supra note 27.

244 Telephone Interview with Mr. Sid Clemans, Chief, Legislative, Regulatory, and Automated Systems, Office of Budget and Program Analysis, USDA, August 14, 1984 [hereinafter cited as Clemans Interview II].

input of many Departmental units before drafting the agenda for the all-important policy guidance sessions.

5. The Impact of the Centralized Regulatory Analysis Office on the Decisionmaking Process.

Under the formal Departmental procedures, the Office of Budget and Program Analysis is a resource that upper level policymakers (the Under and Assistant Secretaries and their immediate staffs) may call upon at their discretion. An Under or Assistant Secretary may ask for OBPA's advice on whether agency rules cross the thresholds for RIA and RFA preparation and on whether rules should be designated for close Departmental attention. In addition, OBPA has been assigned a role in reviewing regulatory analysis documents for major rules and in advising the regulatory analysis offices in the agencies on regulatory analysis issues. Finally, OBPA is the formal liaison between the Services and OMB.

At one time, OBPA played a fairly prominent role in the internal deliberations of the individual agencies within the Department. The Departmental procedures implementing Executive Order 12291, however, assigned OBPA the "resource" role described above with substantive responsibility only for major rules. While OBPA analysts have been given a resource role in some nonmajor regulatory actions, the Under and Assistant Secretaries have apparently reserved most substantive decisionmaking responsibility for themselves and their agency heads. This is entirely consistent with USDA's overall decentralized management approach. Line managers bear the responsibility for most nonmajor regulatory decisions, and Departmental analysts are called upon only for aid in resolving significant

issues. Although OBPA is the formal communications point between OMB and the agencies, OBPA has encouraged the agencies to develop informal links to OMB through which major points of contention can be resolved prior to the formal review stage. Since OBPA rarely sends representatives to agency working group meetings,[245] it plays a very minor role in the internal options identification and analysis process.

With the implementation of Executive Order 12291, OBPA has confined its attention to regulatory impact analyses for major regulatory actions. This has reduced the number of regulatory analysis documents that OBPA has reviewed by approximately 60 percent. Because OBPA currently reviews only the most important rules, it has become more actively involved in the decisionmaking process for these rules very early on at the budget and legislative review stage or during the informal discussions that precede regulatory efforts long before the proposed rule stage.

The extent of OBPA participation in agency decisionmaking depends upon the individual agency. For example, the Assistant Secretary for Marketing and Inspection Services has not requested OBPA involvement in very many nonmajor regulatory actions. Similarly, OBPA participation has not been great in FSIS and APHIS regulatory activities. On the other hand, OBPA is heavily involved in nonmajor actions in the commodity programs areas.

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245 OBPA is a regular attender of the ASCS "policy guidance sessions," and it can be an important contributor to the decisions that are made in those sessions. This fairly prominent role can be explained, however, by the fact that ASCS determinations have very large consequences for the Department's budget, another responsibility of OBPA.

6. Conclusions.

In none of the USDA agencies studied here did it appear that the formal regulatory analysis documents played a very prominent role in the decisionmaking process. In some agencies, the formal document is prepared too late in the process to affect decisionmaking, although the regulatory analyst on the working group typically makes the contents of the document available to the group. In other agencies, the regulatory analysis documents figure prominently in the decisionmaking process. In most cases, the agencies use the formal document to prepare the preamble to the proposed or final rule. Moreover, participants in the actual decisionmaking process indicate that the thinking behind the formal documents can play a major role in the informal agency discussions where real world decisionmaking often takes place.

The foregoing discussion suggests that it may be a mistake to place too much emphasis upon the timing of formal document preparation. The important question is the extent to which analysis and persons with an analytical orientation are integrally involved in the internal decisionmaking process. On this point, it seems clear that the regulatory analysis office in one of the agencies studied here had a fairly prominent role in the actual decisionmaking process. The fact that the Administrator of FSIS has placed a fairly heavy emphasis on regulatory analysis has created an atmosphere in which the opinions of the regulatory analysis office personnel are often solicited and taken into account, even for ordinary rules in which there are currently no working groups to provide forums for regulatory analysis office input. When the program office itself generates a rulemaking proposal, it generally consults with the regulatory analysis office, and it often amends

its rulemaking documents to reflect the regulatory analysis office's input. For specially designated rules, the regulatory analysis office personnel sit on the high level working group and contribute to its daily deliberations. Members of the working groups generally regard their input as helpful, even if they cannot always identify particular instances in which the regulatory analysis office personnel have been especially insightful.

In APHIS the regulatory analysis office can identify and "cost out" options and otherwise provide information to the program office and the Regulatory Coordination Staff. However, that office does not normally participate in the agency decisionmaking process. It can participate only when the program office or the Regulatory Coordination Staff requests its participation. In general, the regulatory analysis office's impact has been limited to identifying minor alternatives to options that the other offices have already identified.

The regulatory analysis offices in AMS and ASCS contribute very little to the decisionmaking process. Indeed, it is probably inappropriate to refer to them as regulatory analysis offices, because their function consists more of document coordination than regulatory analysis. Indeed, the names of these offices do not suggest any connection to agency policymaking. In both of those agencies the same program employee who drafts the rulemaking documents drafts the regulatory analysis documents. In AMS no real attempt is made to bring independent regulatory analysis to bear on regulatory problems. The formal rulemaking hearing that accompanies major rulemaking efforts, however, can bring independent analysis from affected parties directly to bear on the agency decisionmaking process, and cross-examination can subject the program specialist's analysis to critical

scrutiny. The heavy reliance of decisionmakers in ASCS upon the input of regulatory analysts in OBPA similarly secures a measure of independent analysis in that agency.

The conclusions of a high level Departmental employee who has had an opportunity to observe the regulatory analysis process at close range may provide an apt summary to the preceeding description of the role that regulatory analysis plays in USDA decisionmaking. This employee is enthusiastic about the theoretical value of regulatory analysis, but pessimistic about its current efficacy in USDA (and most other Departments).[246] While some agencies have a strong analytical orientation, he believes that most bureaucrats (like most other people) are not comfortable with thinking analytically. They bring their experience and intuitive perspective to bear on a problem, and when they are presented with a regulatory analyst's work product, they intuitively search for the "bottom line" before agreeing with or critiquing that analysis. If they agree with the analyst's preferred option, they do not heavily critique the document. If they do not agree, they critique the analysis and demand greater certainty.

In this employee's experience, some decisionmakers always rely upon analysis, while many do not. The regulatory analysis requirements have had little effect on analysis-oriented decisionmakers, such as those with the commodity programs, because they have historically relied upon analysis.

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246 This employee requested anonymity, but his observations demonstrated such keen insight into the practical workings of the regulatory agencies in USDA that the paraphrases of his remarks in the text are almost verbatim quotes. I regret his request for anonymity, because I think that he deserves credit for his insights. Nevertheless, I shall honor that request.

Nevertheless, Executive Order 12291 has created an environment more supportive of analysis. For decisionmakers not already disposed to use analysis, the regulatory analysis documents at best make the decisionmakers modestly more conservative about issuing rules. Whereas decisionmakers in agencies not often subject to judicial review could, prior to the implementation of the regulatory analysis requirements, render decisions without detailed explanations, current decisionmakers "paper" their decisions with a regulatory analysis document. In many cases the available information is so equivocal that a plausible regulatory analysis document can be written to support any decision that is not completely unreasonable. The analyses can therefore be crafted to rationalize decisions previously reached without the benefit of detailed analysis. Only very rarely has this employee seen an "objective analysis" from agencies that were not already favorably disposed to analysis. Nor can this employee think of a case in which an agency's decision has been turned around by analysis, although he is willing to concede that the inability to "paper over" a previously reached decision with a subsequent regulatory analysis may have shaped some final decisions or stopped some program offices from going forward with some options.

Despite his general pessimism about the current state of regulatory analysis in USDA, this employee is optimistic that if the Department continues to channel resources into the effort, analysis will become an increasingly important factor in rulemaking in all agencies in the Department. Citing FSIS as an agency in which the analytical perspective has achieved a firm foothold, he feels that the approach of agencies in the Department toward regulatory analysis will change as people with

non-analytical perspectives deal more frequently with people with analytic perspectives and learn that analysis can be of practical use to them. He is also confident that as more efforts are made to produce data on the costs and benefits of regulations, more hard data will be forthcoming. As this happens, "political" or "intuitive" factors will overshadow "technical" factors on fewer occasions.

Whether even this limited optimism is warranted depends upon the answer to the "political" question whether Congress will give the agencies sufficient substantive latitude to follow the limited guidance that regulatory analysis can provide. It further depends upon whether qualified analysts can learn to craft practical analyses and to communicate the results of their analytical efforts in such a way that even the most jaundiced non-analytical decisionmaker will be affected by their insights.

III. The Use of Regulatory Analysis in the Department of Transportation.

Like the Department of Agriculture, the Department of Transportation is highly decentralized. Several "Operating Administrations" within the Department carry out its regulatory responsibilities. This Report, however, will limit its inquiry to two of the most active Administrations -- the National Highway Traffic Safety Administration (NHTSA) and the Federal Aviation Administration (FAA). NHTSA implements its statutory responsibility for promoting public safety and preventing economic loss on the highways by promulgating motor vehicle safety standards and fuel economy standards. FAA sets standards for aircraft safety and administers a nationwide system of air traffic control.

A. Departmental Structure and Hierarchy.

Table 3-2 sets out the Department's organizational structure. The Department is headed by a Secretary and Deputy Secretary. Five Assistant Secretaries,[247] and five other Offices[248] directly serve the Secretary. The heads of the nine Operating Administrations[249] also report directly to

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247 The Assistant Secretary for Policy and International Affairs, the Assistant Secretary for Budget and Programs, the Assistant Secretary for Governmental Affairs, the Assistant Secretary for Administration, and the Assistant Secretary for Public Affairs.

248 The Office of Civil Rights, the Office of Small and Disadvantaged Business Utilization, the Office of Commercial Space Transportation, the Office of General Counsel, and the Office of Inspector General.

249 The Federal Aviation Administration, the U.S. Coast Guard, the Federal Highway Administration, the Federal Railroad Administration, the National Highway Traffic Safety Administration, the Urban Mass

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the Secretary without going through one of the Assistant Secretaries.[250]

The Office of General Counsel serves as the centralized coordinator for all rules that agencies within the Department promulgate. Pursuant to that function, the Office of General Counsel screens the "threshold" determinations whether regulatory analysis documents should be prepared and supervises the review of regulatory analysis documents within the Office of the Secretary.

The chief repositories of expertise on regulatory analysis in the Office of the Secretary are in the Office of Economics and the Office of Industry Policy under the Assistant Secretary for Policy and International Affairs. The Assistant Secretary for Policy and International Affairs has existed since the agency's inception, but did not assume responsibility for reviewing Regulatory Impact Analyses until the enactment of Executive Order 12044 in 1978. The Office of Industry Policy has a major responsibility for reviewing regulatory analyses.[251] Approximately 10 professionals in the Office of Industry Policy work on regulatory analysis review, and they devote approximately one man-year to this effort.

The Office of Economics has a Policy Analysis Division that is concerned with broad Departmental policy. Although it frequently involves

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249 Transportation Administration, the Saint Lawrence Seaway Development Corporation, the Maritime Administration, and the Research and Social Programs Administration.

250 In this regard, DOT differs from USDA where the regulatory agencies report first to an Assistant or Under Secretary.

251 Telephone Interview with Mr. John Peak, Legislative and Regulatory Coordination Staff Director, Office of Industry Policy, Office of the Assistant Secretary for Policy and International Affairs, DOT, June 5, 1984 [hereinafter cited as Peak Interview II].

itself in the policy questions that arise in individual rulemaking proceedings, it only becomes involved in a regulatory impact analysis review when it has been determined that an analysis may be inadequate.[252] If the Office of Industry Policy identifies an issue that it thinks might be of concern to the Policy Analysis Division of the Office of Economics, it will refer the regulatory analysis document to that office for comment. Otherwise, the Office of Economics might identify a rule that it has an interest in from examining the Departmental semi-annual regulatory agenda.[253] As many as ten people in the Office of Economics might work on regulatory analysis review during any given year, although the total effort devoted to that function is probably considerably less than one man-year.[254]

Each Operating Administration with regulatory responsibilities has its own regulatory analysis office that operates more or less independently of the regulatory analysts serving the Assistant Secretary for Policy and International Affairs.

1. The National Highway Traffic Safety Administration.

The National Highway Traffic Safety Administration (NHTSA) was

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252 Telephone Interview with Mr. Shelton Jackson, Chief, Policy Analysis Division, Office of Economics, Office of Policy and International Affairs, DOT, June 5, 1984 [hereinafter cited as Jackson Interview].

253 Peak Interview II, supra note 251.

254 Telephone Interview with Mr. John Peak, Legislative and Regulatory Coordination Staff Director, Office of Industry Policy, Office of the Assistant Secretary for Policy and International Affairs, DOT, May 9, 1983 [hereinafter cited as Peak Interview I].

established in 1966 to establish safety standards for motor vehicles.[255] Later the agency was given responsibility for reducing the economic costs of automobile accidents and for promoting fuel conservation.[256] An Administrator and Deputy Administrator head the agency. The Office of the Administrator includes the Office of the Chief Counsel, the Office of Civil Rights, and the Office of Public and Consumer Affairs. Six Associate Administrators report directly to the Administrator.[257] Of these, three Associate Administrators and the Chief Counsel are intimately associated with the agency's rulemaking functions.

Rules originate in the two Offices under the Associate Administrator for Rulemaking. The Office of Market Incentives concerns itself mainly with fuel economy standards and product information. The Office of Vehicle Safety Standards does the vast bulk of the agency's rulemaking work. It is made up largely of "Rulemaking Program Directors" who prepare the Rulemaking Support Papers that provide the technical basis for the rules that the agency promulgates. This office in turn is composed of two divisions -- the Crash Avoidance Division and the Crashworthiness Division. Both of these divisions are made up largely of professionals with engineering backgrounds. The entire Office of Vehicle Safety Standards employs about 26

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255 National Traffic and Motor Vehicle Safety Act of 1966, 15 U.S.C. §§ 1381 et seq. (1982).

256 15 U.S.C. §§ 1901 et seq (1982).

257 The Associate Administrator for Administration, the Associate Administrator for Enforcement, the Associate Administrator for Plans and Programs, the Associate Administrator for Research and Development, the Associate Administrator for Rulemaking, and the Associate Administrator for Traffic Safety Programs.

engineers.[258] The Office of Vehicle Safety Standards also employs two persons with training in economics.[259]

The Associate Administrator for Plans and Programs is responsible for program evaluation and regulatory analysis. The Office of Plans and Programs contains two sub-offices. The Office of Program Evaluation periodically reviews major existing regulations to evaluate their costs and benefits based upon real-world data, as compared to the projections made when the regulations were promulgated. Since late 1976, the Office of Planning and Analysis (formerly the Office of Program and Rulemaking Analysis) has been the agency's regulatory analysis office. Among other responsibilities,[260] that Office prepares a regulatory analysis document (not necessarily a "Regulatory Impact Analysis" which is the term of art for the document required by Executive Order 12291 for major rules)[261] for

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258 Telephone Interview with Mr. Ralph Hitchcock, Director, Office of Vehicle Safety Standards, Office of Rulemaking, National Highway Traffic Safety Administration, DOT, June 5, 1984 [hereinafter cited as Hitchcock Interview II].

259 Hitchcock Interview II, supra note 258.

260 The Office also is involved in long range agency planning and participates in agency task forces on particular regulatory issues.

261 There is some room for confusion in terminology here. The DOT personnel referred to the documents prepared for major rules in the Carter Administration as "Regulatory Analyses." Documents prepared for major rules in the Reagan Administration are called "Regulatory Impact Analyses." All other analyses for rules are called "Regulatory Evaluations." This Report will use the generic term "regulatory analysis document" to refer to any separate document containing regulatory analysis, whether or not it accompanies a "major" or "nonmajor" rule.

virtually every rule that the agency promulgates.[262] For "major" rules and rules with significant impacts on small businesses, that office prepares the agency's Regulatory Impact Analyses and Regulatory Flexibility Analyses. The office has 10-12 economists and regulatory analysts on its staff to do this work.[263] In addition the Office employs 2-3 engineers who likewise serve as regulatory analysts.[264] The Director of the office attempts to foster a broad base of experience among this interdisciplinary staff.[265]

The Associate Administrator for Research and Development is responsible for undertaking research on motor vehicle safety. The National Center for Statistics and Analysis, under the Associate Administrator, gathers and organizes information on motor vehicle accidents and the causes of injury and death in such accidents. The Office of Vehicle Research, which also serves the Associate Administrator, gathers information and conducts original research into crash avoidance and crashworthiness. Automobiles are tested for their ability to withstand various simulated conditions at the Vehicle Research and Test Center.

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262 Personal Interview with Mr. Barry Felrice, Associate Administrator for Rulemaking (then Associate Administrator for Plans and Programs), National Highway Traffic Safety Administration, DOT, May 18, 1983 [hereinafter cited as Felrice Interview I]; Telephone Interview with Ms. Ellen Kranidas, Acting Associate Administrator for Plans and Programs, National Highway Traffic Safety Administration, DOT, June 13, 1984 [hereinafter cited as Kranidas Interview II]. See generally, Hall Hearings, supra note 17, at 247-50 (testimony of Mr. Frank Berndt, Chief Counsel, National Highway Traffic Safety Administration).

263 Felrice Interview I, supra note 262.

264 Kranidas Interview II, supra note 262.

265 Kranidas Interview II, supra note 262.

2. The Federal Aviation Administration.

The Federal Aviation Administration is headed by an Administrator and Deputy Administrator. The Office of the Chief Counsel, the Office of Civil Rights, and the Office of Public Affairs are located in the immediate Office of the Administrator. Of the six Associate Administrators that serve the Administrator,[266] two -- the Associate Administrator for Aviation Standards and the Associate Administrator for Policy and International Aviation -- carry the primary rulemaking responsibilities. The Associate Administrator for Aviation Standards is responsible for developing standards for aviation safety. These responsibilities are lodged in four offices that serve the Associate Administrator.[267]

Two of the agency's primary rulemaking functions are to promulgate operational rules for aircraft operations and to promulgate standards for certifying aircraft.[268] The first function is performed largely by personnel in the agency's Washington, D.C. headquarters. The agency has adopted a "key region" approach for implementing much of the second function. Under this approach, rules are developed in the geographic regions that have primary expertise with particular aircraft. For example,

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266 The Associate Administrator for Airports, the Associate Administrator for Aviation Standards, the Associate Administrator for Development and Logistics, the Associate Administrator for Policy, the Associate Administrator for Air Traffic, and the Associate Administrator for Administration and International Aviation.

267 The Office of Airworthiness, the Office of Aviation Medicine, the Office of Aviation Security, and the Office of Flight Operations.

268 In addition to aircraft operations and certification standards, FAA is responsible for promulgating airman certification standards, including pilot, flight engineer, air traffic control tower operator, mechanic and medical certification standards.

the key region for certification standards for large fixed wing aircraft is the region headquartered in Seattle, because of that office's proximity to the major jet aircraft builders.[269] Personnel in the key regions do most of the work of assembling the rulemaking documents. The officials with the ultimate authority over whether to go forward with a rule, however, are located in the Washington, D.C. Headquarters.

The Office of Aviation Policy and Plans, under the Associate Administrator for Policy and International Aviation, is the agency's regulatory analysis office. A Branch of that Office is composed of seven economists who prepare regulatory analysis documents for most of the rules that the agency generates. Since that office acquired a regulatory analysis responsibility in 1978 as a result of Executive Order 12044, most agency rulemaking working groups include one of its analysts.[270]

B. The Formal Regulatory Process.

Departmental Policies and Procedures Guidelines govern most aspects of the rulemaking process in the Operating Administrations.[271] In addition

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269 Personal Interview with Mr. Harvey Safeer, Mr. Norman Weil, and Mr. Ken Harris, May 18, 1983 [hereinafter cited as Safeer, Weil and Harris Interview]. Similarly, the key region for helicopter certification standards is the region headquartered in Fort Worth, because of that office's proximity to major helicopter builders. The key region for small aircraft is headquartered in Wichita, because of that office's proximity to major small aircraft builders. The New England Region is responsible for aircraft engines.

270 Safeer, Weil and Harris Interview, supra note 269.

271 See Department of Transportation, Office of the Secretary, Improving Government Regulations: Regulatory Policies and Procedures, 44 Fed. Reg. 11034 (1979) [hereinafter cited as Policies and Procedures]. Although these guidelines were promulgated during the Carter

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many of the Administrations have their own guidelines to govern the process internally.

1. Origin and Threshold Analysis.

Nearly all rules in the Department of Transportation originate in one of the Operating Administrations.[272] Before initiating the rulemaking process, the head of an Operating Administration must independently consider the need for the regulation, the major issues involved, and the alternative approaches to be explored.[273] If the head of the Operating Administration determines that further action is warranted and that the resulting rule is likely to be significant, his agency must prepare a "work plan," which must describe:

(1) The need for the regulation;
(2) The objective(s) of the regulation;
(3) The legal authority for the regulation;
(4) The names of the individual or organizational unit primarily responsible for developing the regulation and of the accountable official;
(5) Whether a Regulatory Analysis is likely to be required and how and where it will be produced;
(6) The probable reporting requirements (direct or indirect) that may be involved;

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271 Administration, they have had to be amended in only very minor ways since they were promulgated. Telephone Interview with Mr. Samuel Podberesky, Deputy Assistant General Counsel for Regulation and Enforcement, DOT, April 27, 1984 [hereinafter cited as Podberesky Interview III].

272 Policies and Procedures, supra note 271, at 11042. A few rules that cut across several Operating Administrations originate in the Office of the Secretary. These rules follow approximately the same procedural route at the Departmental level as the rules that originate in the Operating Administrations.

273 Policies and Procedures, supra note 271, at 11042.

(7) A tentative plan for how and when the Congress, interest groups, other agencies, and the general public will have opportunities to participate in the regulatory process; and
(8) The tentative target dates for completing each step in the development of the regulation.[274]

The Operating Administration then submits the work plan to the Departmental Office of the General Counsel for his or her information. The action is then placed on the Department's Regulatory Agenda, and the Operating Administration may begin working on the rule. The Office of the General Counsel provides the Assistant Secretaries' offices with copies of the work plan for review. Any comments that the Office of the General Counsel receives from those offices are forwarded to the Operating Administrations.

As the Departmental rules have evolved over two Administrations, three thresholds have become important. First, there is the "majorness" threshold for regulations requiring Regulatory Impact Analyses under Executive Order 12291. Second, the Department still requires a regulatory analysis document (called a "regulatory evaluation") for "significant" rules as defined in the Rulemaking Policies and Procedures that the Department promulgated to implement Executive Order 12044 during the Carter Administration.[275] By

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274 Policies and Procedures, supra note 271, at 11042.

275 Under the implementing guidelines, a regulatory analysis is required if a proposed regulation:
(1) will result in an annual effect on the economy of $100 million or more;
(2) will result in a major effect on the general economy in terms of costs, consumer prices, or production;
(3) will result in a major increase in costs or prices for individual industries, levels of government, or geographic regions;
(4) will have a substantial impact on the United States balance of trade; or

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definition, all major rules are significant, but some significant rules are not technically major. Nevertheless, the agencies must prepare a regulatory evaluation for these rules, even though they are not required by Executive Order 12291.[276] In addition, "significant" rules must receive the concurrence of the Secretary's office before they are signed and later published in proposed or final form in the Federal Register.[277] The regulatory evaluations for nonmajor significant rules can be somewhat less detailed and formal. Third, rules that may have a significant economic impact on a substantial number of small business entities must be accompanied by a Regulatory Flexibility Analysis.[278]

The RIA and RFA threshold determinations are made initially by the Operating Administrations subject to review at the Departmental level.[279] The Operating Administrations' "significance" determinations are likewise reviewed by the Departmental Office of General Counsel based upon the criteria in the Rulemaking Policies and Procedures (including the predicted costs and benefits of the rule) and upon its assessment of the probable

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275 (5) The Secretary or head of the initiating office determines it deserves such analysis.

Policies and Procedures, supra note 271,at 11043.

276 Peak Interview I, supra note 254; Telephone Interview with Mr. Neil Eisner, Assistant General Counsel for Regulation and Enforcement, DOT, May 6. 1983 [hereinafter cited as Eisner Interview].

277 Eisner Interview, supra note 276.

278 5 U.S.C. § 603 (1982).

279 Peak Interview I, supra note 254; Podberesky Interview III, supra note 271.

desire of the Secretary's Office to review the rule.[280] Finally, Departmental regulations require that the agencies prepare regulatory analysis documents of some kind even for minor rules.[281] Minor rules, however, are not reviewed in the Office of the Secretary except for a brief review by the Office of the General Counsel prior to transmitting the rule to OMB for clearance under Executive Order 12291.[282] On occasion an agency with insufficient in-house capability may contract out the bulk of the preparatory work, but most agencies prepare their regulatory analysis documents in-house.[283]

The Office of Industry Policy under the Assistant Secretary for Policy and International Affairs plays a role in the threshold designation. That office regularly reviews the computer printout of the Department's semi-annual regulatory agendas. It pays particular attention to rules that might affect more than a single agency within the Department. If it sees a rule that in its opinion should be designated major or significant and that is not so designated, it will communicate this to the Office of General Counsel. If the Office of General Counsel and the Operating Administration agree, the rule will be redesignated.[284] Otherwise the interested entities attempt to "work out" an agreement on how to designate the rule. If agreement cannot be reached, the Secretary may be called upon to make the

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280 Podberesky Interview III, supra note 271.

281 Eisner Interview, supra note 276; Peak Interview I, supra note 254.

282 Podberesky Interview III, supra note 271.

283 Peak Interview, supra note 254.

284 Peak Interview II, supra note 251.

designation. The Departmental analysts rarely work on the actual drafting of regulatory analysis documents.[285]

a. The National Highway Traffic Safety Administration.

Rulemaking actions in NHTSA frequently result from petitions to the agency from the automobile industry or other outside groups.[286] In addition, agency employees in any of the Directorates within NHTSA may identify the need for a rule as a result of their day-to-day activities. For example, research carried out at one of the agency's major auto safety research centers may reveal the need to promulgate a new rule. In addition, the Office of Plans and Programs has a continuing program of reexamining rules that the agency has already promulgated to see if the predictions and analysis that supported the initial rulemakings are borne out in the real world.[287] Finally, the Office of Plans and Programs coordinates the development of the agency's Safety Priorities Plan, which incorporates research priorities and defines the agency's overall regulatory agenda.[288] The Plan is based upon the analysis and identification of safety problems

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285 Peak Interview I, supra note 254.

286 Personal Interview with Ms. Dianne Steed, Administrator, National Highway Traffic Safety Administration, DOT and Ms. Erika Jones, Special Counsel to the Administrator, National Highway Traffic Safety Administration, DOT, May 19, 1983 [hereinafter cited as Steed and Jones Interview I]. Ms. Steed was only present for a brief part of this interview.

287 Felrice Interview I, supra note 262; Kranidas Interview II, supra note 262.

288 National Highway Traffic Safety Administration, Order 800-1, Rulemaking Procedures: Motor Vehicle Standards (February 2, 1977) [hereinafter cited as NHTSA Order 800-1], Attachment 1 at 1.

and potential alternatives for resolving them. Accident data, the agency's research findings, program evaluation results, and other information derived from day-to-day activities provide the foundation for the identification of problems and possible regulatory alternatives. The Plan is updated and revised on an annual basis.[289]

The petition to promulgate a rule or the internally generated idea that a rule be promulgated or changed is forwarded to the Associate Administrator for Rulemaking.[290] The appropriate Office under the Associate Administrator for Rulemaking[291] will then consider whether to recommend to the Administrator that a rulemaking action go forward. Usually, the Rulemaking Office will study the matter in some detail prior to making a recommendation. For example, a staff member of the Rulemaking Office might examine the accident data that the agency compiles to determine whether there is any statistical association between accidents and the subject matter of the petition.[292]

Once the need for regulatory action is identified, the initiating Program Director, who can be located in the Rulemaking Office, the Plans and Programs Office, or the Office of Research and Development, directs his or her staff to prepare a Project Plan Description.[293] The Project Plan

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289 NHTSA Order 800-1, supra note 288, Attachment 1 at 1.

290 Steed and Jones Interview I, supra note 286.

291 Either the Office of Market Incentives or the Office of Vehicle Safety Standards.

292 Personal Interview with Mr. Ralph Hitchcock, Director, Office of Vehicle Safety Standards, Office of Rulemaking, National Highway
(Continued on page 114)

293 See, NHTSA Order 800-1, supra note 288.

Description must include in outline form a summary of the proposed regulatory approach; the objectives of and rationale for the rule; the potential impact of the regulatory action; the estimated resource requirements; the anticipated research needs; and a timetable for completing the various steps in the regulatory process.[294] It is meant to provide a brief statement of the problem, the potential solutions, and a plan of action. It is meant to be a planning document, rather than a rulemaking document.[295]

The Rulemaking Program Director then forwards the document for comment to the Deputy Administrator, the various Associate Administrators, the Chief Counsel, and the Director of the Office of Public and Consumer Affairs. Each office submits its comments to the Rulemaking Program Director. In addition, the Associate Administrator for Research and Development at this time prepares a research support plan for submission to the Program Director. This plan normally includes a description of the supporting research that the Office of Research and Development will perform and a timetable for completing that research. The Associate Administrator for Plans and Programs must also notify the Program Director of any impact assessment data requirements and formulate a schedule for generating cost and benefit data and for developing the required analyses. The Program

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(Continued from page 113)

292 Traffic Safety Administration, DOT, May 19, 1983 [hereinafter cited as Hitchcock Interview I].

294 See, NHTSA Order 800-1, supra note 288, Attachment 2 at 2, Exhibit I.

295 Telephone Interview with Ms. Ellen Kranidas, Acting Associate Administrator for Plans and Programs, National Highway Traffic Safety Administration, DOT, August 16, 1984 [hereinafter cited as Kranidas Interview III].

Director then either revises the Project Plan Description to reflect the comments he has received or explains in a memo the reasons for not incorporating any significant comments and submits the document, along with the information received from the Research and Development Office and Policy and Planning Office, to the Administrator for approval.[296] Copies go to all of the offices that commented.[297]

The Office of Planning and Analysis in the Office of Plans and Programs is responsible for long-range agency planning.[298] Employees in that office are assigned to track the development of rules on the agency's regulatory agenda. As the research results begin to come in, that office can look at the findings and inform the Assistant Administrator for Plans and Programs. In this way the agency's regulatory analysis office can keep track of research agendas and the likely shape of future proposals from the program offices.[299]

The Office of Plans and Programs makes the initial threshold determination. While there is no fixed point at which the agency decides

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296 Telephone Interview with Mr. Larry Blincoe, Office of Program and Rulemaking Analysis, Office of Plans and Programs, National Highway Traffic Safety Administration, DOT, April 10, 1984 [hereinafter cited as Blincoe Interview]; Kranidas Interview II, supra note 262.

297 NHTSA Order 800-1, supra note 288. The description above reflects the formal process established in Order 800-1. As the agency practice has evolved, however, the Project Plan Description has not played a large role in securing feedback from other offices within the agency. The feedback function has devolved to the Draft Rulemaking Support Paper, which emerges somewhat later in the development of a rule. Kranidas Interview III, supra note 295.

298 Kranidas Interview II, supra note 262.

299 Blincoe Interview, supra note 296; Kranidas Interview II, supra note 262.

whether a regulation will require an RIA, RFA, or regulatory evaluation, the threshold determination is usually made at the time that the Office of Plans and Programs receives the Rulemaking Support Paper.[300] Yet since the Office of Plans and Programs prepares a regulatory analysis document of some kind for all important agency rules, it may not designate the document that it is working on an "RIA" or "RFA" until it is well along in the document-drafting process and has a clear feel for the costs that the regulation will impose on the regulated industry.[301] As a practical matter, the threshold question is not a very important one for the agency, because the analysis that the agency undertakes does not depend much on how the Office of Plans and Programs characterizes the rule.[302]

b. The Federal Aviation Administration.

Most rules in the Federal Aviation Administration arise out of the development of a new aviation technology, a petition from an outside party, National Transportation Safety Board recommendations, or a problem that one of the program offices has identified. Usually, the need for a rule is identified at FAA Headquarters in Washington, D.C.

Most important rulemaking initiatives are undertaken by headquarters personnel in Washington, D.C.[303] The agency has in the last few years,

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300 Kranidas Interview II, supra note 262.

301 Kranidas Interview II, supra note 262.

302 Kranidas Interview II, supra note 262.

303 Operating Rules, Maintenance Rules, Airworthiness Directives, and Certification Rules for pilots and air carriers are prepared by headquarters personnel.

however, attempted to decentralize the rulemaking process for most certification rules.[304] In the case of most certification rules, regional offices are given the responsibility for shepherding the idea through the initial process of determining whether the agency should go forward with a rulemaking action.[305] A high level Regulatory Review Board, made up of personnel from headquarters and the relevant regions, meets approximately twice a year to go through new and existing rulemaking projects.[306] These meetings serve to keep headquarters personnel apprised of the status of rules in the regions and to give them input into the process of deciding which new actions ought to be pursued. As its nickname "Murder Board" implies, the Board has the power to eliminate projects from the list of proposed and pending projects.[307]

The Director of the Office that has responsibility for pursuing an action appoints a "team" to "work up" the idea into a concrete proposal. The team is composed of a representative from the technical office (usually a regional office for certification rules), an attorney, and a regulatory

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304 See text accompanying notes 268-69, supra.

305 The accountable Certification Directorates have full rulemaking responsibility, from initiating the action to signing the notice of proposed rulemaking and preparing the final rule. These offices are responsible for ensuring that all required documentation is developed and is accurate.

306 Telephone Interview with Mr. Edward Faberman, Deputy Chief Counsel and Acting Chief Counsel, Federal Aviation Administration, DOT, June 6, 1984 [hereinafter cited as Faberman Interview II].

307 Personal Interviews with Mr. J.E. Murdock III, Acting Deputy Administrator and Chief Counsel, and Mr. Edward Faberman, Deputy Chief Counsel, Federal Aviation Administration, DOT, May 18, 1983 [hereinafter cited as Murdock and Faberman Interview]; Faberman Interview II, supra note 306.

analyst from the Office of Aviation Policy and Plans.[308] At the end of its initial deliberations, the team drafts a "Project Report," which consists of a brief (approximately four pages) resume of the project's objectives, resource and personnel requirements, and a proposed schedule. The Office of Aviation Policy and Plans, for example, will attempt to estimate at this point whether or not the agency should hire a contractor to generate cost and benefit data.[309] The Project Reports, which are more in the nature of management tools than policymaking documents, are updated periodically to reflect changes in the status of the action.

The initial Project Report is presented at the next meeting of the Regulatory Review Board, and at that point the upper level agency decisionmakers decide whether or not to pursue the rulemaking action. If that group decides to go forward with the rule, the appropriate staff will begin to initiate research and to draft the necessary documents.

There is no set time at which the agency makes the threshold determination whether a rule is "major" or "significant." That determination could be made at the point at which the Regulatory Review Board approves the project, or it could be made after the Office of Aviation

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308 Faberman Interview II, supra note 306. Rules originating under the Associate Administrator for Aviation Standards must follow an initial procedure prior to the formation of the "team." The appropriate technical office prepares an "issue paper" for presentation to the Regulatory Review Board. This issue paper later forms the basis for the work plan, should one be required. Comments of Mr. Edward P. Faberman, Acting Chief Counsel and Deputy Chief Counsel, Federal Aviation Administration, DOT, August 29, 1984 [hereinafter cited as Faberman Comments].

309 Safeer, Weil, and Harris Interview, supra note 269.

Policy and Plans finishes its draft regulatory analysis document.[310] Since the agency has never determined that one of its rules was "major," it is not clear at what point in the evolution of a rule the agency would make that determination.[311] On the other hand, the agency prepares some kind of regulatory analysis document for virtually all of its important rules. The sophistication of the analysis will depend upon many of the same factors that go into the threshold determination for the Executive Order and the Regulatory Flexibility Act.[312] If the agency finds that the proposed action is likely to be significant, a work plan is prepared and forwarded to the Office of the Secretary of Transportation.[313]

2. The Proposed Rule and the Preliminary Regulatory Analysis Document.

The Operating Administrations have the responsibility for drafting the rulemaking documents and regulatory analysis documents. Departmental officials limit themselves almost exclusively to a review function -- they are only rarely involved in agency working groups and in internal agency debates.[314] The operating agencies prepare some sort of regulatory

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310 Faberman Interview II, supra note 306; Telephone Interview with Mr. Joseph Hawkins, Regulatory Analysis Branch, Systems Analysis Division, Office of Aviation Policy and Plans, Federal Aviation Administration, DOT, June 5, 1984 [hereinafter cited as Hawkins Interview]. The agency may have promulgated a major rule in 1977 or 1978, but none since the promulgation of Executive Order 12291.

311 Safeer, Weil and Harris Interview, supra note 269; Hawkins Interview, supra note 310.

312 Safeer, Weil and Harris Interview, supra note 269.

313 Faberman Comments, supra note 308.

314 Hawkins Interview, supra note 310.

analysis document for all substantive rules that they promulgate.[315] The intensity of the analysis may vary, however, with the perceived importance of the regulation,[316] and the agency may on occasion incorporate the analysis directly into the preamble of the proposed regulation, rather than prepare a separate regulatory analysis document.[317]

a. The National Highway Traffic Safety Administration.

After the Administrator approves the Project Plan Description, the Rulemaking Office and the Office of Research and Development gather the engineering and statistical information necessary to formulate and support a rule. The two offices attempt to complete the data gathering process within 120 days, but the process often takes somewhat longer than that.[318] On rare occasions, it can take as long as two years.[319] The Rulemaking Office may rely upon data from the agency's own data center, or it may survey the industry for relevant cost and engineering data.[320] It appears

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315 Personal Interview with Mr. Samuel Podberesky, Deputy Assistant General Counsel for Regulation and Enforcement, DOT, May 20, 1983 [hereinafter cited as Podberesky Interview I]; Felrice Interview I, supra note 262. In this sense, agencies in DOT have generally gone beyond the analytical requirements of the Executive Orders.

316 Podberesky Interview I, supra note 315.

317 See, Policies and Procedures, supra note 271, at § 10(e). Felrice Interview I, supra note 262.

318 Telephone Interview with Ms. Erika Jones, Special Counsel to the Administrator, National Highway Traffic Safety Administration, DOT, August 20, 1984 [hereinafter cited as Jones Interview III].

319 Hitchcock Interview I, supra note 292; Steed and Jones Interview I, supra note 286.

320 Steed and Jones Interview I, supra note 286; Hitchcock Interview I, supra note 292.

that officials in the Rulemaking Office carefully review the cost data that has been generated by the auto industry, because documents generated during the comment period are viewed as "advocacy documents."[321] The Plans and Programs Office is not as skeptical of industry-generated information when it is used in its appropriate context, and that Office uses such data in preparing its regulatory analysis documents.[322] The agency prefers, however, to generate its own data.

The agency's final source of information is independent contractors. This source of information has occasionally proved controversial because the agency has in the past done little to ensure against real and apparent conflicts of interest on the part of its contractors.[323] With the appointment of Secretary Dole, there has been less reliance upon contractor-generated data in the DOT agencies.[324]

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321 Hitchcock Interview I, supra note 292.

322 Jones Interview III, supra note 318. For a time, NHTSA and the Motor Vehicles Manufacturers Association engaged in "coordinated" research efforts to produce data on the causes of accidents. See, Hall Hearings, supra note 17, at 195 (testimony of Mr. Thomas Hanna, Motor Vehicle Manufacturers Ass'n).

323 See, Hearings on Cost-Benefit Analysis: The Potential for Conflict of Interest Before the Subcomm. on Oversight and Investigations of the House Comm. on Interstate and Foreign Commerce, 96th Cong., 2d Sess. 19 (1980) [hereinafter cited as Conflict of Interest Hearings] (statement of H. L. Krieger, Director, Federal Personnel and Compensation Division, General Accounting Office); id. at 35-40 (statement of Congressman Robert Eckhardt) (describing NHTSA-initiated contracts with a consultant who was at the same time conducting a very similar study for Ford and General Motors).

324 Personal Interview with Mr. Neil Eisner and Mr. Samuel Podberesky, November 16, 1984 [hereinafter cited as Eisner/Podberesky Interview].

After these studies have been completed, the Rulemaking Office produces a Draft Rulemaking Support Paper. This document includes an environmental review; a statement of the manner in which the proposed rule meets the relevant statutory criteria; and a discussion of the potential costs, benefits, and "other impacts" of several technical alternatives.[325] The alternatives identified in the Rulemaking Support Paper are generally technical engineering alternatives, rather than broad rulemaking alternatives such as performance standards or statutory amendments.[326] The document represents a synthesis of all of the technical information that the agency has been able to locate on the subject matter.[327] In more recent times, the economic analyses in the Rulemaking Support Paper has not been as extensive as it once was, because the Rulemaking Office depends to a greater extent on the Plans and Programs Office to undertake the economic analysis.[328]

There is usually very little contact between the Rulemaking Office and the Plans and Programs Office prior to the preparation of the Draft Rulemaking Support Paper.[329] As a general rule, the Rulemaking Office has

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325 NHTSA Order 800-1, supra note 288, Attachment 2 at 2; Hitchcock Interview I, supra note 292.

326 Hitchcock Interview I, supra note 292.

327 Telephone Interview with Mr. Barry Felrice, Associate Administrator for Rulemaking, National Highway Traffic Safety Administration, DOT, April 11, 1984 [hereinafter cited as Felrice Interview III].

328 Felrice Interview III, supra note 327.

329 Felrice Interview III, supra note 327; Hitchcock Interview I, supra note 292. Prior to 1981, the agency made some attempt to allow the participation of all offices in the process prior to the completion of the Rulemaking Support Paper, but resource limitations now preclude this. Hitchcock Interview I, supra note 292.

defined what it considers to be the relevant options prior to the time that the Plans and Programs Office sees the Rulemaking Support Paper.[330]

The ultimate purpose of the Rulemaking Support Paper is to present a "safety rationale" for the agency's proposed action. Because it is intended to be an informal technical document for staff use, it is never made public. It is rarely seen by the Administrator.[331]

The Rulemaking Office also circulates the Draft Rulemaking Support Paper to other Offices in the agency for comments on completeness and information gaps. The Plans and Programs Office in particular examines the draft closely to determine whether the draft Rulemaking Support Paper has asked the right questions. If the Plans and Programs Office identifies places where it believes additional information is necessary, it will communicate this to the Rulemaking Office.[332] The Rulemaking Office then redrafts the Rulemaking Support Paper to reflect the comments that it has received.[333]

When the Final Rulemaking Support Paper is finished, the Associate Administrator for rulemaking transmits it to the Office of Plans and Programs, the Office of Chief Counsel, and other program offices for further review and comment. The draft of the Final Rulemaking Support Paper is then submitted to the Office of Plans and Programs for the additional purpose of

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330 Steed and Jones Interview I, supra note 286.

331 Steed and Jones Interview I, supra note 286; Hitchcock Interview I, supra note 292.

332 Kranidas Interview III, supra note 295.

333 Kranidas Interview III, supra note 295.

preparing the regulatory analysis document, although the Plans and Programs Office may have begun drafting the document at the time that it received the Draft Rulemaking Support Paper or even earlier.[334] The Office of Plans and Programs then uses the Rulemaking Support Paper, along with other information obtained through its independent literature review, to draft the regulatory analysis document.

The Director of the Office of Planning and Analysis in the Office of Plans and Programs does not assign a single rule to a single regulatory analyst. Instead, a single analyst might be on several "teams" of regulatory analysts working on separate rules.[335] Thus, each regulatory analyst can gain expertise in several regulatory areas. In part, this arrangement reflects the Director's desire to foster an interdisciplinary approach to regulatory analysis.[336] In part, it arises out of the Office's resource constraints. The Director cannot afford to have "pockets of expertise."[337] Moreover, the Director believes that the office begins to lose objectivity when it develops such pockets of expertise. On the

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334 Kranidas Interview III, supra note 295. The term "impact assessments" is used throughout NHTSA Order 800-1. This is a generic term that is meant to include any assessments required by Executive Order 12291, the Regulatory Flexibility Act, and any other federal law. If the Environmental Review Report indicates that an Environmental Impact Assessment is required, procedures outlined in NHTSA Order 560-1 governing Environmental Impact Statements must be followed.

335 Kranidis Interview II, supra note 262; Blincoe Interview, supra note 296.

336 Kranidis Interview II, supra note 262.

337 Kranidis Interview II, supra note 262.

other hand, whenever possible the Director will attempt to assign an analyst who has worked on a similar rule to an analytical team.[338]

The regulatory analysts in the Office of Planning and Analysis view their task as primarily one of drafting detailed regulatory analysis documents. They do not participate actively in the agency decisionmaking process after they have completed their task of information gathering and analysis.[339] The Director of the Office of Program and Rulemaking Analysis and the Associate Administrator for Plans and Programs, however, do actively participate in the agency decisionmaking process.[340]

Just as the Rulemaking Support Paper receives very little input from the Plans and Programs Office, the regulatory analysis documents are drafted entirely independently of the Rulemaking Office. The Plans and Programs Office may rely upon the costs and benefits information in the Rulemaking Support paper, but it usually does not limit itself to that source of information. Because the regulatory analysis document, unlike the Rulemaking Support Paper, will eventually become a public document, the Plans and Programs Office usually attempts to produce a substantially more

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338 Kranidas Interview II, supra note 262.

339 Blincoe Interview, supra note 296; Telephone Interview with Ms. Carol Warlick, Office of Planning and Analysis, Office of Plans and Programs, National Highway Traffic Safety Administration, DOT, April 9, 1984.

340 Telephone Interview with Mr. Barry Felrice, Associate Administrator for Rulemaking (then Associate Administrator for Plans and Programs), National Highway Traffic Safety Administration, DOT, August 2, 1983 [hereinafter cited as Felrice Interview II]; Kranidas Interview II,

detailed analysis of the costs and benefits of alternatives.[341] The analysts in the Plans and Programs Office often read the underlying studies that the rulemaking office relies upon, and they may interpret those studies differently.[342] Although the Office does not generally conduct or contract for empirical research,[343] it frequently conducts its own surveys of the relevant literature and unpublished information to find information that the Rulemaking Office may have missed.[344] The Office of Plans and Programs will also make telephone calls or send written requests to auto manufacturers, health organizations, insurance companies, and other appropriate sources to request data that can be used to estimate the costs and benefits of safety technologies.[345] It may take the Office of Plans and Programs 6-8 weeks from the time that it receives the Rulemaking Support Paper to prepare its regulatory analysis document.[346] Most analyses, however, are prepared in less than one month.[347] The regulatory analysis

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341 Felrice Interview III, supra note 327; Blincoe Interview, supra note 296; Kranidas Interview II, supra note 262.
supra note 262; Steed and Jones Interview I, supra note 286.

342 Blincoe Interview, supra note 296.

343 Kranidas Interview II, supra note 262.

344 Felrice Interview III, supra note 327. Analysts in the Office of Plans and Programs do not view the fact that an outside study was prepared by or funded by the regulated industry as disqualifying. They examine the content of the study, rather than its source. Kranidas Interview II, supra note 262.

345 Blincoe Interview, supra note 296.

346 Comments by Ms. Ellen Kranidas, Acting Associate Administrator for Plans and Programs, National Highway Traffic Safety Administration, DOT, on an earlier draft of this Report, September 25, 1984 [hereinafter cited as Kranidas Comments].

347 Kranidas Comments, supra note 346; Jones Interview III, supra note 318.

document will update and supplement the information derived from the Rulemaking Support Paper.[348]

There is a functional difference between the job of the Rulemaking Office and the job of the Plans and Programs Office. The engineers in the Rulemaking Office will measure the "engineering effectiveness" of various technological alternatives without necessarily reducing "effectiveness" to lives or dollars saved. For example, in measuring the effectiveness of restraints such as seat belts and airbags, the engineers in the Rulemaking Office might commission crash tests to determine the effectiveness of particular technological alternatives in reducing injuries. The economists in the Plans and Programs Office might take that information and combine it with available statistics on automobile accidents and seatbelt use to translate technological effectiveness into lives saved.[349] This will ultimately form a part of the benefits analysis in the regulatory analysis document.

The regulatory analysis documents are intended to be entirely independent of the rulemaking documents. They set out the independent thinking of the regulatory analysts in the Office of Plans and Programs.[350] This may very well differ from the analysis of the Rulemaking Office as to technical questions, economic analysis, and policy preferences.[351] Frequently, the regulatory analysis documents will

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348 Blincoe Interview, supra note 296.

349 Blincoe Interview, supra note 296.

350 Steed and Jones Interview I, supra note 286.

351 Hitchcock Interview I, supra note 292.

explore regulatory alternatives that are broader and more comprehensive than the technical alternatives listed in the Rulemaking Support Paper.[352] The Rulemaking Office can in turn comment on the Plans and Programs Office's regulatory analysis.[353] Although the Rulemaking Office seldom comments on the technical economics section of the regulatory analysis document, it frequently comments on other aspects of the document, such as cost and benefit assumptions.[354]

An explicit purpose of the independent review function of the Plans and Programs Office is to bring an independent analytical perspective to bear on regulatory issues and to raise questions that the public will probably raise at the public comment stage.[355] There may, for example, be more than one way to interpret data, and the Plans and Programs Office may interpret them differently from the Rulemaking Office.[356] In addition, the Plans and Programs Office may identify safety considerations that the Rulemaking Office did not consider.[357] The economists in the Plans and Programs Office believe that one of their roles is to restrain the natural tendency of the engineers in the Rulemaking Office to issue rules without a

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352 Felrice Interview III, supra note 327; Hitchcock Interview I, supra note 292; Kranidas Interview II, supra note 262; Blincoe Interview, supra note 296.

353 Blincoe Interview, supra note 296; Kranidas Interview II, supra note 262.

354 Kranidas Comments, supra note 346.

355 Felrice Interview III, supra note 327; Conflict of Interest Hearings, supra note 323, at 763-64 (testimony of Ms. Joan Claybrook, then-Administrator, National Highway Traffic Safety Administration).

356 Kranidas Interview III, supra note 295.

357 Kranidas Interview III, supra note 295.

sufficient inquiry into their consequences.[358] While the analytical process inevitably slows down the rulemaking process somewhat, upper level decisionmakers believe that it ultimately produces better decisions.

The current Administrator has encouraged the Plans and Programs Office to play the role of institutional gadfly.[359] Even more regulation-oriented administrations, however, have likewise encouraged the Plans and Programs Office to maintain a sense of "skeptical independence" from the Rulemaking Office,[360] so that a wide variety of views can be available to higher level decisionmakers at the end of the internal intra-agency deliberations.[361] Since an idea for a rule can germinate within the agency for several years, most upper level decisionmakers see the value of subjecting the product of that effort to an analysis from a fresh, independent perspective before the agency takes a public position.[362]

If, in its opinion, the analysis does not support the proposed action, the Plans and Programs Office will notify the Rulemaking Program Director.[363] This might be done by memorandum or telephone call.

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358 Felrice Interview III, supra note 327.

359 Steed and Jones Interview I, supra note 286. The Administrator during the Carter Administration likewise encouraged the adversarial approach. See, Conflict of Interest Hearings, supra note 323, at 764 (testimony of Ms. Joan Claybrook, then-Administrator, National Highway Traffic Safety Administration).

360 Steed and Jones Interview I, supra note 286.

361 Felrice Interview I, supra note 262.

362 Kranidas Interview II, supra note 262; Felrice Interview III, supra note 327.

363 NHTSA Order 800-1, supra note 288. Usually the staff of the Plans and Programs Office will meet informally with the Staff of the Rulemaking Office before escalating the matter to the Assistant Administrator Level. Blincoe Interview, supra note 296. Nevertheless, it is not uncommon for issues to get elevated to the Administrator's level.

Occasionally, the two offices will have a meeting to discuss differences in analysis or interpretations.[364] The Rulemaking Program Director and his or her staff must then attempt to modify the rule to satisfy the Plans and Programs Office within 15 working days. If the Office is unable to develop a mutually acceptable solution, the Rulemaking Program Director and the Associate Administrator for Plans and Programs send a joint memorandum outlining the points of contention to the Administrator for resolution.[365] The Administrator usually pays very close attention to these memoranda outlining the disagreements between the two offices.[366]

At this point, the Administrator may call a meeting of the Chief Counsel, the Associate Administrator for Rulemaking, the Associate Administrator for Plans and Programs, and occasionally the Associate Administrator for Research and Development and their supporting staffs to discuss how the Administrator should decide the issues that remain unresolved.[367] These meetings, which occur no more than 3-4 times per year, are intended to be adversarial in nature, with each side given time to air its views and to rebut the views of the other side. Typically,

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364 Kranidas Interview III, supra note 295.

365 NHTSA Order 800-1, supra note 288, Attachment 2 at 3.

366 Steed and Jones Interview I, supra note 286; Conflict of Interest Hearings, supra note 323, at 764 (testimony of Ms. Joan Claybrook, then-Administrator, National Highway Traffic Safety Administration).

367 The Administrator chairs a senior staff meeting on Monday mornings. The existence of unresolved issues in particular rulemaking proceedings are often brought to his or her attention at these meetings. Occasionally, the Administrator can resolve the issues on-the-spot at the staff meetings, but more frequently the Administrator sets a time for a special meeting to discuss the particular rulemaking. Steed and Jones Interview I, supra note 286.

participants raise fundamental questions, such as whether or not to go forward with a regulation at all.[368] While is is possible for the two offices to reach an accommodation at this meeting, its adversarial character usually ensures that the meeting will end with one side prevailing over the other.[369]

The upper level decisionmakers in the agency actively encourage this "creative tension" between the Rulemaking office and the Plans and Programs Office.[370] The two offices are viewed as equal partners in the rulemaking process.[371] The current Administrator feels that the adversarial mode is the best way to ensure that issues do not get submerged within the consensus-building process in a single office. She also believes that the adversarial approach helps to maximize the real options available to the Administrator. Finally, the adversarial model provides the Administrator with a thorough airing of the pros and cons of regulatory options and minimizes the likelihood that the staff-prepared options memorandum is "loaded" in favor of a single option.[372]

The employees of the Plans and Programs Office seem pleased with the adversarial approach.[373] They point out that the adversarial model

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368 Steed and Jones Interview I, supra note 286. Felrice Interview I, supra note 262; Kranidas Interview II, supra note 262.

369 Steed and Jones Interview I, supra note 286.

370 Steed and Jones Interview I, supra note 286.

371 Felrice Interview I, supra note 262.

372 Steed and Jones Interview I, supra note 286.

373 Felrice Interview I, supra note 262; Kranidas Interview II, supra note 262; Blincoe Interview, supra note 296.

provides a dynamic decisionmaking process that lends many different perspectives to the Administrator's judgment. It likewise provides for the broadest possible exchange of information within the agency before it takes a public position. Not infrequently the agency debates surface problems of which neither office was aware prior to the adversarial efforts.[374]

Employees in the rulemaking office are less convinced of its value. They point out that while the process is generally successful in producing tension between the two offices, the result is not always creative. Confrontation between the two offices can degenerate to acrimonious exchanges of memoranda. The process can devolve to one-upsmanship and bickering.[375] It is also possible that the outcome of oral confrontations before the Administrator can rest more on the oral communications abilities of the two representatives than on the correctness of their respective positions.[376] The process can undermine the morale of an office if it loses a large proportion of the battles.

The "adversarial" process as currently structured also does not provide any natural point at which options can be examined and rejected. As one of the Office Directors in the Rulemaking Office observed, for most regulatory actions there are an infinite variety of options that the agency could

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374 Kranidas Interview II, supra note 262.

375 All participants of these meetings who were interviewed in connection with this Report, however, cautioned that bickering and one-upsmanship is rare in NHTSA.

376 The current Administrator takes care to see that oral communications skills do not prevail over second analysis. Jones Interview III, supra note 318.

theoretically consider.[377] It is very difficult for the Rulemaking Office to know early in the rule development process when it has identified a suitable range of options. The normal place in the current structure of the agency decisionmaking process for personnel outside the Rulemaking Office to suggest new options and critique old options is the point at which the Plans and Programs Office comments on the Draft Rulemaking Support Paper from the Rulemaking Office. The Rulemaking Office can become frustrated when it feels that it is being "ambushed" with fresh options from the Plans and Programs Office after it has expended substantial effort analyzing the options that it has already identified.[378]

Typically, the two offices work out among themselves which options will be seriously considered in the Final Rulemaking Support Paper and in the regulatory analysis document. On very rare occasions, however, the offices will meet informally with the Administrator to select the options that will be considered.[379] If the Administrator concludes that the agency should seriously consider additional options that the Plans and Programs Office identified late in the process, then the technical support documents and the Rulemaking Support Paper must be redone. It is even possible that the Research Office will have to undertake or contract for more engineering studies.[380] Taking the Rulemaking Support Paper through a series of such iterations can be time-consuming and expensive. Perhaps more importantly,

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377 Hitchcock Interview I, supra note 292.

378 Hitchcock Interview I, supra note 292.

379 Jones Interview III, supra note 318.

380 Hitchcock Interview I, supra note 292.

it is possible that the process of modifying the document can increase the likelihood of mistakes in the technical analysis in the Rulemaking Support Paper.[381]

The former Associate Administrator for Plans and Programs agrees that it would be better if the regulatory analysis office could participate in the options identification process at an earlier stage in the process. The Office, however, lacks the resources for such full-scale participation in rule development.[382] In addition, full participation by the Plans and Programs Office in the early deliberations on a rule would take away some of the "adversarial" character that has been consciously designed into the process. Although the two offices attempt to communicate with each other as a rule develops to eliminate misunderstandings and unnecessary disagreements,[383] irreconcilable differences still arise.

Once the Administrator has decided an issue, debate within the agency is no longer appropriate, and the parties to the dispute must fall in line behind the Administrator. The rationale and conclusions sections of the Rulemaking Support Paper and the regulatory analysis documents must be amended to reflect the Administrator's decision. While the regulatory analysis documents are not meant to be a "rubber stamp" for the Administrator's decision, their conclusions cannot, in the opinion of upper

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381 Hitchcock Interview I, supra note 292.

382 Felrice Interview I, supra note 262.

383 Kranidas Interview III, supra note 295. This is especially true in the last year or two since the former Associate Administrator for Plans and Programs became the Associate Administrator for Rulemaking.

level decisionmakers, be inconsistent with the rule.[384] The data and facts in the documents are not changed in light of the Administrator's decision; the changes are limited to the rationale and conclusions sections of the regulatory analysis document and the preamble to the proposed or final rule.[385] To have the regulatory analysis documents vary significantly from the Administrator's decision would, in their opinion, only confuse the public.[386] Perhaps more importantly, Department attorneys suggest that for the Administrator to choose an option that was not supported by the regulatory analysis document, which constitutes an important component of the record supporting the agency's action, would violate the Administrative Procedure Act.[387] In practice, there is always enough uncertainty in the calculations in the regulatory analysis documents that the numbers do not have to be "fudged" for the documents to support the Administrator's decision, so long as it is within a range of reasonable options.[388] Regulatory analysts in the Office of Plans and Programs would not consider it proper to change the numbers in the regulatory analysis documents to fit the Administrator's decision if the numbers did not otherwise support that decision.[389]

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384 Steed and Jones Interview I, supra note 286.

385 Jones Interview III, supra note 318.

386 Jones and Steed Interview I, supra note 286.

387 Eisner/Podberesky Interview, supra note 324.

388 Felrice Interview I, supra note 262.

389 Comments by Mr. Barry Felrice, Associate Administrator for Rulemaking, National Highway Traffic Safety Administration, DOT, on an earlier draft of this report, August 23, 1984 [hereinafter cited as Felrice Comments].

After the issues are resolved, the Rulemaking Program Director must transmit a copy of the Rulemaking Support Paper and the impact assessments (the draft package) to the Deputy Administrator, the Associate Administrators, the Chief Counsel, the Director of Public and Consumer Affairs and, if the proposed rule is a motor vehicle safety standard affecting trucks, to the Director of the Bureau of Motor Carrier Safety in the Federal Highway Administration. The Rulemaking Program Director then submits the package, together with any comments that the other offices have provided, to the Administrator for approval.[390] Any remaining differences between the relevant officials are highlighted in the memorandum.[391] It is especially important to the Administrator that the Plans and Programs Office concur in this final memorandum.[392] Copies are, again, sent to those who commented.[393]

If the Administrator approves the package, he or she transmits it to the Chief Counsel who prepares the Federal Register notice. In addition, the Chief Counsel, in consultation with the Program Director in the Rulemaking Office, drafts a memorandum to the Administrator summarizing major issues, expected reactions from outside parties, and the pertinent dates (e.g., the deadline for public comment).[394] The Chief Counsel then

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390 NHTSA Order 800-1, supra note 288.

391 Steed and Jones Interview I, supra note 286. It is rare, however, that any difference will still exist at this point, because the meeting with the Administrator usually resolves these differences. Steed and Jones Interview I, supra note 286.

392 Steed and Jones Interview I, supra note 286.

393 NHTSA Order 800-1, supra note 288.

394 NHTSA Order 800-1, supra note 288.

prepares an "approval package," which includes the rulemaking document, the memorandum, the support paper and the impact assessments. The package is forwarded to the Rulemaking Program Director who, in turn, forwards it to the Deputy Administrator, the Associate Administrators, the Director of Public and Consumer Affairs and, if necessary, the Director of the Bureau of Motor Carrier Safety, for another round of internal comments to be completed by a stated date. Once comments are received, the documents are revised as appropriate.[395]

The Rulemaking Program Director consolidates the documents, prepares a transmittal memorandum explaining the rationale behind any substantive changes as well as the reasons for not incorporating significant comments, and transmits the package to the Administrator for approval. In the case of a proposed rule, the Administrator indicates his or her approval or disapproval on the transmittal memorandum and returns the package to the Rulemaking Program Director. If disapproved, the package is revised accordingly. Otherwise, the Program Director signs the proposal and forwards the entire package to the Chief Counsel who sends it to the DOT General Counsel for Departmental review.[396]

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395 The Rulemaking Program Director is responsible for modifying the Rulemaking Support Paper, the Chief Counsel modifies the rulemaking document and the "highlight" memorandum, and Policy and Programs Office modifies the impact assessments and, if the regulation is "significant," prepares a memorandum from the Administrator notifying the Secretary of the planned publication of the proposed or final rule. NHTSA Order 800-1, supra note 288.

396 NHTSA Order 800-1, supra note 288; Policies and Procedures, supra note 271, at 11042.

b. The Federal Aviation Administration.

The Federal Aviation Administration's approach to drafting the proposed rule and the preliminary regulatory analysis document varies substantially from the NHTSA practice. Rather than the "adversarial" approach that NHTSA uses, FAA uses a "team" approach to decisionmaking and regulatory analysis. When the engineers in one of the accountable directorates request the participation of the Office of Aviation Policy and Plans, one of its staff employees will become a member of the working group that drafts the proposed rule and other rulemaking documents. The team meetings usually give rise to "painstaking discussions" among the engineers, the regulatory analysts, and the attorneys from the Office of Chief Counsel[397] about the merits of several alternatives for addressing the regulatory problem. The goal of the meetings is to reach a consensus on the content of the rule.[398]

While the team is meeting, the regulatory analyst assigned to the team acquaints himself with the technical issues and prepare a cost-benefit analysis for the rule.[399] Even though the agency only very rarely promulgates a "major" or "significant" rule, it prepares a cost-benefit analysis for nearly all rules.[400] Personnel in the Office of Aviation

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397 For rulemaking actions that originate in the regions, regional attorneys are members of the rulemaking team.

398 Faberman Interview II, supra note 306; Hawkins Interview, supra note 310.

399 The team member from the Office of Aviation Policy and Plans will not always prepare the benefits analysis. Sometimes a staff member from the safety offices will draft this part of the document [Safeer, Weil and Harris Interview, supra note 269].

400 The regulatory analysts do not prepare cost-benefit analyses for some minimally burdensome rules, such as those that merely codify current industry practice [Safeer, Weil and Harris Interview, supra note 269].

Policy and Plans believe that the agency does this because it is interested in promulgating rules that "give the most safety for the buck."[401] The analysts will generally prepare a more thoroughgoing analysis for rules that are likely to be controversial.[402] In preparing these documents the staff relies heavily upon an extensive manual that the Office of Aviation Policy and Plans drafted in 1982 that specifies in some detail the contents of an appropriate cost-benefit analysis.[403]

The regulatory analysts have numerous sources of cost and impact data. Although the agency does not conduct routine surveys of industry cost schedules, it does maintain contact with industry engineers and economists. The agency's regulatory analysts carefully scrutinize cost and economic impact information submitted by outside sources for possible bias and exaggeration.[404] The agency regulatory analysts also examine carefully the economic information that the agency's engineers compile to ensure that they do not underestimate the costs of the regulations that they propose.[405]

Over time, the agency has developed several in-house data bases. The agency frequently purchases data, such as scheduling models, from the same sources that provide the data to the industry. The office also hires

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401 Safeer, Weil and Harris Interview, supra note 269.

402 Safeer, Weil and Harris Interview, supra note 269.

403 Office of Aviation Policy and Programs, Federal Aviation Administration, Economic Analysis of Investment and Regulatory Decisions -- A Guide (1982) [hereinafter cited as FAA Handbook].

404 Safeer, Weil and Harris Interview, supra note 269.

405 Safeer, Weil and Harris Interview, supra note 269.

consultants to conduct cost surveys.[406] On one occasion the agency contracted with a consultant to design a "paper" airplane from scratch using the costs of parts purchased on the open market to meet the proposed regulation.[407] This was, however, a very expensive undertaking for the agency. In this instance, however, the regulatory analysis office's input was outcome-determinative, because the data from the exercise demonstrated that the rule that the agency engineers had suggested was prohibitively expensive. The agency therefore dropped the proposal.[408] In other cases, however, the cost information that the regulatory analysts assembled demonstrated that costs were trivial, and this information made it much easier for the rule to survive upper level agency and Departmental scrutiny.[409]

The regulatory analysis documents generally limit their discussion to alternatives that the program office has identified. The Office of Aviation Policy and Plans does not make an attempt to identify regulatory options beyond the technical alternatives that the program offices suggest.[410] Often this amounts to no more than a cost-benefit analysis of the single alternative that the program office has identified.[411] The regulatory

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406 The agency may hire contractors to work on as many as one fifth of the currently pending projects. Safeer, Weil and Harris Interview, supra note 269.

407 Safeer, Weil and Harris Interview, supra note 269.

408 Safeer, Weil and Harris Interview, supra note 269.

409 Safeer, Weil and Harris Interview, supra note 269.

410 Hawkins Interview, supra note 310. Safeer, Weil and Harris Interview, supra note 269.

411 Safeer, Weil and Harris Interview, supra note 269.

analysis office, however, is often a strong proponent of the "no action" alternative that the program office sometimes neglects.[412] The regulatory analysis documents do not examine alternatives beyond the agency's statutory authority.[413]

Disagreements between the accountable Directorates and the Office of Aviation Policy and Plans occur very infrequently.[414] Indeed, more disputes over regulations in FAA occur between parallel rulemaking offices (e.g. between aviation standards and air traffic control) than between any particular program office and the Office of Aviation Policy and Plans.[415] The Office of Aviation Policy and Plans regards itself as a provider of a service to the program offices.[416] Its members feel that their primary responsibility is to draft regulatory analysis documents for the program office and upper level decisionmakers. They do not regard themselves as co-equal decisionmakers. In their opinion, the value of the office lies in providing neutral advice from the perspective of an entity with no vested interest in the rulemaking proceeding.[417] If that office disagrees with the approach taken by the program office, the program office nearly always accepts the regulatory analysis office's advice.[418] Ultimately, however,

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412 Safeer, Weil and Harris Interview, supra note 269.

413 Hawkins Interview, supra note 310.

414 Hawkins Interview, supra note 310.

415 Hawkins Interview, supra note 310.

416 Hawkins Interview, supra note 310.

417 Hawkins Interview, supra note 310.

418 Hawkins Interview, supra note 310. ("I can't think of a time when they [the program office] did not adopt our recommendation when we said their proposal was too expensive.")

the decision is that of the accountable Directorate, and the rulemaking documents are forwarded up the chain of command together with the regulatory analysis office's (perhaps inconsistent) regulatory analysis document. If the issue remains unresolved, it must ultimately be decided by the Administrator.

When disputes do occur and cannot be resolved at the team level, the issues can be escalated up the hierarchy in each office. The Deputy Chief Counsel, however, cannot remember a single instance in which the Administrator has been called upon to resolve such a dispute.[419]

c. Departmental Review.

According to Departmental procedures, proposals for all rules must be sent to the Office of the Secretary before being transmitted to OMB for review. In addition, all "significant" regulations must obtain the concurrence of the Secretary of Transportation.[420] The General Counsel coordinates the Departmental review of the packages for proposals for significant regulations. An attorney in the General Counsel's Office will review the incoming package and send copies of it to the other offices within the Department that might have expertise on the subject matter of the

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419 Faberman Interview II, supra note 306.

420 Policies and Procedures, supra note 271, at 11042. The criteria for defining "significance" are somewhat broader than those for defining "majorness" under Executive Order 12291. Hence, while all "major" rules are "significant," not all "significant" rules are "major." Eisen Interview, supra note 276; Peak Interview I, supra note 254. The Departmental review procedures therefore apply to a broader range of rules than the procedures dictated for major rules by Executive Order 12291.

regulation. Usually, recipients include the Assistant Secretary for Policy and International Affairs, the Assistant Secretary for Governmental Affairs, the Assistant Secretary for Budget and Programs, the Assistant Secretary for Administration, and, if the proposed action might have a "cross-modal" impact, the agency whose regulations might be affected.[421] In addition, the Office of the General Counsel itself will review and make recommendations on the packages.[422] This review process can last from a single day to a month, but averages approximately one and one-half weeks.[423]

The Departmental review process is intended to provide an independent and unbiased review of the agencies' rationales for their rules. Also, Departmental review, like OMB review, is intended to supply specific policy input on policy-dominated issues and to ensure that the operating agencies are implementing the broad policy preferences of the Secretary of Transportation.[424] Finally, review in the Office of the General Counsel ensures that the agencies operate within their statutory mandates.[425]

Reviewers in the Office of Economics and the Office of Industry Policy under the Assistant Secretary for Policy and International Affairs are

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421 Podberesky Interview I, supra note 315.

422 Podberesky Interview I, supra note 315.

423 If there are problems with the package, the process can take even longer [Podberesky Interview I, supra note 315]. The Office of Industry Policy aims for a five day turnaround time for its review of regulatory analysis documents. Peak Interview I, supra note 254.

424 Podberesky Interview I, supra note 315.

425 The Office of the General Counsel also reviews agency actions for consistency with agency policy.

primarily responsible for Departmental review of the economics in regulatory analysis documents. The Office of Industry Policy reviews approximately five regulatory analysis documents per month to ensure that they comply with the Executive Order and the Departmental guidelines for RIA preparation.[426] This office pays special attention to the cost-effectiveness of agency rules.[427] The Office of Economics, the Office of Industry Policy, the Office of the General Counsel, and other offices in the Office of the Secretary review the documents for consistency with overall Departmental regulatory and legislative policy.[428] Although these offices generally see the regulatory analysis documents for the first time when the General Counsel's Office circulates them, it is not uncommon for the regulatory analysts in the Operating Administrations to make contact with their counterparts in the Office of Industry Policy prior to that point to ensure that the documents do not come as a surprise to the reviewers.[429]

If one of the Departmental reviewing offices finds fault with the agency's analysis[430] or thinks that the agency should consider additional

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426 Peak Interview I, supra note 254.

427 Peak Interview I, supra note 254.

428 Jackson Interview, supra note 252; Peak Interview II, supra note 251.

429 Podberesky Interview I, supra note 315; Telephone Interview with Mr. Samuel Podberesky, Deputy Assistant General Counsel for Regulation and Enforcement, DOT, April 4, 1984 [hereinafter cited as Podberesky Interview II]; Peak Interview I, supra note 254.

430 The Departmental offices most frequently find fault with the substance of the agencies' proposals or with the failure to consider additional options, rather than with the analyses of the options that the agencies have identified. Podberesky Interview I, supra note 315.

options, it communicates its concerns to the Office of the General Counsel. The General Counsel's Office will then attempt to facilitate an agreement between the agency and the reviewing office, which may be the Office of the General Counsel itself, as to the appropriate course of action.[431] Often the Office of the General Counsel will invite the Departmental Office and the Operating Administration to a meeting to discuss their differences.[432] If agreement can be reached, the agency makes whatever changes are necessary and the Office of the General Counsel prepares a briefing memorandum for the Secretary.[433] If agreement cannot be reached, the Office of the General Counsel prepares a decision memorandum that details all sides of the dispute, and it may include recommendations for resolving the dispute. The Secretary will then resolve the dispute. This dispute resolution mechanism, however, is only used approximately three or four times per year for the entire Department.[434]

The extent to which Departmental review can affect the substantive outcome of agency decisionmaking depends upon the extent to which the Secretary of Transportation desires to direct agency rulemaking efforts. Some past Secretaries have preferred to establish no strong Departmental policies and leave decisionmaking largely up to the discretion of the Administrators of the Operating Administrations. Under these Secretaries,

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431 Podberesky Interview I, supra note 315; Peak Interview I, supra note 254.

432 Peak Interview I, supra note 254.

433 Podberesky Interview I, supra note 315. The Secretary only very rarely signs rulemaking documents, but the Secretary must concur in "significant" rules.

434 Podberesky Interview I, supra note 315.

the review process can, as a practical matter, have very little impact on the outcome of actual decisions. With no clear policy direction at the outset of the rulemaking effort, the Operating Administration must resolve policy questions as it goes. By the time that the Operating Administration has expended the effort on resolving internal disputes and achieving consensus within its ranks, it is understandably reluctant to open the entire process up for a reevaluation of the regulatory options. Indeed, even if the Operating Agency agreed with the Office of the General Counsel or one of the other offices in the Office of the Secretary that it had not adequately considered an option or that it should have examined additional options, assembling the data and analysis necessary to do this might take an additional year or two. In reality, unless the office is prepared to argue that the rule should not go forward at all, it is constrained to identifying patchwork changes that can be worked into the existing documents within a reasonable period of time.[435] The role of centralized review can therefore be limited largely to suggesting changes in the "tone" of the public documents and in the intensity with which the regulatory analysis documents discuss particular alternatives.[436]

For example, during the years 1981-1983, the Secretary did not assign a high priority to interjecting his policy preferences into the decisionmaking process of the Operating Administrations beyond sending a strong signal that he had a preference for regulatory relief. The Administrations were then by and large free to regulate or deregulate as they pleased. The Office of the

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435 Podberesky Interview II, supra note 429.

436 Blincoe Interview, supra note 296.

General Counsel and the other Departmental offices with policy input did get involved early on in a few rules of very high Departmental importance, such as the very controversial "passive restraints" rulemaking.[437] Even for such large rules, the Departmental analysts only provided guidance on broad policy matters, because they did not have sufficient expertise to second-guess the agency experts on technical matters.[438] Departmental analysts played a reactive and largely ineffectual role in the decisionmaking process. The Special Assistant to the Administrator of NHTSA could think of no instance between 1981 and 1983 in which the Departmental review process had caused the agency to change its rulemaking or regulatory analysis documents.[439]

More recently, however, the Secretary has taken a stronger interest in guiding the substantive output of the Operating Administrations, especially those dealing with safety questions. Early in her administration, she sent strong signals to the Administrators that her office would be heavily involved in major rulemaking efforts, and she gave the Administrators a clear idea of the policies that she wanted them to implement. Although still plagued with resource shortages and a lack of expertise on technical questions, the Office of the General Counsel and other offices in the Office of the Secretary began to object more frequently to the agencies' analytical efforts. More regulatory analysis documents were sent back to the Operating Administrations for failure adequately to discuss options and for departures from Departmental policy preferences. When the Operating Administrations

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437 Podberesky Interview II, supra note 429.

438 Podberesky Interview II, supra note 429.

439 Steed and Jones Interview I, supra note 286.

did not respond rapidly to these "remands" the Secretary ordered personnel at the Office of the Secretary to draft the relevant documents or portions thereof. Faced with the real possibility of having the rulemaking and regulatory analysis documents returned for time-and-resource-consuming changes, the Operating Administrations have begun to seek out policy guidance from the Office of the Secretary at early stages in the development of rules, and the Office of the Secretary appears to be willing to give this guidance.

3. Interagency Review of Proposed Rules and Regulatory Analysis Documents.

The Departmental Office of the General Counsel is the primary contact between agencies within the Department of Transportation and OMB.[440] Yet while all formal communications between DOT agencies and OMB flow through the DOT General Counsel's Office, in practice OMB routinely communicates directly with staff members in the individual Operating Administrations to facilitate the formal review of the final products. Still, the Office of the General is a major institutional player in the interactions with OMB. A representative from that office usually attends meetings between OMB officials and the technical staff of the Operating Administrations. And while the Office of the General Counsel has little to say about technical disputes, it is the chief negotiator for the Department, on matters of policy. That office is empowered to make concessions in negotiations with OMB without consulting with the Operating Administrations, and it will do so if it believes that it has the support of the Secretary or the Deputy

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440 Podberesky Interview I, supra note 315.

Secretary. Departmental-level offices other than the Office of the General Counsel play a substantive role in OMB interactions only in rare instances.[441]

In general, OMB review has not been especially burdensome to the agencies within DOT. The DOT Office of General Counsel feels that the OMB desk officers who review DOT rules have a good understanding of the Department's problems and needs, although there are occasional complaints from staff in the Operating Administrations that OMB officials lack the expertise to understand highly technical questions that occasionally arise in agency rulemaking.[442] OMB almost never criticizes the quality of the analysis in the Preliminary RIAs. At the Preliminary RIA stage, OMB ordinarily limits its input to suggestions that the agency add additional options to the Preamble to the proposed regulation or pose additional questions for public comment.[443]

Most disputes between DOT and OMB involve minor matters and amount to "silly disagreements" that are relatively easily worked out at the staff level. Occasionally, however, OMB and DOT have disagreements over regulatory policy. Most of these disputes are also resolved at the staff level.[444] The agency staffs generally attempt to accommodate OMB comments

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441 Podberesky Interview I, supra note 315.

442 Eisner Interview, supra note 276.

443 Podberesky Interview I, supra note 315. Steed and Jones Interview I, supra note 286.

444 Podberesky estimates that 95 percent of the disputes that arise between OMB and operating agencies are resolved at the staff level [Podberesky Interview I, supra note 315]. See also, Hall Hearings, supra note 17, at 111-112 (testimony of Ms. Joan Claybrook, former Administrator, National Highway Traffic Safety Administration).

and seek to work OMB's concerns into the rulemaking or regulatory analysis documents, rather than delaying the rulemaking effort further.[445] On very rare occasions, however, DOT staff disagrees with OMB's input strongly enough to press ahead despite OMB's objections. When this has happened, OMB has in a few rare instances ruled that agency proposals have been "inconsistent with the Executive Order," and "remanded" them to the agency.[446] The agency then has the option to drop the regulation or to escalate matters to the Secretary's Office. If the Secretary agrees with the agency, he or she can attempt to work out an accommodation informally in a telephone conversation with high level officials in OMB. Failing this, he or she can appeal to higher authorities in the White House.[447] On these rare occasions, the Secretary's view usually prevails.[448]

a. The National Highway Traffic Safety Administration.

OMB has had very little direct impact on regulatory analysis in NHTSA.[449] Although the agency has promulgated several rules, the extensive analyses that the agency prepares have by and large been

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445 Podberesky estimates that in 90 percent of the cases in which there are disputes between OMB and operating agencies, the agency staff accommodate OMB's concerns [Podberesky Interview I, supra note 315].

446 Eisner Interview, supra note 276.

447 At one time the appropriate route of appeal was to the Vice President's Task Force on Regulatory Relief, but that Task Force is now defunct. The Department has appealed OMB determinations to higher authorities on only two occasions. Podberesky Interview I, supra note 315.

448 Podberesky Interview I, supra note 315.

449 Felrice Interview I, supra note 262.

satisfactory to OMB. At most, OMB has suggested changes in "tone" in the regulatory analysis document.[450] NHTSA has rarely made significant changes in regulatory analysis documents based on OMB's input.[451] It is impossible to say whether this record is attributable to the quality of NHTSA's analysis or to the fact that OMB has generally agreed with the agency's actions, which until very recently have been deregulatory in nature. Another possible explanation is the in terrorum effect of OMB review on the agency. It may be that the agency's analysis is more thorough because of the high probability that a regulation will encounter problems at the OMB review stage if the analysis is not done well the first time. Finally, it is possible that officials in the Office of the Secretary use OMB review as a lever to improve analysis in the Operating Administrations.[452] The predictions of the Office of the Secretary about how OMB will view particular rules might have an impact on the substance of the rules.[453]

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450 Steed and Jones Interview I, supra note 286. The Chief Counsel of NHTSA testified in 1983 that all of OMB's comments were "in the nature of editorial comments, clarifying questions, asking us questions, so that they could understand what it was that we were doing." Hearings on H. R. 2327 Before the Subcomm. on Administrative Law and Governmental Relations of the House Comm. on the Judiciary, 98th Cong., 1st Sess. 250 (1983) (testimony of Mr. Frank Bendt, Chief Counsel, NHTSA).

451 Felrice Interview I, supra note 262. This is not to say, however, that OMB has had no effect on substantive agency policymaking. A former Administrator of the agency maintains that OMB has directly affected the content of several important agency rules. Hall Hearings, supra note 17, at 124-25 (testimony of Ms. Joan Claybrook, former Administrator, National Highway Traffic Safety Administration).

452 Eisner/Podberesky Interview, supra note 324.

453 Eisner/Podberesky Interview, supra note 324.

As of mid-1983, OMB had on only one occasion "remanded" a regulation for reconsideration by NHTSA. That proceeding involved a rule requiring a mandatory national standard for radar for state police. OMB questioned the need to promulgate the rule and told the agency to reconsider it. The agency reconsidered the rule and decided to convert it to a voluntary standard. High level agency decisionmakers believe that the changes brought about through the OMB intervention worked out very well in practice. The agency did not place a burdensome requirement on every state, but many states voluntarily adopted the NHTSA guidelines in their radar purchasing specifications.[454]

On the other hand, NHTSA officials believe that now that the agency has made regulatory analysis an integral part of the decisionmaking process, there is little need for OMB to continue the same "micro-management" that characterized its earlier rulemaking reviews. OMB should still review some agency rules, according to this view, but OMB review should be a "spot check" to ensure that the agency continues to produce acceptable regulatory analyses. According to one upper level agency decisionmaker, the value of particularized OMB review may now be outweighed by the time that it consumes.[455]

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454 Steed and Jones Interview I, supra note 286.

455 Steed and Jones Interview I, supra note 286. A former Administrator of NHTSA puts the matter more forcefully. She maintains that "with regard to NHTSA, current OMB review of rules is cursory, and generally a waste of time." She maintains, however, that OMB has had direct substantive input into several important agency rules and has acted as a conduit for transmitting communications from the regulated industry to the agency. Hall Hearings, supra note 17, at 111-12, 124-25 (testimony of Ms. Joan Claybrook, former Administrator, National Highway Traffic Safety Administration).

b. The Federal Aviation Administration.

The Federal Aviation Administration has had a number of meetings on agency rulemakings with OMB, even though the agency has almost never promulgated a "major" rule.[456] OMB has had almost no impact on the agency's decisions.[457]

4. Agency Responses to Public Comment.

Responses to public comments are handled entirely at the agency level. Historically, the Departmental attorneys and economists have not read and evaluated the public comments except to the extent that they were summarized in the final rulemaking documents that the operating agencies prepared.[458] More recently, however, the Office of the General Counsel has been somewhat more actively involved in some of the larger rulemaking initiatives of the Operating Administrations. In the large rulemakings, a staff person from the Office of the General Counsel will read the public comments as part of the Departmental review of the final rule.[459]

The operating agencies cannot publish a "significant" final rule without receiving the concurrence of the Secretary. Before submitting a final rule for the Secretary's concurrence, however, the head of the operating agency must determine at a minimum that

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456 Murdock and Faberman Interview, supra note 307; Safeer, Weil and Harris Interview, supra note 269.

457 Murdock and Faberman Interview, supra note 307; Safeer, Weil and Harris Interview, supra note 269.

458 Podberesky Interview I, supra note 315; Peak Interview I, supra note 254; Peak Interview II, supra note 251.

459 Eisner/Podberesky Interview, supra note 324.

(1) The regulation is needed;
(2) The direct and indirect effects of the regulation have been adequately considered;
(3) Alternative approaches have been considered and the least burdensome of the acceptable alternatives has been chosen;
(4) Public comments have been considered and an adequate response has been prepared;
(5) The regulation is written in plain English and is understandable to those who must comply with it;
(6) An estimate has been made of the new reporting burdens or recordkeeping requirements necessary for compliance with the regulation;
(7) The name, address and telephone number of a knowledgeable agency official is included in the publication; and
(8) A plan for evaluating the regulation after its issuance has been developed.[460]

The final rulemaking documents then go through the same Departmental review process that the documents for the proposed rulemaking documents had to negotiate.

The public comments on Operating Administrative rules focus more on the preambles and the text of the rules than on the content of the regulatory analysis documents. Only the largest and most controversial regulations induce substantial public comment addressed to the regulatory analysis documents.[461] All comments are, however, scrutinized carefully by the Operating Administrations.[462]

A general problem with comments addressed to DOT rulemaking proposals is that they are often composed largely of assertions without supporting

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460 Policies and Procedures, supra note 271, at 11042.

461 It should be noted, however, that the preambles to proposed rules often draw heavily upon the analysis in the regulatory analysis documents. Hence, comment on the preamble may, in fact, be current on the analysis in the regulatory analysis document that has been incorporated into the preamble.

462 Podberesky Interview I, supra note 315.

data. The regulatory analysis documents can help focus public comment on particular facts, but they have not always successfully performed this function.[463] Even when the preliminary regulatory analysis documents explicitly solicit factual input to fill gaps in the agency's data, the public comments do not often provide concrete information capable of filling the data gaps.

a. The National Highway Traffic Safety Administration.

Comments directed toward the technical analyses and conclusions are reviewed primarily by personnel in the rulemaking office, and comments directed to the economic analysis and regulatory analysis documents are reviewed primarily by the Office of Plans and Programs. Each office, however, may review all of the comments that it deems relevant. In some cases the RIA can be a very important focal point for public comment. For example, the agency will occasionally use the regulatory analysis document as a source of questions to pose to the public in the rulemaking preamble.[464] The exercise of preparing the Preliminary RIA can identify gaps in information that the public comment might fill.

External comments sometimes suggested alternatives that the agency had not considered, and the agency has made an effort to address these alternatives in the final rulemaking documents.[465] The Plans and Programs Office will often change the regulatory analysis documents on the basis of

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463 Eisner Interview, supra note 276.

464 Eisner/Podberesky Interview, supra note 324.

465 Podberesky Interview I, supra note 315.

substantive comments that the agency receives.[466] On the other hand, the Plans and Programs Office will work together with the Cost Evaluation Section of the Rulemaking Office to ensure that industry cost estimates are not inflated. If necessary, the Cost Evaluation Section will conduct a "tear down" study to achieve a realistic cost estimate.[467]

Personnel in the Plans and Programs Office believe that it is important to provide the public with detailed information on the likely impacts of proposed rules.[468] Although many public comments are philosophical diatribes, the regulatory analysis documents can, in the opinion of agency regulatory analysts, enhance the quality of the serious comments by forcing them to rebut the specific analysis laid out in the regulatory analysis documents.[469]

The Plans and Programs Office will occasionally use the industry comments to ensure that the Rulemaking Office addresses all relevant considerations in the final rulemaking documents.[470] In the Field of Direct View rulemaking proceeding, for example, the Plans and Programs office seized upon the General Motors' comments that the proposed rule would not appreciably save lives, a position that Plans and Programs had taken

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466 Kranidas Interview II, supra note 262; Blincoe Interview, supra note 296.

467 Kranidas Interview II, supra note 262; Hitchcock Interview II, supra note 258.

468 Kranidas Interview II, supra note 262.

469 Kranidas Interview II, supra note 262; Hitchcock Interview II, supra note 258.

470 Felrice Interview III, supra note 327.

earlier in the intra-agency deliberations, to force the Rulemaking Office to explain the basis for its disagreement with that position. The Plans and Programs office then relied heavily on the specific industry comments in the internal debates before the Administrator. Ultimately, the Plans and Programs office prevailed.[471]

b. The Federal Aviation Administration.

The outside commentors address their comments to the regulatory analysis documents in FAA rulemakings only extremely rarely.[472] The regulatory analysis documents are not published, but are publicly available in the rulemaking dockets.[473] Portions of the regulatory analysis documents are summarized in the preamble to the Notice of Proposed Rulemaking, but the summaries rarely attract public comment.[474] Public comment is most likely to result from an explicit request for information in the Preamble.[475] Otherwise, the regulatory analysis documents do very little to focus or enhance the quality of public comment.[476]

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471 Felrice Interview I, supra note 262.

472 Faberman Interview II, supra note 306; Hawkins Interview, supra note 310.

473 Faberman Interview II, supra note 306.

474 Faberman Interview II, supra note 306.

475 Hawkins Interview, supra note 310.

476 Faberman Interview II, supra note 306; Hawkins Interview, supra note 310.

5. Interagency Review of the Final Rule and Final Regulatory Analysis Documents.

Before the final rule can be published in the Federal Register, it must be routed to OMB for review of the rulemaking and regulatory analysis documents. OMB review at this stage may be just as thoroughgoing as its review at the proposal stage. But the process need not be as lengthy if the OMB and DOT staff have ironed out significant differences prior to the publication of the proposed rule.

6. Retrospective Analysis.

There is a general Departmental requirement that the Operating Administrations review existing rules to determine whether they should be amended or repealed.[477] But this directive does not explicitly require the Operating Administrations to prepare retrospective analyses of the predictions made in regulatory analysis documents in previous rulemaking proceedings.

NHTSA has an extensive retrospective analysis program housed in the Office of Program Evaluation in the Office of Plans and Programs.[478] This program, which employs seven analysts, attempts to reevaluate every important agency rule on a periodic basis.[479] For example, the

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477 Policies and Procedures, supra note 271.

478 Kranidas Interview II, supra note 262; Hitchcock Interview II, supra note 258.

479 More important rules get evaluated more often that less important rules. Kranidas Interview II, supra note 262.

retrospective analysis of the agency's standard for automobile bumpers led the agency to amend that standard in 1983.[480]

FAA has no institutional mechanism for retrospective analysis of previous regulatory analyses.[481] The agency has, however, conducted retrospective studies in isolated instances.[482] The FAA analysts find retrospective studies difficult, because the aviation industry does not always react to the agency's rules in the way that the policy analysts expected.[483]

C. Level of Analysis in Regulatory Analysis Documents.

The Office of Industry Policy under the Assistant Secretary for Policy and International Affairs has prepared two detailed documents to guide regulatory analysts in the operating agencies in preparing regulatory analyses. The first document, entitled "Guidance for Regulatory Evaluations: A Handbook for DOT Benefit-Cost Analysis," contains twenty-seven pages of guidance and several Appendices.[484] The purpose of the document is:

> to assure that all DOT regulatory evaluations are done with a consistently high level of quality -- that they involve the requisite

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480 Felrice Interview I, supra note 262.

481 Hawkins Interview, supra note 310.

482 Safeer, Weil and Harris Interview, supra note 269.

483 Safeer, Weil and Harris Interview, supra note 269.

484 Office of Industry Policy, Office of the Assistant Secretary for International Affairs, Guidance for Regulatory Evaluations: A Handbook for DOT Benefit Cost Analysis (1982) [hereinafter cited as DOT Handbook].

procedures for selecting alternatives, types of impacts, discount rate, price base, dollar conversion values, period of analysis, estimates of costs and benefits, ranking indicators, and sensitivity studies.[485]

The regulatory analysis documents must demonstrate "that not only do the benefits of any proposed or existing regulation warrant the costs to various groups, but that it is superior to competing alternatives for achieving the desired goal."[486] The Handbook acknowledges that the operating agencies will not be able to subject all regulations to the same intensity of analysis. It therefore suggests that the level of analysis should depend upon:

(1) The intensity of public and Congressional interest and controversy;
(2) the magnitude of costs and benefits accruing to various impacted groups and to the nation as a whole;
(3) the time, manpower, and budget resources available for the analysis; and
(4) data availability and cost of collecting additional data.[487]

The Handbook suggests that more effort should be spent analyzing a regulation which is controversial or imposes heavy costs on consumers, industry, or government than on a regulation which is not controversial or costly to any group or to the nation as a whole. A Regulatory Impact Analysis as required by Executive Order 12291 is the most stringent level of analysis mentioned in the Handbook.[488]

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485 DOT Handbook, supra note 484, at 2.

486 DOT Handbook, supra note 484, at 1.

487 DOT Handbook, supra note 484, at 5.

488 DOT Handbook, supra note 484, at 5.

All regulatory evaluations must contain a concise statement of the regulatory problem that must explain "why the regulatory action is justified and will achieve the cited public goal."[489] Every regulatory analysis document must also identify several alternatives. It must always define the "base alternative," which represents an estimate of the situation without regulation.[490] The document must then identify and examine one or more alternative actions that would ameliorate the concern being addressed. The Handbook suggests that the agency consider broad-ranging alternatives, including "market-oriented means of achieving the solution, such as providing better information and labeling, changing insurance programs, adopting new juridical approaches, using innovative technology, or introducing new economic incentives and disincentives in the form of fees, charges, or marketable permits."[491] The agency need not limit its range of alternatives to options that are within DOT's power to implement: "Institutional or legal constraints, such as agency jurisdiction, should not automatically preclude otherwise worthy alternatives."[492] The Department may use the analysis to suggest legislative changes. Finally, the discussion of alternatives should indicate any constraints on any of the proposed alternatives, including institutional, political, sociological, or

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489 DOT Handbook, supra note 484, at 3.

490 The base alternative for DOT regulations is often an industry standard, but it can also be the requirements of state and local regulation [DOT Handbook, supra note 484, at 6].

491 DOT Handbook, supra note 484, at 6.

492 DOT Handbook, supra note 484, at 6.

legal constraints. All alternatives that the agency considers should be recorded with an assessment of pros and cons.[493]

The Handbook gives some general guidance on estimating the benefits and costs of regulatory action. First, it suggests four elements of an impact analysis: identifying affected groups; identifying types of impacts; categorizing impacts as costs or benefits; and choosing a measure of impact. As to the measure of impact, the Handbook expresses a preference for reducing impacts to monetary terms, but recognizes that there are limitations to the extent that analysts can do this.[494]

Second, the Handbook suggests methods for quantifying costs and benefits that are not easily quantified. It stresses that analysts should calculate indirect costs and benefits, even though they are often hard to identify and quantify. Appendix 3 of the Handbook details some conventions for valuing direct and indirect costs and benefits such as "economic lives for facilities or equipment, personnel and other administrative costs,

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493 DOT Handbook, supra note 484, at 7.

494 The Handbook suggests that an analysis may present a mix of types of measures, as follows:

(a) Impacts which are already in monetary terms (e.g., construction costs)
(b) Impacts which are quantifiable in monetary terms (e.g., consumer time expressed in terms of monetary units per hour of time saved or utilized)
(c) Impacts which are quantifiable but not in monetary terms (e.g., air or noise pollution measured in terms of pollutant particles per million or in decibels, respectively)
(d) Impacts which are considered nonquantifiable (e.g., aesthetic effects, loss of competition)

DOT Handbook, supra note 484, at 9-11.

time-phased costs and benefits and suggested values of life and time."[495] The Appendix suggests a value of $340,000 as the average monetary value for a human fatality, $230,000 as the average monetary value for a critical injury, and $102,000 as the average monetary value for a severe injury.[496] According to an official in the Office of Policy and International Affairs, most of the operational administrations consider these guidelines for valuing lives to be official DOT policy, but they often use different values in individual regulatory analysis documents.[497] NHTSA, however, does not monetize human lives in its regulatory analysis documents.[498] In addition to assessing overall costs and benefits, the Handbook suggests that agency regulatory analysts break down the calculations by affected groups so that distributional impacts may be observed.[499]

Third, the Handbook suggests three approaches to evaluating benefits and costs: numerical benefit-cost analysis (to be used when benefits and costs can both be reduced to a common monetary measure); cost effectiveness analysis (to be used when costs can be monetized, but some significant component of benefits cannot be monetized); and tradeoff analysis (to be used when neither costs nor benefits can be monetized and there is more than a single simple objective).

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495 DOT Handbook, supra note 484, at 12.

496 DOT Handbook, supra note 484, Appendix 3, at A-7.

497 Peak Interview I, supra note 254.

498 Podberesky Interview II, supra note 429.

499 DOT Handbook, supra note 484, at 24.

Fourth, the Handbook suggests some standard conventions for reducing calculations to present value and expressing them in constant dollars.

Finally, the Handbook addresses in detail how regulatory analysis documents should treat uncertainties in their calculations. It suggests two approaches to expressing uncertainties:

> Expected value approach (i.e., weighting of various possible consequences by the probability of each consequence occurring in order to find a weighted average or mean). When the probability distribution of an impact component is known, it is generally preferable to calculate an expected value of that component. This technique can be helpful for cases involving impacts with very high values and very low probabilities, such as a regulation to lower the probability or consequences of a catastrophic accident. In these cases a decision is sometimes made to spend more than the expected value as a hedge against uncertainty.
>
> Pessimistic/optimistic approach (i.e., use of various possible values of impact components to determine the corresponding range of efficacy of the alternative). When the probability distribution of an impact component is not known, but the range of values is known, the analyst first performs the analysis using the lowest reasonable value of each benefit subject to uncertainty and the highest reasonable value of each cost subject to uncertainty (the pessimistic approach); and then performs the analysis using the highest reasonable value of benefits and the lowest reasonable level of costs (the optimistic approach). This method is a form of sensitivity analysis. . . .[500]

The Handbook further suggests that the regulatory analysts use "sensitivity analysis" to probe the sensitivity of the predictions to the assumptions that went into the calculations. The object of sensitivity analysis is "to see how sensitive the ranking of alternatives is to variations in the uncertain parameters."[501]

The Handbook concludes with a checklist for regulatory evaluations that is reproduced below:

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500 DOT Handbook, supra note 484, at 18.

501 DOT Handbook, supra note 483, at 19.

A CHECKLIST FOR DOT REGULATORY EVALUATIONS
PROBLEM STATEMENT, ASSUMPTIONS, AND ALTERNATIVES

a. Is the objective properly stated with regard to the real problems?
b. Is a base case explicitly stated and all cost components identified?
c. Are all assumptions reasonable; are they identified and explained?
d. Are assumptions neither too restrictive nor too broad?
e. Are intuitive judgments identified as such? Are uncertainties treated as such? Can the facts be verified?
f. Are all feasible alternatives considered, including those outside the scope of the specific legislative provision?
g. Are the alternatives well-defined and discrete? Do they overlap?

COMPARISON OF COSTS AND BENEFITS

a. Does the study indicate why certain costs and benefits were considered relevant and others not? What impacts may have been overlooked?
b. Are the sources of data included? Are those sources valid? Are estimates current and supportable?
c. Are sunk costs and benefits excluded?
d. Are extrapolations adequately justified?
e. Are the parties bearing the costs and reaping the benefits identified? Has any differential time-phasing of costs and benefits been noted?
f. Have external or indirect costs and benefits been included? Are the real resource costs differentiated from financial transfers?
g. Is the arithmetic correct? Were calculations done in constant dollars and discounted?
h. Could benefits be expressed in dollar terms? If not, were cost-effectiveness techniques used? Were all nonmonetary benefits specifically identified?

SELECTING FROM ALTERNATIVES

a. What criteria were used in evaluating alternatives?
b. Have alternatives been ranked according to those criteria?
c. Is the alternative with the greatest net benefits chosen? If not, why did the ranking criterion produce a different result?
d. Are the recommendations logically derived from the material?
e. Is it clear that the proposed action would produce better results than no regulatory change or having regulation at all?
f. Is overlap from related alternatives avoided?
g. Are the recommendations based upon significant differences between the alternatives? Have all the variables that might affect the outcome been identified? If necessary, was a sensitivity analysis conducted?
i. Are recommendations intuitively satisfying? If not, can the reasons be identified?
j. Were the methods and sources of the study adequately documented?[502]

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502 DOT Handbook, supra note 484, at 26-27.

The Office of the Assistant Secretary for Policy and International Affairs has also published a detailed document entitled "Methods for Economic Assessment of Transportation Industry Regulations" that sets out in some detail an approach to risk assessment and methods for estimating industry costs.[503] This document was prepared by a private contractor as a supplement to the Handbook.

1. The National Highway Traffic Safety Administration.

The National Highway Traffic Safety Administration does not have its own handbook for guiding its regulatory analysts in drafting regulatory analysis documents. That agency, however, generally prepares an analysis at least as sophisticated as that called for in the DOT Handbook for all of its important rules.[504] But the agency does not attempt to place a value on a statistical fatality or serious injury as the DOT Handbook recommends.[505] As a matter of policy, NHTSA has taken the position that human life cannot be adequately valued in monetary terms. The agency estimates the benefits of life-saving rules in terms of lives saved and injuries avoided, and it may sometimes combine these estimates with cost estimates to determine the estimated cost per life saved for each alternative.[506] In this sense, the

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503 D. Couts, E. Hargardine, E. Lofgren & R. Main, Methods for Economic Assessment of Transportation Industry Regulations (1982).

504 Kranidas Interview II, supra note 262. NHTSA regulatory analysis documents, in fact, provided many of the examples of good analysis that the DOT Handbook provided.

505 Felrice Interview I, supra note 262; Blincoe Interview, supra note 296.

506 Kranidas Comments, supra note 346.

agency often undertakes a cost-effectiveness analysis for each of several alternatives.[507] In other regards, however, the NHTSA regulatory analysis documents comply with the Departmental guidelines' recommendations that the agency undertake a cost-benefit analysis for all reasonable alternatives.

The NHTSA regulatory analysts find that the problem of how to address uncertainties is one of the most difficult issues that they face on a routine basis. NHTSA regulatory analysts do not attempt to place statistical "confidence limits" on uncertainties. Instead, they attempt to analyze carefully the assumptions that go into their predictions and to undertake "sensitivity analysis" to probe the extent to which the predictions depend upon the assumptions.[508] For most of NHTSA's important rules, the predictions are only as good as the underlying assumptions, and the assumptions are largely judgmental.[509]

2. The Federal Aviation Administration.

The Office of Aviation Policy and Plans of the Federal Aviation Agency has published two documents relevant to regulatory analysis. The first, entitled "Economic Analysis of Investment and Regulatory Decisions -- A Guide," is a theoretical treatment of the problem of economic valuation of regulatory impacts.[510] It sets out a methodology for applying economic analysis to problems that the FAA commonly encounters. Using numerous

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507 Kranidas Interview II, supra note 262.

508 Felrice Interview I, supra note 262.

509 Felrice Interview I, supra note 262.

510 FAA Handbook, supra note 403.

examples from past FAA practice, the document details eight steps in the economic analysis of a regulatory problem:

1. Define the Objective
2. Specify Assumptions
3. Identify Alternatives
4. Estimate Benefits and Costs
5. Describe Intangibles
6. Compare Benefits and Costs and Rank Alternatives
7. Perform Sensitivity Analysis
8. Make Recommendations[511]

FAA regulatory analysts rely heavily upon this document in structuring the regulatory analysis documents that they draft for individual FAA rules.[512]

A second document, entitled "Economic Values for Evaluation of Federal Aviation Administration Investment and Regulatory Programs," sets out in great detail precisely how the agency's regulatory analysts should place monetary values on the costs and benefits of FAA regulations.[513] The "critical values" specified in the report include "the value of time of air travelers, the value of a statistical life, unit costs of statistical aviation injuries, unit replacement and restoration costs of damaged aircraft, and aircraft variable operating costs."[514] Regulatory analysts in FAA generally use the approaches set out in this document for stating "critical values" in the agency's regulatory analysis documents.[515]

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511 FAA Handbook, supra note 403, at 2-4.

512 Safeer, Weil and Harris Interview, supra note 269.

513 Office of Aviation Policy and Plans, Federal Aviation Administration, Economic Values for Evaluation of Federal Aviation Administration Investment and Regulatory Programs (1981) [hereinafter cited as FAA Values].

514 FAA Values, supra note 513, at i.

515 Safeer, Weil and Harris Interview, supra note 269.

D. The Impact of Regulatory Analysis on the Decisionmaking Process.

1. The Impact of the Regulatory Analysis Documents.

It is very difficult to draw any general conclusions about the extent to which regulatory analysis documents are read and used in the decisionmaking process in DOT. It is clear that a great deal of emphasis is placed on the documents at the Departmental level, as is evidenced by the ambitious attempts to draft guidelines for regulatory analysis documents. On the other hand, it appears that some regulatory analysis documents are drafted after the fact to justify decisions previously arrived at on other grounds.

Departmental officials can think of many examples in which well-prepared regulatory analysis documents led agency and Departmental decisionmakers to amend rules in relatively minor ways. On the other hand, regulatory analysis has not caused such decisionmakers to enhance or reduce the stringency with which they regulate more important activities.[516] In this sense, the regulatory analysis documents have, in the minds of some, only yielded "modest successes."[517]

It is not clear that the recent Executive orders are responsible for the successes that have resulted. At least some upper level Departmental officials believe that the Department would have insisted that the Operating Administrations begin serious analysis of rules, even in the absence of Executive Orders requiring such analyses. The Department, in other words,

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516 Peak Interview I, supra note 254.

517 Peak Interview I, supra note 254.

would have made an independent decision to structure comprehensive analytical rationality into the agency decisionmaking processes. The fact that the Department requires that the Operating Administrations prepare a regulatory evaluation for "significant" rules, whether or not they are "major," supports this conclusion.[518] Other DOT officials doubt that the agencies would have seriously brought analysis to bear on regulatory problems absent the RIA process that the Executive Orders mandated.[519]

a. Departmental Review.

Since only "significant" regulations receive full Departmental review, the regulatory analyses, if any, that are prepared for nonsignificant rules can have little impact on these rules. The regulatory analysis documents can have an impact on the Departmental review of significant rules, because the regulatory analysis documents are completed prior to that review. The upper level decisionmakers usually take a close look at the regulatory

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518 Attorneys in the Departmental Office of the General Counsel point out that rational analytical support for a rule may be required by the Administrative Procedure Act in any event. Eisner/Podberesky Interview, supra note 324 A 1976 evaluation of the Inflation Impact Statement Program concluded that the statements themselves had little impact upon the Department of Transportation, because that Department had independently incorporated economic impact assessment into the decisionmaking process. Staff of the Council on Wage and Price Stability and the Office of Management and Budget, An Evaluation of the Inflation Impact Statement Program 70 (1976) [hereinafter cited as IIS Evaluation].

519 Peak Interview I, supra note 254; Steed and Jones Interview I, supra note 286. ("The existence of a mechanism for regulatory impact assessment has contributed to the process. It makes us all sensitive to concerns for economics. If they stop doing this, the agencies would be more sloppy.")

analysis documents for important rules and at the summaries of the contents of those documents.[520]

Departmental review of rulemaking and regulatory analysis documents can perform at least three functions: (1) it can serve as a vehicle for communicating the policy preferences of the Secretary to the Operating Administrations; (2) it can present a final in-house opportunity to examine the assumptions and analysis in the regulatory analysis documents prior to making the documents public; and (3) it can provide an opportunity for the Operating Administrations to communicate to Departmental officials the need for legislative and policy changes.

The regulatory analysis document (RIA for major rules) can provide a convenient vehicle for communicating the Secretary's policy preferences to lower level employees in the Operating Administrations. The regulatory analysis document is the place where the agency should be explicitly measuring the action that it proposes against the policies that guide the agency. By reading the regulatory analysis document (or a summary of it), upper level decisionmakers should be able to determine whether or not the agency is implementing the policy preferences of the Secretary.

The success of Departmental review in DOT with respect to this "policy communication" function has depended heavily upon the management style of particular Secretaries. In the early 1980s, when the Operating Administrations were largely in a "deregulatory" mode, the Secretary of Transportation was content to let the Administrations promulgate regulations

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520 Eisner Interview, supra note 276; Peak Interview I, supra note 254; Podberesky Interview I, supra note 315; Felrice Interview I, supra note 262.

in a relatively autonomous fashion. In that atmosphere, review of rules and regulatory analysis documents in the Office of the Secretary very rarely resulted in a "remand" of a rule to an Operating Administration for a consideration of fresh options or for the application of a different policy approach. Departmental review of regulatory analysis documents was not especially effective in communicating upper level policy preferences to low level employees, because the Secretary apparently did not have strong policy preferences with respect to most of the regulations that were being promulgated at that time.

With the advent of a new Secretary in 1983 with stronger policy preferences with respect to safety regulations, Departmental review became more important to the rulemaking process.[521] The Secretary made an attempt to communicate her policy preferences to the Operating Administrations early in her tenure. The regulatory analysis documents that accompanied individual rules, however, occasionally revealed agency departures from those policy preferences, and the Secretary began to "remand" the rules to the Operating Administrations. As remands from the Secretary's Office became more frequent, the staff of the Operating Administrations began to request that the Office of the Secretary be involved early in the rulemaking process for important rules. The Office of the General Counsel and other Departmental-level offices began to take a more active role in policymaking in the rulemaking process.

The DOT experience indicates that regulatory analysis documents can aid upper decisionmakers communicate policy preferences to lower level

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521 See text accompanying notes 434-39, supra.

employees. But it seems equally clear that effective policy communication depends heavily upon the desire of upper level decisionmakers to communicate particular policy preferences to lower level decisionmakers. The regulatory analysis document seems to be a fairly effective tool in the hands of an upper level decisionmaker who wants to use it. Otherwise, Departmental review of the regulatory analysis document is not likely to have much impact on the agencies' output.

Departmental review in the Office of the Secretary can also perform a quality-control function by providing an independent review of the contents of regulatory analysis documents before making them public. The documents that the Operating Administrations have produced have generally been of sufficiently high quality that the debates that occur at the Departmental level turn on the validity of the assumptions underlying the analyses. The documents usually identify the assumptions adequately, and once the debates over the assumptions are over, there is little debate about the quality of the data or validity of the predictions based on the assumptions.[522] One value of the regulatory analysis documents to the Departmental decisionmakers is that they can bring about this sort of serious analytical debate.[523]

The fact that regulatory analysis documents, unlike the rulemaking documents, can discuss alternatives that are beyond the statutory authority of the agency can motivate upper level Departmental decisionmakers to seek legislative changes. In one instance the fact that the regulatory analysis

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522 Eisner Interview, supra note 276.

523 Eisner Interview, supra note 276.

document discussed an alternative that was not within the agency's statutory authority (after demonstrating that the preferred alternative that was within the agency's authority was extremely expensive) impelled the Office of the Secretary to approach members of the relevant Congressional committees to suggest amending the statute to give the agency sufficient authority to implement the less costly alternative.[524] Congress, however, was unreceptive to the suggestion, and the agency had to promulgate the more expensive regulation.[525] Still, the experience indicates that the exploration of alternatives beyond the agency's statutory authority in regulatory analysis documents can have an impact on upper level Departmental decisionmakers.[526]

b. The National Highway Traffic Safety Administration.

The regulatory analysis documents play a very large role in NHTSA. The Plans and Programs Office drafts the document as an independent product of the agency's regulatory analysts. The document contains their independent assessment of the costs and benefits of the alternatives that the Rulemaking Office proposes, and many regulatory analysis documents identify options

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524 Eisner Interview, supra note 276; Peak Interview I, supra note 254.

525 Peak Interview I, supra note 254.

526 On another occasion, upper level Departmental decisionmakers identified an alternative that was beyond the agency's statutory authority and suggested that the agency consider that option. The agency responded that if the Department sought to have the statute amended to allow the agency the flexibility to consider the suggested option, Congress would undoubtedly amend the statute to make the statute even more restrictive. The Departmental decisionmakers at that point decided not to pursue the matter. Podberesky Interview I, supra note 315.

that the Rulemaking Office either missed or ignored. The regulatory analysis documents almost always analyze the "do nothing" option, an option that the rulemaking office does not often treat in the Rulemaking Support Paper. The process of preparing a regulatory analysis document leads agency personnel to reject early on alternatives that are obviously not cost-effective.

In addition to providing an independent analysis of the relevant issues in a given rulemaking, the regulatory analysis document provides the vehicle for the Plans and Programs Office's input into the intra-agency debates that the "adversarial" approach is intended to foster. Finally, for most important regulations, the NHTSA Administrator and her high level staff do read the regulatory analysis documents, which, unlike the Rulemaking Support Papers, are attached to the Administrator's briefing package.[527] In at least one recent rule -- the bumper standard -- the RIA was, in the opinion of the former Associate Administrator for Plans and Programs, the primary decisionmaking document.[528]

The Administrator of NHTSA and her aides are convinced that the formal process of Executive Order 12291 creates a framework for analysis that will lead to better decisions than the agency reached in the past. It provides a vehicle for rational debates within the agency on the costs and benefits of rules. In her opinion, the fact that the regulatory analysis documents and rulemaking documents are reviewed by upper level decisionmakers (in the

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527 Felrice Interview I, supra note 262; Steed and Jones Interview I, supra note 286. ("If there is a disagreement or if it is a major rule, the Administrator will read the regulatory impact assessment.")

528 Felrice Interview I, supra note 262; Hitchcock Interview I, supra note 292.

agency, the Department, and OMB) who are committed to comprehensive analysis of regulatory problems serves as a constant inducement to agency employees who might not otherwise be committed to the philosophy of Executive Order 12291.[529]

On the other hand, even though many of the agency's decisions are informed by comprehensive analysis, they are at bottom judgmental. The available facts typically can support more than a single regulatory conclusion. The analysis can, of course, aid the decisionmaking. Yet because of the large uncertainties that becloud many of NHTSA's regulatory issues, a large component of many of the agency's most important rulemaking actions is the policy preference of the Administrator within the discretionary bounds allowed by the agency's statutes.[530]

This may help explain why, despite the efforts of its regulatory analysts and despite the availability of "rational" regulatory analysis documents, the agency's rulemaking efforts do not always survive judicial review. Reviewing courts have held two of the agency's most important rules to be "arbitrary and capricious" after reviewing the reasoning process revealed in the rulemaking documents and the regulatory analysis documents.

In State Farm Mutual Casualty Co. v. NHTSA,[531] the Supreme Court reviewed the agency's withdrawal of its "passive restraint" regulations. After almost a decade of studying the matter, the Secretary of Transportation in 1977 had issued Modified Standard 208, which required

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529 Steed and Jones Interview I, supra note 286.

530 Blincoe Interview, supra note 296.

531 ___ U.S. ___, 77 L.Ed.2d 443 (1983).

automobile manufacturers to install passive restraints (e.g., automatic seatbelts or airbags) on a phased basis beginning with large automobiles in the 1982 model year and extending to intermediate and small automobiles in the 1983 and 1984 model years. In February, 1981, the new Secretary of Transportation reviewed the standard in light of the economic difficulties of the domestic auto industry. After taking public comments and further studying the matter, the agency decided to withdraw the passive restraint requirements. The agency determined that in light of the fact that automobile manufacturers had almost universally elected to install automatic seatbelts rather than airbags and the fact that its RIA predicted had determined RIA that few people would be protected by automatic seatbelts, the standard would not produce significant safety benefits.

The agency noted that manufacturers planned to install detachable automatic seatbelts in 99 percent of all new automobiles. This would meet the 1977 Modified Standard, but it would make it relatively easy for passengers to detach the automatic seatbelts permanently, thus requiring an affirmative action of the passenger to make the seatbelts automatic once again. The agency predicted in the RIA that large numbers of passengers would permanently detach the automatic seatbelts, thereby rendering the standard inefficacious. Since the automatic seatbelts would not produce significant safety benefits under these conditions, the agency concluded that the Modified Standard should be withdrawn.[532]

The Supreme Court found this reasoning process to be arbitrary and capricious.[533] First, the Court found that the agency was arbitrary and

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532 46 Fed. Reg. 53,419 (1981).

533 77 L. Ed.2d at 455.

capricious in failing to consider modifying the standard to require that manufacturers use airbag technologies. Assuming that automatic seatbelts would not significantly enhance safety, the agency made no attempt whatsoever to explain why it concluded that the passive restraint standard should be rescinded altogether. At best, that conclusion would only justify amending the Modified Standard to prevent the detachable automatic seatbelt option. In no way did it cast doubt on the need for a passive restraint standard or upon the efficacy of the airbag technology. The agency irrationally failed even to consider the airbags-only option.[534]

The Court also found that the agency too quickly dismissed the safety benefits of automatic seatbelts. The Court agreed with the agency that substantial uncertainties about the efficacy of a regulation could justify its withdrawal, if such uncertainties were supported by the record and reasonably explained.[535] The Court recognized that "[i]t is not infrequent that the available data does not settle a regulatory issue and the agency must then exercise its judgment in moving from the facts and probabilities on the record to a policy conclusion."[536] Nevertheless, it is not sufficient for an agency "to merely recite the terms 'substantial uncertainty' as a justification for its actions."[537] In this case the agency's explanation was not sufficient to enable the Court to conclude that "the rescision was the product of reasoned decisionmaking."[538]

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534 77 L. Ed.2d at 463.

535 77 L. Ed.2d at 463.

536 77 L. Ed.2d at 463.

537 77 L. Ed.2d at 463.

538 77 L. Ed.2d at 463.

According to the Court, the record contained no direct evidence that an automatic seatbelt requirement would not increase seatbelt usage substantially. The evidence at best was equivocal. The Court reasoned that the agency's conclusion that it could not predict even a five percent increase failed to take into account a critical difference between automatic seatbelts and manual seatbelts -- viz. inertia. The agency had earlier found that inertia operated against the efficacy of the manual seatbelts, because an affirmative act of "buckling up" was required to take advantage of their safety benefits. The Court reasoned that the same inertia would operate in favor of automatic seatbelts, because it would take an affirmative act to detach the seatbelt. The agency had failed to bring its expertise to bear on this issue.

The agency also failed adequately to explain why it did not require nondetachable belts, such as "continuous spool" belts. The agency's primary rationale for this was its conclusion that such a requirement might trigger adverse public reaction. The Court found this to be unsupported by the record and unexplained.[539]

The agency's experience with the passive restraint standard would seem to indicate that regulatory analysis and the adversarial decisionmaking model do not necessarily enhance the quality of the agency's decisions. The RIA for this rulemaking was one of the most thorough and extensive that the agency has ever produced. On the other hand, the information in the RIA did not compel the agency's decision. Indeed, the information in many ways helped to undermine the agency's decision. The Court drew on information

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539 77 L. Ed.2d at 466.

contained in the RIA to reveal the inadequacy of the agency's reasoning process.[540] The decision may perhaps be characterized as a "judgment call" that showed poor judgment. The Administrator apparently had a result in mind and used a path of reasoning to achieve that result that was not supported by facts or rational analysis. Interviews with several participants in both the regulatory analysis and program offices reveal a general dissatisfaction with the Administrator's decision in this case. In other words, the passive restraint case may be an instance in which the Administrator failed to use both techno-bureaucratic and comprehensive analytical thinking in reaching a decision that was dominated by policy considerations.

Yet the regulatory analysis process in this case did fail to implement the goal of bringing the competing considerations before Congress, the reviewing courts, and the public. For example, it is inconceivable that no one in the agency identified the option of requiring airbags. Many of the people who worked on the 1981 rescision had worked on the 1977 Modified Standard in which that option was considered and rejected to provide more flexibility for the automobile industry. But in the deregulatory fervor of 1981, it does seem clear that no one in either the regulatory analysis office or the rulemaking office was willing to press strongly for that option. It was clear to everyone that the Administrator would not be receptive to that option. It was therefore not carefully examined in the RIA, and it did not become part of the agency's public rationale. That option, however, did not escape the attention of the reviewing courts.

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540 77 L. Ed.2d at 464 n. 16, 465 n. 18-19, 466 n. 20.

Rather than citing the passive restraint litigation as an example of the failure of regulatory analysis, it may more appropriately be cited as an example of its limitations. Regulatory analysis cannot and should not attempt to dictate a precise regulatory result. There is always room for the exercise of "policy judgment," in addition to "scientific" and "engineering" judgment, in regulatory decisionmaking. It is, however, inappropriate for an agency to pervert its regulatory analysis to justify a result that the agency decisionmakers want to reach on policy grounds, just as it would be wrong to pervert the technical analysis to the same end. The regulatory analysis documents, like the technical rulemaking documents, should reveal the extent to which there are facts for the agency to rely upon and the extent to which uncertainties cloud the analysis. This will necessarily reveal the extent to which the decisionmaker substituted "policy judgment" for facts and analysis. In the end, the decision is subject to review in the courts, which must determine the extent to which an agency may substitute "policy judgment" for techno-bureaucratic and comprehensive analytical rationality.

c. The Federal Aviation Administration.

The regulatory analysis documents can have a substantial impact on FAA decisionmaking. As in NHTSA, regulatory analysis documents are prepared for all except the most minor rules. The upper level decisionmakers in FAA do not decide on proposed or final rules until the preliminary or final regulatory analysis document is available. For most regulations of any significance, the Administrator reads a summary of the regulatory analysis document's contents that has been prepared by the Office of Aviation Policy

and Plans.[541] In many cases, the Administrator also reads that actual regulatory analysis document.[542] The fact that the regulatory analysis documents must be signed by their authors and the fact that the Administrator may read any given document enhances the quality of all of the documents.[543]

The principal impact of the regulatory analysis documents has been to "cost out" alternatives that the technical staff has identified. This aids the program office and the upper level decisionmakers to choose the least costly alternative to a given regulatory result.[544] Even if the least costly alternative is not as efficacious as more expensive options, the cost analysis will cause the program office to take a closer look at the less costly option.[545] On a few occasions, the information contained in the regulatory analysis document has convinced the program office to withdraw a suggestion for rulemaking.[546]

2. The Impact of the Regulatory Analysis Office.

The regulatory analysis office had a high profile in both of the two agencies studied in connection with this Report. Both regulatory analysis offices seem to be influential in agency decisionmaking, and in NHTSA the

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541 Murdock and Faberman Interview, supra note 307.

542 Murdock and Faberman Interview, supra note 307.

543 Murdock and Faberman Interview, supra note 307.

544 Hawkins Interview, supra note 310.

545 Faberman Interview II, supra note 306.

546 Hawkins Interview, supra note 310.

regulatory analysis office has on many occasions dominated the decisionmaking process. The influence of Departmental regulatory analysts on the decisionmaking process is less clear, depending to a large extent upon who occupies the position of Secretary of Transportation.

a. Departmental Review.

The role of the Departmental Office of Industry Policy is to provide general guidance to the regulatory analysts in the operating administrations and to review regulatory analysis documents when they are circulated for Departmental review. In addition, that office will occasionally suggest an alternative or a consideration that the agency did not mention in the regulatory analysis document, and this might in turn persuade the agency to change the substance of the rule.[547] The Office of Industry Policy may play an indirect role in the decisionmaking process of the Operating Administrations through the detailed Handbook and guidance document that it prepared for use by regulatory analysts in the agencies.[548] For example, the fact that the Department placed a uniform value for a human fatality in that document may prove helpful to the agencies in calculating the costs and benefits of rules that attempt to reduce risks to life.[549] It is not clear, however, how much those documents affect the actual decisionmaking

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547 Peak Interview II, supra note 251.

548 The Office of the General Counsel has played a similar indirect role in agency decisionmaking by suggesting alternative procedures for regulation. Recently, it has undertaken a project to encourage the operating administrations to promulgate regulations through negotiations with interested parties. Peak Interview II, supra note 251.

549 Peak Interview I, supra note 254. Despite this explicit guidance, however, NHTSA does not attempt to place an explicit value on human life in its rulemaking efforts.

process within the agencies. FAA, for example, has its own set of guidance documents for drafting regulatory analysis documents.

b. The National Highway Traffic Safety Administration.

In its early days, the Office of Program and Rulemaking Analysis in the Office of Plans and Programs played a very tangential role in the NHTSA decisionmaking process. It was required to prepare Inflation Impact Statements that were little more than post hoc rationalizations for decisions that the Rulemaking Office had reached on technical grounds.[550] In 1977, however, the Administrator made an explicit determination that the Plans and Programs Office would have a higher profile in the agency. It is now quite clear that the office plays a major role in the agency's "adversarial" decisionmaking process. It is at least an "equal partner" in that process,[551] and in some administrations it is "more equal" than the Rulemaking Office. Upper level agency decisionmakers encourage the Plans and Programs Office to be independent, even when that means disagreeing with the Administrator. That office is meant to be an "institutional skeptic," with the assigned role of forcing the results-oriented Rulemaking Office to consider the costs as well as the benefits of the regulations that it proposes.

Morale in the Office of Program and Rulemaking Analysis in the Office of Plans and Programs is quite high. Although the work load is great, most analysts are willing to work on weekends to get the job done.[552] This

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550 Felrice Interview I, supra note 262.

551 Felrice Interview I, supra note 262.

552 Blincoe Interview, supra note 296; Kranidas Interview II, supra note 262.

willingness to work overtime is attributable to the opportunity that the Office gives its professional employees to practice their profession creatively. Obviously, the professionals would not be as dedicated to their task if they believed that high level decisionmakers were ignoring their input.

Perhaps the most effective role of the Plans and Programs Office is not as a drafter of regulatory analysis documents, but as a participant in the internal debates that the agency has built into the decisionmaking process. On many occasions the product of the Rulemaking Office has changed dramatically as a result of the internal dialogue between the Plans and Programs Office and the Rulemaking Office.[553]

For example, when the Rulemaking Office recently proposed that the agency promulgate lock strength requirements for the locks on hatchback doors, the Plans and Programs Office questioned the benefits of the standard. The Rulemaking Office pointed to five fatalities that had occurred in hatchbacks. The data, however, did not indicate that the fatalities resulted from the force of the collision ejecting the victim through the rear of the automobile. The Plans and Programs Office insisted that the Rulemaking Office point to better evidence of benefits before the agency required the automobile industry to expend substantial funds on strengthening the locks on hatchbacks. The Rulemaking Office was impatient with this request, and it suggested that since it was possible that weak locks on hatchbacks had caused the deaths, and since it was relatively inexpensive to increase the lock strength on hatchbacks, the agency should

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553 Blincoe Interview, supra note 296.

mandate stronger locks. The Administrator agreed with the Plans and Programs Office,[554] and no standard was promulgated.[555]

The Plans and Programs Office has, of course, lost internal battles, and it has produced regulatory analysis documents that appear to undercut the agency decisions made on policy grounds.[556] No Administrator has ordered the regulatory analysis office to "fake" its analysis when the policy decision seems to vary from the conclusion of the regulatory analysis document. This forces the decisionmaker to be explicit about his or her reasons for adopting a solution that does not appear to be indicated by the regulatory analysis documents. On the other hand, there is room to change the discussion in the conclusion and rationale sections of a regulatory analysis document when it does not seem to support the Administrator's decision, and there are considerable pressures within the agency to "fall in line" behind the Administrator once he or she has decided an issue. In addition, the Administrator can always determine that no action is appropriate while the agency studies the matter further.[557]

A former Associate Administrator for Plans and Programs acknowledges that the adversarial model limits that office's effectiveness to the extent that it is not involved in the decisionmaking process at an earlier

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554 Felrice Interview I, supra note 262.

555 Similarly, in the Field of Direct View proceedings, it was largely the concerns that the Plans and Programs Office voiced about the Rulemaking Office's failure to substantiate the proposed rule's benefits that resulted in its ultimate withdrawal. Felrice Interview I, supra note 262.

556 Felrice Interview I, supra note 262; Steed and Jones Interview I, supra note 286.

557 Felrice Interview I, supra note 262.

stage.[558] Even if the Plans and Programs Office can take a fresh and independent look at the issues after the Rulemaking Support Paper has been completed, some options can be lost solely by virtue of the difficulty of going back to the drawing board and studying them. If the Plans and Programs Office objects to the failure to include an option in the Rulemaking Support Paper, the Rulemaking Office can often legitimately complain that the Plans and Programs Office should have voiced its concerns at the time that the Rulemaking Office was considering options and undertaking research. Still, with its current limited resources, it is simply impossible for the Plans and Programs Office to involve itself earlier in the rulemaking process than it does.[559] Moreover, to participate earlier would undermine to some extent the adversarial character of the dialogue between the two offices.

c. The Federal Aviation Administration.

The personnel in the Office of Aviation Policy and Plans of the Federal Aviation Administration consider themselves consultants to the program offices. A representative from that office will only be present on the working group if the accountable Directorate requests that it participate.[560] On the other hand, the accountable Directorates know that it will often be difficult to get an important rule through upper level review without the kind of detailed analysis that the Office of Aviation

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558 Felrice Interview I, supra note 262.

559 Felrice Interview I, supra note 262.

560 Safeer, Weil and Harris Interview, supra note 269.

Policy and Plans can provide.[561] The representative on the work group from that office attempts to familiarize himself with the technical aspects of the rule and then attempts to locate who the rule will impact and what the magnitude of the impact will be.[562]

The contribution of the Office of Aviation Plans and Programs can be outcome-determinative in both directions. In the proceeding in which that office hired a contractor to design an aircraft from scratch, the study demonstrated convincingly that the proposed rule was prohibitively expensive. Conversely, the Office's cost studies frequently indicate that the burden of a rule will be trivial or that the cost of repealing an existing rule will be substantial.[563] The Director of the Office of Aviation Plans and Programs is confident that the agency's rules would not be as cost-effective if his office did not participate in rulemaking activities.[564] Officials in the Office of Chief Counsel agree that the Office of Aviation Plans and Programs has played an important role in recent regulatory decisionmaking.[565]

The contribution of the Office of Aviation Policy and Plans, however, seems to be limited to the preparation of cost-benefit analyses of alternatives that the program office has already identified. There is little evidence that the representatives from the Office of Aviation Policy

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561 Safeer, Weil and Harris Interview, supra note 269.

562 Safeer, Weil and Harris Interview, supra note 269.

563 Safeer, Weil and Harris Interview, supra note 269.

564 Safeer, Weil and Harris Interview, supra note 269.

565 Murdock and Faberman Interview, supra note 307.

and Plans has produced innovative new options that the technical specialists in the accountable directorate failed to identify.[566] Their chief function, beyond preparing regulatory analysis documents, is to provide an economic perspective on issues that are discussed at team meetings.[567] Their input can change the direction that a rule takes toward a less expensive option, but it rarely changes the broader outcome of a rulemaking proceeding.[568]

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566 Members of the Office of Aviation Policy agree that they have very rarely discovered options that the program office failed to identify. Hawkins Interview, supra note 310.

567 Faberman Interview II, supra note 306.

568 Faberman Interview II, supra note 306.

IV. The Use of Regulatory Analysis in the Department of Labor.

The Department of Labor (DOL) has several important regulatory functions that are implemented through rulemaking subject to Executive Order 12291 and the Regulatory Flexibility Act. The Occupational Safety and Health Administration (OSHA) issues the vast majority of the major rules that the Department promulgates. This Report will therefore focus exclusively upon that Administration and Departmental review of its rules. The Departmental review process, however, is the same for rules from all regulatory agencies within DOL.

A. Departmental Structure and Hierarchy.

1. Departmental Review Structure.

The Department is headed by a Secretary and Under Secretary. There are three Deputy Under Secretaries,[569] nine Assistant Secretaries,[570] a Solicitor, and an Inspector General. Table 3-3 sets out the Department's organizational structure.

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569 The Deputy Under Secretary for Employment Standards Administration, the Deputy Under Secretary for Intergovernmental Affairs, and the Deputy Under Secretary for International Affairs.

570 The Assistant Secretary for Administration and Management, the Assistant Secretary for Employment and Training Administration, the Assistant Secretary for Labor-Management Relations, the Assistant Secretary for Legislative Affairs, the Assistant Secretary for Mine Safety and Health Administration, the Assistant Secretary for Occupational Safety and Health Administration, the Assistant Secretary for Policy, and the Assistant Secretary for Veteran's Employment and Training.

As in the Department of Transportation, but unlike the Department of Agriculture and EPA, the Solicitor's Office performs the centralized Departmental regulation tracking function. The Solicitor's Office is also the designated Departmental contact with OMB for regulatory review. The Special Assistant for Regulatory Affairs performs this function with the aid of a staff law clerk.

The Office of Regulatory Economics and Economic Policy Analysis under the Assistant Secretary for Policy plays a central review role for regulatory analysis documents. All Regulatory Impact Analyses must be cleared through that office.[571] The office also performs the primary regulatory analysis drafting function for some programs that lack their own regulatory analysis staffs.[572] The office is responsible for ensuring that the RIAs meet the OMB guidelines.

2. The Occupational Safety and Health Administration.

The Occupational Safety and Health Administration (OSHA) was established in 1970 to promulgate health and safety standards to protect workers and to ensure that employers comply with their "general duty" to provide a place of employment free from recognized hazards.[573] Many of

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571 Telephone Interview with Mr. Robert Shapiro, Special Assistant to the Solicitor of Labor for Regulatory Affairs, January 8, 1984.

572 Personal Interview with Ms. Marguerite Connerton, Senior Economist, Office of Regulatory Economics and Policy Analysis, Office of Policy, DOL, May 17, 1983 [hereinafter cited as Connerton Interview].

573 See generally, M. Rothstein, Occupational Safety and Health Law (1983). Other functions of the agency are to assist and encourage the states in their efforts to assure safe and healthful working conditions, to promote research, information, education in the field

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the agency's large rulemaking efforts have been devoted to promulgating health standards to protect workers from the harmful effects of toxic substances in the workplace.[574]

The Assistant Secretary of Occupational Safety and Health and a Deputy Assistant Secretary head the agency. Seven Directorates conduct the agency's day-to-day business.[575] Of these, four -- the Directorate of Health Standards Programs, the Directorate of Policy, the Directorate of Safety Standards Programs, and the Directorate of Technical Support -- are usually involved in rulemaking activities. The Directorate of Health and the Directorate of Safety are the agency's "program offices." They contain the scientists, engineers, and project managers who draft the Federal Register documents and other supporting documents. The two Directorates promulgate approximately two or three proposed or final health and safety standards per year.[576] The Directorate of Technical Support provides engineering and scientific expertise to the program offices.[577] The

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573 of occupational safety and health, and generally to assure safe and healthful working conditions. Occupational Safety and Health Act of 1970, 29 U.S.C. § 651 et seq.

574 See, e.g., Industrial Union Department, AFL-CIO v. American Petroleum Institute, 448 U.S. 607 (1980) and American Textile Manufacturers Institute v. Donovan, 452 U.S. 490 (1981).

575 The Directorate of Administrative Programs, the Directorate of Federal-State Operations, the Directorate of Field Operations, the Directorate of Health Standards Programs, the Directorate of Policy, the Directorate of Safety Standards Programs, and the Directorate of Technical Support.

576 See, McGarity, OSHA's Generic Carcinogen Policy: Rulemaking under Scientific and Legal Uncertainty, in Law and Science in Collaboration ch. 5 (Nyhart & Carrow eds. 1983).

577 The Office of Technical Support has support responsibilities that cut across several regulatory areas. It provides chemical sample analysis

(Continued on page 193)

Policy Directorate contains the agency's regulatory analysts and economists; the latter are located in the Office of Regulatory Analysis. That Office has a staff of approximately twenty-three, including support personnel and editors, and a budget of approximately three million dollars in fiscal year 1984 for contractor support.[578] The Occupational Safety and Health Administration is one of the very few agencies within the Department of Labor that has an independent staff of regulatory analysts. The Office of Regulatory Analysis prepares the regulatory analysis documents for the agency, and they are reviewed by the Office of Regulatory Economics and Economic Policy Analysis under the Assistant Secretary for Policy.[579]

B. The Formal Regulatory Process.

The Department gives the individual Administrations a large degree of autonomy in structuring their rulemaking procedures. The head of each Administration is responsible for identifying regulatory needs and for

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577 for enforcement efforts, field reports for medical officers, and industrial hygenists and engineers for rulemaking efforts. On rare occasions the technical staff from the Office of Technical Support will be a member of a rulemaking team. Telephone Interview with Ms. Pat Atamik, Administrative Officer, Directorate of Technical Support, Occupational Safety and Health Administration, DOL, July 23, 1984.

578 Telephone Interview with Mr. Anthony E. Goldin, Director, Directorate of Policy and Mr. Larry Braslow, Chief of Economics, Office of Regulatory Analysis, Directorate of Policy, Occupational Safety and Health Administration, DOL, July 26, 1984 [hereinafter cited as Goldin and Braslow Interview]. [This interview was a combined interview conducted over speaker phone. Where possible, the author attempted to distinguish Mr. Braslow from Mr. Goldin.]

579 Telephone Interview with Ms. Mary Ellen Weber, Office of Regulatory Analysis, Directorate of Policy, Occupational Safety and Health

(Continued on page 194)

establishing procedures for meeting those needs. The Department does, however, maintain a regulatory oversight function that is lodged in the Policy Review and Coordinating Committee, which reviews all policy and regulatory initiatives.[580] The Secretary of Labor chairs the Policy Review Coordinating Committee, and the Assistant Secretary for Policy serves as its Executive Director. Its other members include the Secretary's Chief of Staff (who chairs the meetings in the Secretary's absence), the Under Secretary, the Solicitor, the Assistant Secretary for Administration and Management, the Assistant Secretary for Employment and Training Administration, and the Deputy Under Secretary for Intergovernmental Affairs.[581] The Committee is aided by a Secretariat composed of representatives of the Deputy Under Secretaries and Assistant Secretaries.[582] The purpose of the Policy Review and Coordination Committee is to communicate policy prescriptions from the upper level Departmental Decisionmakers to lower level staff and to facilitate upper level Departmental input into the regulatory process.

(Continued from page 193)

579 Administration, DOL, May 10, 1983 [hereinafter cited as Weber Interview].

580 See, Memorandum from Raymond J. Donovan to the Executive Staff on Improving the Management and Policy Processes Within the Department, November 17, 1982 [hereinafter cited as Improving Management Memo]; Memorandum from John Cogan to Members of the Secretariat of the Policy Review and Coordinating Committee on PRCC Operating Procedures, November 29, 1982 [hereinafter cited as PRCC Procedures Memo].

581 Improving Management Memo, supra note 580, at 1.

582 Improving Management Memo, supra note 580, at 1. These representatives must be at the Deputy Assistant Secretary or Associate Deputy Under Secretary level.

1. Origin and Threshold Analysis.

a. Departmental Procedures.

Rules in the Department of Labor typically originate in one of the Agencies within the Department. The Office of the Secretary, however, can also be the impetus for a rule or an amendment to a rule, in which case that Office communicates its desire to an Administration.

At the time that an agency begins to devote staff or other resources to a rulemaking effort, Departmental procedures require the agency to prepare a "Concept Analysis Paper," and send it to the Assistant Secretary for Policy and the Solicitor.[583] The purposes of this paper is to inform the Office of the Secretary, the Assistant Secretary for Policy, and the Solicitor that the agency is planning to address a particular issue and to aid in the Departmental tracking of pending regulatory issues.[584] The Concept Analysis Paper must contain:

1. A brief description of the issue, with as much detail as may be necessary for a general understanding of the problem;
2. A description of possible actions which the Agency intends to consider taking with respect to the issue;
3. The Agency's estimated timetable (including any statutory or other deadlines); and
4. Other Departments or Agencies that may have a significant interest in the issue.[585]

b. The Occupational Safety and Health Administration.

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583 Memorandum from Raymond Donovan to Executive Staff on Departmental Decision Making Procedures -- Overall Policies, October 23, 1981 [hereinafter cited as Departmental Procedures Memo].

584 Departmental Procedures Memo, supra note 583, at 2.

585 Departmental Procedures Memo, supra note 583, at 2-3.

The Occupational Safety and Health Administration (OSHA) has developed a Regulation Management System to complement the Departmental procedures for generating rules.[586] The Procedural Directive that establishes the Regulation Management System begins with the following statements of policy:

A. Each standard must address a demonstrable significant risk of material health impairment or injury;
B. Alternative approaches, including nonregulatory means, must be explored to mitigate the adverse effects of the risk;
C. Each standard must be reasonably necessary and appropriate to substantially reduce employee risk;
D. Each standard must be shown to be both technically and economically feasible on an industry-by-industry basis to the extent practicable;
E. The cost-effectiveness of alternative approaches must be considered;
F. The most cost-effective approaches which ensure protection from the risk must be chosen;
G. Facts to support the standard must be developed, with special attention given to the documentation of the risk and the technological and economic feasibility of the standard;
H. The public must have an early and meaningful opportunity to participate in the development of each standard. Affected parties, including States, must be requested to provide relevant information concerning risk, feasibility and cost-effectiveness, and all information obtained must be considered fully when developing each standard.[587]

The Directive implementing the Regulation Management System lists the following sources for OSHA rules:

(1) NIOSH Criteria Document;
(2) Petition or request from a labor group, company, association or public interest group;
(3) Issues raised by Congress;
(4) Issues identified by the field staff;
(5) Regulatory Flexibility, Paperwork, or other reviews of existing standards; and,
(6) Widespread public concern.

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586 OSHA Instruction RUL.1, March 1, 1982 [hereinafter cited as OSHA Instruction RUL.1].

587 OSHA Instruction RUL.1, supra note 586, at II-1.

Historically, the most common source of OSHA rulemaking efforts has been NIOSH Criteria Documents. The National Institute for Occupational Safety and Health (NIOSH) is a sister agency in the Department of Health and Human Services that is directed by the Occupational Safety and Health Act to investigate the causes of injury and disease in the workplace and to recommend safety and health standards.[588] A NIOSH investigation may result from a request by the Assistant Secretary for OSHA, or the agency may decide to undertake an investigation on its own.[589] OSHA need not react to a NIOSH recommendation within any set period of time, and in the past such recommendations have tended to pile up, because the standard setting process is so resource-intensive.[590] Since the agency has a good deal of discretion to pick and choose from among the available recommendations, the decision to go forward with a particular rule is often dominated by practical and political considerations, such as pressure from constituency groups. In addition, the agency has on one or two occasions been ordered by a court to initiate or complete the standard setting process.[591]

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588 Occupational Safety and Health Act of 1970 § 20, 29 U.S.C. § 669 (1982).

589 See, M. Rothstein, supra note 573, at § 52.

590 See generally, McGarity, supra note 576.

591 See, e.g., Organized Migrants in Community Action v. Brennan, 520 F.2d 1161 (D.C. Cir. 1975). One purpose of the agency's Regulatory Management System, which was established in 1982, is to provide information to the agency staff that will allow a more rational priority-setting. Comments on an Initial Draft of this Report of Mr. Anthony E. Goldin, Director of Policy and Mr. Larry Braslow, Chief of Economics, Office of Regulatory Analysis, Directorate of Policy, Occupational Safety and Health Administration, DOL, April 9, 1985 [hereinafter cited as Goldin and Braslow Comments].

i. The Assistant Secretary's Initial Determination.

Ideas for rules generally germinate in either the Directorate of Health Standards or the Directorate of Safety Standards. In order to justify a substantive rulemaking effort, the Directorate must be able to support a preliminary determination that a workplace or work practice poses a "significant risk" to employee health or safety.[592] Since economic analysis has little to contribute to this question, there is little interaction between personnel in the Health and Safety Directorates and regulatory analysts in the Directorate of Policy during this germination period.[593] Any of the agency's seven Directors may bring a regulatory issue to the attention of the Regulation Review Committee.

The Regulation Review Committee is responsible for "coordinating issues among the directorates and reviewing documents and issues resulting from the standards development process prior to the Assistant Secretary's review."[594] The Committee is composed of an Executive Committee consisting of seven permanent members who sit in all Regulation Review Committee Meetings and additional members as required by the issue before the Committee. The Executive Committee is composed of (1) the Director of the Directorate of Health Standards Programs; (2) the Director of the Directorate of Safety Standards Programs; (3) the Director of Policy, Legislation, and Regulatory Analysis; (4) the Director of the Office of

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592 Goldin and Braslow Interview, supra note 578.

593 Telephone Interview with Mr. Robert P. Beliles, Office of Risk Assessment, Directorate of Health Standards Programs, Occupational Safety and Health Administration, DOL, July 23, 1984 [hereinafter cited as Beliles Interview].

594 OSHA Instruction RUL.1, supra note 586, at III-2.

Regulatory Analysis; (5) a Field Coordinator from the Office of Field Coordination under the Directorate of Field Operations; (6) the Associate Solicitor and the Counsel for Standards for Occupational Safety and Health; and (7) the Executive Director of the Committee. Additional members of the Committee, who sit on the Committee when it addresses an issue relevant to their responsibilities, are: (1) the Director of the Directorate of Technical Support; (2) the Director of the Directorate of Federal Compliance and State Programs; (3) the Director of the Directorate of Training, Education, Consultation and Federal Agency Programs; and (4) the Director of the Office of Information and Consumer Affairs. Finally, others whose expertise may be needed can be invited to join the Committee to discuss particular issues. The Regulation Review Committee is very similar in composition to the Steering Committee in the Environmental Protection Agency.

The Regulation Review Committee must recommend to the Assistant Secretary whether the agency should go forward with an idea for a rule to the next step of the standard development process. While the agency procedural memoranda do not provide any criteria for making this important initial decision, considerations that go into the Committee's deliberations include (1) agency resources; (2) preliminary assessments of the nature of the risk; (3) the extent of the populations at risk; (4) the importance of other agency regulatory efforts; and (5) jurisdictional issues concerning other agencies in the Department and throughout the federal government.[595]

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595 Telephone Interview with Mr. Gary Strobel, Special Assistant to the Assistant Secretary for Regulatory Affairs, Occupational Safety and Health Administration, DOL, July 23, 1984 [hereinafter cited as Strobel Interview].

Hence, the Committee might decide on the merits that the risks that the rule would address are not large enough to warrant the regulatory effort.[596]

Personnel from the Directorates report, however, that the Regulation Review Committee does not always come to a definite conclusion on a rulemaking idea. Ideas are, in effect, tabled indefinitely without informing the originators of the reasons for failing to authorize further efforts. Two members of the regulation Review Committee, however, deny that the Committee allows rules to languish without making a final determination within a reasonable period of time.[597]

After the Regulation Review Committee has made an initial determination whether to pursue a rulemaking effort, it conveys its conclusion to the Assistant Secretary for Occupational Safety and Health. The Assistant Secretary makes the ultimate decision whether to begin the standard-setting process.[598]

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596 Strobel Interview, supra note 595. Since only a very few rulemaking efforts have begun since the agency implemented its new regulation management system, the agency's experience with Regulation Review Committee approval of rulemaking ideas is not extensive. The agency went through the approval process for rules that were already in process at the time that the regulation management system was implemented, but those rules generally received perfunctory treatment. Telephone Interview with Mr. Arthur Gass, Office of Risk Reduction Technology, Directorate of Health Standards Programs, Occupational Safety and Health Administration, DOL, July 23, 1984 [hereinafter cited as Gass Interview I].

597 Goldin and Braslow Interview, supra note 578; Strobel Interview, supra note 595. Strobel suggests that the regulations that appear to languish in the Regulation Review Committee may have come to the Committee without the required "sign-offs" and were therefore not technically ripe for committee action. Strobel Interview, supra note 595.

598 Strobel Interview, supra note 595; Goldin and Braslow Interview supra note 578; Beliles Interview, supra note 593.

ii. The Preliminary Team, the Research and Analysis Plan, and the Concept Analysis Paper.

If the Assistant Secretary decides to go forward with a rulemaking effort, the Regulation Review Committee appoints a "Preliminary Team," in consultation with all Directors of Directorates, to prepare a "Research and Analysis Plan" and Part I of the Assistant Secretary's Summary.[599] The Preliminary Teams always include a technical person from the Health or Safety Directorate, a regulatory analyst from the Policy Directorate, and an attorney from the Solicitor's Office.[600]

The Research and Analysis Plan is "an outline of the facts to be documented and analyses to be made to justify a standard."[601] It is meant to be broad and tentative and should "be based on available or easily attainable information and an outline of the factual bases and issues which need to be addressed.[602] The Plan must conform to the following outline:

I. Significance of Risk
   A. Summary of Risks to be Addressed
   B. Relation to Subpart, if any, or to Existing Standard.
   C. Nature of Risk
   D. Definition and Scope: Risk Situation to be Covered.
   E. Comparison with other Risks
   F. Description of Possible Risk Documentation[603]

II. Economic and Technical Profiles
   A. Impact on Industries and Jobs

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599 OSHA Instruction RUL.1 supra note 586, at III-4, III-8.

600 Beliles Interview, supra note 593; Gass Interview, supra note 596; Golden and Braslow Interview, supra note 578.

601 OSHA Instruction RUL.1, supra note 586, at V-7.

602 OSHA Instruction RUL.1, supra note 586, at V-7.

603 The description must identify probable sources of data and methods for documenting risks. It must include an assessment of the expected confidence level in the data.

B. Influences on Risks[604]
C. Other Existing or Potential Federal, State, Local, and Private Efforts to Reduce the Risks.

III. Alternative Strategies
A. Program Choices
1. Under the Occupational Safety and Health Act[605]
2. Other Programs -- Other Federal Agencies, State and Local Governments, Private Programs
B. Regulatory Method Choices
1. Performance or Design Standards
2. Personal Protection Equipment or Engineering Controls
3. Tiering or Phasing Regulations
4. Innovative Techniques to Reduce Compliance Costs or Improve Risk Reductions
5. Nonregulatory Guidelines in Conjunction with Performance Standards
C. Probable Components of the Standard

IV. Preliminary Listing of Factual, Legal and Policy Issues.[606]

The Preliminary Team must also prepare Part I of the Assistant Secretary's Summary. The Assistant Secretary's Summary is a document that is intended to provide the Assistant Secretary with a concise summary of the crucial information and issues being developed in the rulemaking process. Part I of the Summary must adhere to the following outline:

I. Identification
A. Title
B. Purpose and Summary Description
C. Authority

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604 This section must describe why the risk exists and identify the factors that influence risk and describe how they affect it. Suggested factors include poor equipment, inadequate training, carelessness, lack of administrative controls, lack of information on risk, failure to use equipment properly, inadequate substitute materials, lack of capital, and competitive disadvantages that would result from risk reduction.

605 The Plan must consider regulatory choices such as health and safety standards and nonregulatory choices such as education and training, voluntary protection programs, variances and information disclosure.

606 OSHA Instruction RUL.1, supra note 586, at V-8 through V-11.

II. Justification for Action

III. Key Issues to be Addressed

IV. Possible Agency Actions and Alternatives
  A. Possible Actions
  B. Alternatives

V. Background

VI. Groups with Significant Interests
  A. Government
  B. Private[607]

The Preliminary Team usually consults a variety of sources of information for the factual determinations that make up the Research and Analysis Plan, including the document prepared by the National Institute of Occupational Safety and Health, the regulated industry the general toxicology literature, and personnel in other agencies.[608] In addition, the agency sometimes publishes a "Request for Information" in the Federal Register to solicit information on a potential occupational health or safety risk from the general public.[609] In many cases, however, the data sources available to the Preliminary Team on relatively short notice are not very comprehensive, and the Team must make do with what is available.[610]

The time frame for this apparently ambitious effort is not clear. The agency's Rulemaking Directive says that "[a] Research and Analysis Plan should require 5 to 10 staff days to prepare."[611] This estimate is

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607 OSHA Instruction RUL.1, supra note 586, at V-2 through V-3.

608 Strobel Interview, supra note 595.

609 Strobel Interview, supra note 595.

610 Beliles Interview, supra note 593.

611 OSHA Instruction RUL.1, supra note 586, at V-7.

obviously unrealistically short, given the substantial requirements for the contents of the Plan. As a practical matter, the Preliminary Team does not draft the Plan with anything approaching the detail that the agency rulemaking directive suggests.[612] Instead, the Preliminary Team generally uses the Research and Analysis Plan as an opportunity to identify the data and analyses that the agency will need to support a proposed rule.[613] At this stage, it is largely the work of the Health or Safety Directorate.[614] On average, this effort takes approximately two months.[615]

The Preliminary Team meetings also present an opportunity for the technical staff in the Health and Safety Directorates to interact with regulatory analysts from the Policy Directorate and explore various regulatory options to reduce the risk that the technical staff have identified. While the Team does not undertake extensive efforts to identify options this early in the process,[616] the regulatory analysts have on occasion made some useful suggestions at this point.[617] The Preliminary Team meeting is also an appropriate place for one of the team members to

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612 Beliles Interview, supra note 593.

613 Beliles Interview, supra note 593; Goldin and Braslow Interview, supra note 578.

614 Goldin and Braslow Interview, supra note 578.

615 Beliles Interview, supra note 593.

616 The Policy Directorate believes that there is very little need for its input until the Health or Safety Directorate has identified a concrete proposal for the regulatory analysts to identify. The regulatory analysts at the very least need some idea of the industries that the rule is likely to affect [Goldin and Braslow Interview, supra note 578].

617 Beliles Interview, supra note 593.

suggest that the agency should not go forward with the rulemaking effort, but this has not happened in practice.[618]

After the Preliminary Team has completed the Research and Analysis Plan and Part I of the Assistant Secretary's Summary, it must present them for approval to the Regulation Review Committee. The Committee examines the Plan and occasionally requests revisions before it goes forward to the Assistant Secretary for approval.[619] Since all of the members of the Preliminary Team have a management-level counterpart on the Regulation Review Committee, this meeting is also a place to resolve any disputes that have arisen in the very early stages of the standard-setting process.[620] It is very rare, however, that any significant disputes arise this early in the process. While the Regulation Review Committee meeting is also an appropriate place for any of the high level members of that Committee to suggest alternative approaches to the Preliminary Team, this rarely happens.[621] The Committee has never disapproved a Research and Analysis Plan.[622]

The final task of the Preliminary Team is to prepare the Concept Analysis Paper, which is required for Departmental review of OSHA regulations.[623] The Concept Analysis Paper, which is much less

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618 Goldin and Braslow Interview, supra note 578.

619 Strobel Interview, supra note 595; Goldin and Braslow Interview, supra note 578.

620 Strobel Interview, supra note 595.

621 Beliles Interview, supra note 593.

622 Beliles Interview, supra note 593; Strobel Interview, supra note 595.

623 See text accompanying notes 583-85, supra.

comprehensive than the Research and Analysis Plan, is an informational device to let Departmental decisionmakers know of the agency's determination to proceed ahead with a rulemaking effort.[624] By the time that the Preliminary Team drafts that document, it usually has some idea of the direction that it wants to take,[625] and it can generally rely upon the information that it compiled for the Research and Analysis Plan.

The Research and Analysis Plan, Part I of the Assistant Secretary's Summary, and the Concept Analysis Plan, are then forwarded to the Assistant Secretary, along with the Committee's recommendations, for a determination whether to proceed further with the rulemaking effort. If he or she approves the Plan, the Assistant Secretary will forward the Concept Analysis Paper to the Departmental Policy Review and Coordinating Committee for review.[626] The Policy Review and Coordinating Committee does not engage in substantive debates about the Concept Analysis Papers, and it never disapproves them.[627]

In the view of at least two employees who work on the agency's rulemaking efforts on a day-to-day basis, all of the foregoing preliminary procedures are largely "irrelevancies."[628] In their opinion, if the institutional actors religiously adhered to all of the procedures dictated by the agency's procedural directive, the rulemaking process would become

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624 Goldin and Braslow Interview, supra note 578.

625 Beliles Interview, supra note 593.

626 See notes 580-82, and accompanying text.

627 Beliles Interview, supra note 593; Strobel Interview, supra note 595.

628 The employees quoted here requested that their comments on this question remain anonymous.

totally unworkable. While the procedural directive outlines a good theoretical process, in practice the agency usually faces pressure to act expeditiously. The Regulation Review Committee is often bypassed as the Assistant Secretary directly orders the Directors of the Directorates to begin the rulemaking process. The Research and Analysis Plan, the Assistant Secretary's Summaries and the Concept Analysis Papers are either ignored or treated in a very cursory fashion, and the Preliminary Team may in fact never be appointed. High level input is secured through informal meetings with the Assistant Secretary for which the members of the team prepare memoranda and perhaps a chart to lay out the issues and options. The Assistant Secretary often decides the important issues on the spot. In the opinion of these officials, this informal route is the only way to avoid "total paralysis for the agency."

Interviews with other officials in the agency tended to confirm this less formal version of the decisionmaking process. For example, the Director of the Policy Directorate was unaware of any distinction between the "Preliminary Team" and the "Regulation Team."[629] On the other hand, few new rulemaking efforts have been initiated during two years in which the formal process has been in place. The designers of the new rulemaking management system expected that some of the formal procedures might be bypassed in cases of severe time constraints. They expected, however, that after the procedures had been in place for a time, the more organized system for setting priorities would help ensure adequate time to follow all of the procedures. It may be that the more formal approach envisioned in the

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629 Goldin and Braslow Interview, supra note 578 (Goldin).

agency's procedural directive will more accurately describe the agency's decisionmaking process in the future. It is also possible that the formal approach generally prevails for less important rules for which the agency faces little pressure for immediate action, whereas the less formal approach is necessary for rulemaking efforts requiring expedition.

iii. The Regulation Team, the Workplan, and the Threshold Determination.

If the Assistant Secretary decides to pursue the rulemaking effort further, the Regulation Review Committee must assemble a "Regulation Team" to complete the agency's standard-setting process. The Regulation Team is directed by a team leader, who is a staff member from either the Health or Safety Directorate.[630] The team leaders can come from any of the Offices within a given Directorate.[631] The remainder of the Regulation Team is composed of representatives from the Solicitor of Labor, the Policy Directorate, the Office of Regulatory Analysis in the Policy Directorate, the Technical Directorate, the Training Directorate, and the Information Office.[632]

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630 OSHA Instruction RUL.1, supra note 586, at III-4.

631 The Offices in the Health Directorate are arranged functionally into the Office of Risk Assessment, the Office of Risk Reduction Technology, the Office of Standards Analysis and Promulgation, and the Office of Standards Review. Although it appears at first glance that the Office of Standards Analysis and Promulgation should be the functional home for the Standards Directors from the Health Directorate, this is not the case. Many Standards Directors come from that office, but the other Offices also supply Standards Directors.

632 OSHA Instruction RUL.1, supra note 586, at V-6.

Although the team leader is responsible for guiding the rule through the rulemaking effort, he or she does not have direct authority over any of the individual team members.[633] Indeed it is not unusual for one of the members of a team to outrank the team leader in the bureaucratic hierarchy.[634] Thus, while the team leader gives assignments to various team members at various times, he or she has no authority to ensure that the assignments are completed on time. The team leader must therefore depend heavily upon the commonality of interest that the team has in producing a high quality product. Some team leaders have training in "conflict management."[635] While the way in which a team leader goes about producing a final product through the team mechanism is very much a matter of personal style, most team leaders attempt to guide their teams to a consensus and to avoid unnecessary conflicts.[636]

The first task of the Regulation Team is to prepare a "Workplan" and Part II of the Assistant Secretary's Summary. The Workplan must describe the resources that will be required to complete the rulemaking project and provide a schedule of activities. It can be amended as resource requirements and deadlines change. The Workplan is not an important substantive document, but it is an important managerial document, because it commits the Regulation Team to a definite schedule against which upper level

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633 Gass Interview I, supra note 596.

634 Gass Interview I, supra note 596.

635 Gass Interview I, supra note 596.

636 Gass Interview I, supra note 596.

management can measure its progress. The Workplan is also the point at which the Directorates make initial resource commitments to a given rulemaking effort. Since the Workplan commits the time and resources of all of the Directorates represented on the team, they all play a role in drafting that document.[637]

One of the functions of the Workplan is to address the threshold question whether the agency must prepare an RIA or RFA for the rule at issue.[638] As a practical matter, it is rare that sufficient information on the costs of the possible alternatives for the proposed rule is available at this early stage in the process to make an accurate threshold determination.[639] In addition, the scope of a regulation can be adjusted and readjusted several times before the Regulation Team settles in on a preferred option, and each change can upset the Team's threshold calculations.[640] Rather than expend many of resources on the threshold question at this stage in the rulemaking process, the members of the Regulation Team normally presume that a rule is major until it becomes clear later on that it is not.[641] As more economic impact information becomes available to the Regulation Team, it gets a "feel" for whether or not the rule will be major, and it makes a more definite determination at that

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637 Beliles Interview, supra note 593; Goldin and Braslow Interview, supra note 578.

638 OSHA Instruction RUL.1, supra note 586, at V-5.

639 Goldin and Braslow Interview, supra note 578.

640 Goldin and Braslow Interview, supra note 578.

641 Beliles Interview, supra note 593.

point.[642] In reality, the threshold determination is of minor consequence to the regulatory analysts from the Office of Regulatory Analysis. Since all proposed OSHA rules are subject to OMB scrutiny,[643] the agency feels obliged to prepare a comprehensive analytical document for all rules, whether or not they are designated "major" under Executive Order 12291.[644]

After the Regulation Team has drafted the Workplan, it submits it to the Regulation Review Committee and the Assistant Secretary for review.[645] The Regulation Review Committee and the Assistant Secretary usually have very little to add to the Workplan. Occasionally, however, the Regulation Review Committee, which has an agency-wide perspective on all of the rulemaking efforts in the agency, will "remand" a Workplan to amend the schedule to avoid foreseeable conflicting claims on the agency's resources.[646]

2. The Proposed Rule and Preliminary Regulatory Analysis Document.

a. Departmental Procedures.

Departmental procedures do not specify how an agency must go about gathering data, assessing risks, identifying regulatory options, and

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642 Goldin and Braslow Interview, supra note 578; Beliles Interview, supra note 593.

643 See text accompanying notes 715-729, infra.

644 Beliles Interview, supra note 593; Gass Interview I, supra note 596; Goldin and Braslow Interview, supra note 578; Weber Interview, supra note 579.

645 OSHA Instruction RUL.1, supra note 586, at III-10.

646 Strobel Interview, supra note 595.

otherwise determining how it will address particular regulatory problems. These matters are left up to the individual agencies. The procedures do require, however, that once an agency has determined that there is a need for regulation and has identified specific alternatives for responding to the need, it must prepare an "Options Memorandum" for the Policy Review and Coordination Committee prior to publishing a Notice of Proposed Rulemaking. The Options Memorandum must contain a discussion of:

1. The program and/or statute providing authority for the regulatory action which would be taken.
2. The issue or problem to which the proposed regulatory action pertains.
3. The action which the Agency recommends.
4. The significance or importance of the proposed action, together with summarized information or reasoning supporting this conclusion.
5. The policy reasons for the implementation of the proposed action.
6. The alternatives to the proposed action, including a comparison of the anticipated costs (to the Department and to the relevant industry) and effects of all feasible alternatives. Any alternatives proposed by outside groups such as organized labor, members of Congress or affected industry groups should be described in the list of alternatives along with their estimated costs. The Agency should state its rationale for adopting the proposed course of action.
7. The groups or constituencies outside the government which are expected to have a strong interest in the proposed action, together with their expressed views, if known, and an indication of the degree to which each group has been consulted formally or informally concerning the proposed action. Any known Congressional interest or activity relating to the proposal should be noted.
8. The other agencies or departments (and the responsible individual, if known) within the Executive Branch which will be affected by, or are likely to be interested in, the proposed action, together with a notation of whether such entities have been consulted concerning the formulation of the proposed action or apprised that action is under consideration within the Department.
9. The timetable for completing the proposed action.
10. A summary chronology of previous action on the proposal.
11. Whether the regulatory proposal qualifies as a major rule under Executive Order 12291, thus requiring an Economic Impact Analysis. In addition, the Agency should also indicate whether the regulation is subject to the Regulatory Flexibility Act and the effects of the Paperwork Reduction Act, if any, on this proposal.[647]

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647 Departmental Procedures Memo, supra note 583, at 3-4.

A second memorandum from the Executive Director of the Policy Review and Coordination Committee requires the Options Memorandum to include the following (somewhat duplicative) information:

> (a) An assessment of whether a regulatory analysis and/or regulatory flexibility analysis is required and, if not, specific reasons as to why not.
> (b) An indication of whether the regulation requires any data collection, and, if so, how the information will be processed and used.
> (c) A discussion of interested parties and their likely reactions, including the Congress and interest groups such as organized labor and the business community. If any contacts have been made, a summary of the discussions should be included.
> (d) A proposed public relations plan. This is particularly important if the regulation is likely to be controversial and should include how and by whom the public relations aspect should be addressed.[648]

Options Memoranda must be prepared for all agency rules with the exception of housekeeping proposals, technical modifications to existing rules, and emergency actions.[649]

The Office of the Assistant Secretary for Policy reviews the Options Memorandum for completeness and policy content, and the Office of the Solicitor reviews it for legal sufficiency.[650] The issues are then scheduled for discussion at the next meeting of the Policy Review and Coordination Committee.[651] Only after the Policy Review and Coordination

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648 PRCC Procedures Memo, supra note 580, at 2.

649 Departmental Procedures Memo, supra note 583, at 4.

650 PRCC Procedures, supra note 580, at 1.

651 PRCC Procedures, supra note 580, at 1.

Committee has supplied its policy guidance may the agency proceed ahead to prepare the Notice of Proposed rulemaking.[652]

b. The Occupational Safety and Health Administration.

i. The Risk Analysis, the Alternatives Analysis, and the Action Recommendation.

(I) The Risk Analysis.

After the Regulation Review Committee and the Assistant Secretary approve the Workplan and Part II of the Assistant Secretary's Summary, the Regulation Team begins its primary task of assessing the risks posed by the workplaces or work practices at issue and analyzing the available regulatory alternatives for addressing those risks. The Regulation Team must always undertake a risk analysis and an alternatives analysis, but they need not be reduced to writing unless requested by the Assistant Secretary. According to the agency's procedural directive, the "Risk Analysis" consists of the following steps:

(a) Document significance of risk and, if requested, prepare paper for approval;
(b) Research industry background and, if requested, prepare paper for approval;
(c) Identify risk situations and, if requested, prepare paper for approval; and,
(d) Prepare Risk Analysis based on (a)-(c) and, if requested, prepare paper for approval.[653]

The leader of the Regulation Team often assigns a team member the task

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652 PRCC Procedures, supra note 580, at 2.

653 OSHA Instruction RUL.1, supra note 586, at III-12.

of preparing a written risk analysis. For health standards, this task is usually assigned to the Office of Risk Assessment in the Directorate of Health Standards Programs.[654] The Policy Directorate can also play a role in drafting the Risk Assessment by identifying the affected industries for the "industry background" section of the analysis.[655] The Policy Directorate also plays a role in risk assessments for safety standards by working with the Safety Directorate to develop risk estimates and to evaluate the statistical validity of conclusions drawn from accident data.[656] In many cases, the Health or Safety Standards Directorate has already performed a rudimentary risk assessment to make the "significant risk" determination that is a precondition to going forward to the Regulation Team with an initial proposal for a rulemaking action.[657] If a risk analysis does not already exist, the Regulation Team will usually assign a member the responsibility of drafting an analysis based upon the information that is then available. As more information becomes available to the agency, the analysis is redrafted to reflect newly discovered facts.

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654 The functional distinction between the Office of Risk Assessment and the other Offices in the Directorate of Health Standards Programs has not been fully realized since the recent reorganization that created the distinctions. Therefore, while the Office of Risk Assessment is the logical office to do all risk assessments for health standards, it is not in fact assigned the task of drafting all of those documents. Beliles Interview, supra note 593.

655 This section is intended only to ensure that the subject matter of the anticipated rule will be within OSHA's jurisdiction [Goldin and Braslow Interview, supra note 578].

656 Goldin and Braslow Interview, supra note 578.

657 Beliles Interview, supra note 593.

The agency may not adopt a final risk analysis until it promulgates its final rule.[658]

(II). The Alternatives Analysis.

According to the agency Procedural Directive, the "Alternatives Analysis" must follow the following steps:

> (a) Determine feasible alternatives and, if requested, prepare paper for approval;
> (b) Analyze cost-effectiveness of alternatives and, if requested, prepare paper for approval; and,
> (c) Prepare Alternatives Analysis based on (a) and (b) and, if requested, prepare paper for approval.[659]

The Alternatives Analysis provides the framework for the alternatives that the regulatory analysis documents analyze.[660] The Alternatives Analysis reflects one of the most significant changes in OSHA internal decisionmaking procedure following Executive Order 12291 -- viz. the staff now analyzes alternatives in detail before settling in on a favored alternative, rather than after the fact.[661]

The Policy Directorate and the Health and Safety Standards Directorates have the primary input into the Alternatives Analysis. If the team decides to commit the analysis to writing, the representative to the Regulation Team from the Regulatory Analysis office in the Policy Directorate is normally

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658 Beliles Interview, supra note 593.

659 OSHA Instruction RUL.1, supra note 586, at III-12 through III-13.

660 Goldin and Braslow Interview, supra note 578.

661 Weber Interview, supra note 579.

assigned the responsibility of drafting it.[662] Most members of the team suggest alternative regulatory provisions. The team accepts some alternatives and rejects others.

Generally the Health or Safety Standards Directorate will have some alternatives in mind prior to the first Regulation Team meeting.[663] Since health standards may only be set at a level that is "feasible" for the regulatees,[664] a good part of the alternatives analysis is devoted to locating feasible technologies.[665] Soon after the Research and Analysis Plan is approved, the Health or Safety Directorate and the Office of Regulatory Analysis in the Policy Directorate hire contractors to survey the relevant industry or industries, create an industry profile, and identify a range of feasible engineering controls.[666]

The data-gathering efforts often identify workplaces where exposure to the risk is much lower than in other workplaces. The technologies that produce this result are often feasible in other workplaces.[667] The industry survey may reveal that some exemplary employers have installed controls that are much more effective in protecting workers than controls in other (possibly competing) plants. In addition, controls may be available

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662 Beliles Interview, supra note 593.

663 Goldin and Braslow, supra note 578.

664 Occupational Safety and Health Act of 1970 § 6(b), 29 U.S.C. § 655(b) (1982).

665 In theory, safety standards are not subject to a feasibility test, but the agency also applies a feasibility limitation to safety standards.

666 Beliles Interview, supra note 593; Goldin and Braslow Comments, supra note 591.

667 Beliles Interview, supra note 593.

in other industries with similar health or safety problems. All of the technologies that the contractors identify are potential alternatives for regulatory requirements. The Office of Risk Reduction Technology in the Health Standards Directorate has expertise in assessing the feasibility of various risk reduction technologies. The team can call on this Office for aid if it is not already represented on the team.[668]

The Work Group also seeks out alternatives to engineering controls, such as warnings, medical monitoring and screening, respirators, and work practice changes. The regulatory analyst from the Office of Regulatory Analysis will also attempt to identify market-oriented alternatives that offer more flexibility to regulatees. Some regulatory analysts have a general preference for performance standards over specification standards.[669] For example, when the team working on the rule for field sanitation for farm workers considered a regulation requiring employers to make drinking water available to field workers, the team considered specifying that the drinking water be kept at a particular temperature. The regulatory analyst from the Office of Regulatory Analysis suggested instead that the regulation require only that drinking water be kept "suitably cool."[670] According to the Director of the Policy Directorate, the

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668 Telephone Interview with Mr. Favez Hanna, Director, Office of Risk Reduction Technology, Directorate of Health Standards Programs, Occupational Safety and Health Administration, DOL, July 19, 1984 [hereinafter cited as Hanna Interview].

669 Gass Interview I, supra note 596. Most personnel in the field coordination office and most inspectors, on the other hand, have a general preference for specification standards, because they are easier to enforce. Telephone Interview with Mr. Arthur Gass, Office
(Continued on page 219)

670 Gass Interview I, supra note 596.

economists in OSHA generally favor market-oriented solutions to regulatory problems.[671]

It is unclear how important the regulatory analysts' options-identifying function is to the actual decisionmaking process. The staff personnel from the Health and Safety Directorates generally characterized the role of the regulatory analysts on their teams as that of information provider rather than options identifier. Most believed that the regulatory analysts usually limited their contributions to "costing out" options that others with technical training had already identified.[672] The Director of the Policy Directorate, however, feels that their market-oriented contributions have significantly enhanced the quality of agency decisions. He points out that economists from his office have suggested alternative provisions for many standards that have been adopted on numerous occasions, once team members were convinced of their cost-effectiveness.[673]

When asked to recall specific options that the regulatory analysts identified in particular rulemaking proceedings, the regulatory analysts and

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(Continued from page 218)

669 of Risk Reduction Technology, Directorate of Health Standards Programs, Occupational Safety and Health Administration, DOL, September 17, 1984 [hereinafter cited as Gass Interview II].

671 Goldin and Braslow Interview, supra note 578 (Goldin).

672 Telephone Interview with Ms. Jennifer Silk, Directorate of Health Standards Programs, Occupational Safety and Health Administration, DOL, April 30, 1984 [hereinafter cited as Silk Interview]; Belilles Interview, supra note 593; Gass Interview I, supra note 596.

673 Goldin and Braslow Interview, supra note 578; Goldin and Braslow Comments, supra note 591.

the program office technical staff could think of a few examples.[674] The most prominent example is the Hazard Identification Standard in which OSHA policy analysts in the Office of Regulatory Analysis played a major role in identifying the ten regulatory options listed in the lengthy RIA that the office prepared to accompany that major rulemaking effort. This general failure of agency personnel to recall many instances in which policy analysts have identified innovative options should not, however, lead too rapidly to the conclusion that regulatory analysts in the agency do not play a strong options-identification role. It may mean only that the regulatory analysts are so thoroughly integrated into the Rulemaking Team that it is impossible for any team member to remember who suggested what options. Still, it does suggest that the regulatory analysts do not arrive at strikingly different options that the other members of the Work Group.

The agency's regulatory analysts do, however, act as strong advocates for the options that they perceive to be "cost-effective." The regulatory analysts on the teams attempt to convince other team members to adopt cost-effective alternatives. When they fail to convince team members, the Director of Policy has elevated the matter to the Regulatory Management

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674 Telephone Interview with Ms. Nancy Wentzler, formerly Office of Regulatory Analysis, Directorate of Policy, Occupational Safety and Health Administration, DOL, April 18, 1984 [hereinafter cited as Wentzler Interview]; Silk Interview, supra note 673; Belilles Interview, supra note 593. The only innovative option that an interviewee could call to mind was a "performance oriented" standard for cooling water. However, even in this case, the regulatory analysts were not the strongest proponents of the performance standard on the Work Group, and on the whole the regulatory analysts did not play a very strong role in the Team's deliberations. Gass Interview I, supra note 596.

Committee and even directly to the Assistant Secretary. In the view of the Director of Policy, these efforts are usually successful.[675]

As the contractors working for the Health or Safety Standards Directorate begin to identify feasible control technologies, and as the Regulation Team begins to suggest other regulatory alternatives, the representative from the office of Regulatory Analysis is assigned the job of "costing out" the alternatives. This information provision function was by far the most prominently cited role of the regulatory analysts in OSHA.[676] The Office of Regulatory Analysis generally hires a contractor to aid in this effort.[677] Although the Office generally lacks the resources to calculate the costs of every regulatory alternative, it attempts to cost out as many as possible. This aspect of the Alternatives Analysis is entirely the domain of the Office of Regulatory Analysis.[678]

As the Office of Regulatory Analysis compiles the contractors' reports and calculates the economic impact of the cost projections, it makes these analyses available to the Regulation Team.[679] The preliminary economic impact information is thus available to influence the Regulation Team's

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675 Goldin and Braslow Comments, supra note 591.

676 Gass Interview I, supra note 596; Silk Interview, supra note 673; Beliles Interview, supra note 593; Hanna Interview, supra note 668; Weber Interview, supra note 579.

677 Goldin and Braslow Interview, supra note 578; Wentzler Interview, supra note 674.

678 Goldin and Braslow Interview, supra note 578.

679 Goldin and Braslow Interview, supra note 578.

deliberations long before the Office of Regulatory Analysis has completed the Preliminary Regulatory Impact Analysis.[680]

The regulatory analysts from the Office of Regulatory Analysis and the industrial hygenists and engineers from the Health and Safety Standards Directorates interact frequently during this time of intense analytical effort. Meetings occur on a weekly or even daily basis as the Regulation Team attempts to sort all the feasible alternatives and select the best option.[681] The aim of the Team is to achieve a consensus on the alternatives to be considered and, as the deliberations progress, on the option that the group will recommend to the Assistant Secretary.[682] Although each member of the Team has a special area of expertise, every member reads and has an opportunity to comment upon the work of every other member. In this way the rule can be crafted in an interdisciplinary fashion.[683]

The economic impact analyses that the Team's regulatory analyst prepares can have an important impact on the Team's choice of options. If a particular option "costs out" as being very expensive compared to a slightly

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680 Goldin and Braslow Interview, supra note 578; Gass Interview I, supra note 596.

681 Gass Interview I, supra note 596; Silk Interview, supra note 673.

682 Gass Interview I, supra note 596; Belliles Interview, supra note 593; Wentzler Interview, supra note 674.

683 Silk Interview, supra note 673; Gass Interview I, supra note 596. In response to questions from a congressional committee, OSHA stated that "standards are developed by a team that makes no effort to separate regulatory analysis functions from other standards-development activities." Hall Hearings, supra note 17, at 4, n.1.

less protective rule, the Team may elect to recommend the less expensive option, even though both are technologically feasible.

Not surprisingly, disputes occasionally arise during the Regulation Team's deliberations. For example, disputes can arise between the industrial hygienists and the regulatory analysts over the effectiveness of engineering controls versus worker education for protecting worker health,[684] or over performance-oriented versus specific standards. In most cases, the Team members can resolve disputes through negotiation and compromise.[685] The Team leader, however, is ultimately responsible for the rulemaking effort, and his resolution of the dispute will prevail if no one seeks to raise the dispute to a higher level. The Team leader's resolution of a disputed issue, however, need not be his or her own personal resolution of that issue. At least one Team leader takes votes on disputed issues and generally allows the majority view to prevail.[686] Any member of the Team may orally or by written memorandum "appeal" any Team decision.[687] The first "appeal" is to the Director of the Health or Safety Standards Directorate.[688] If his or her resolution of the matter does note satisfy the disputants, they can seek a meeting with the Assistant Secretary. These appeals to the Directors and the Assistant Secretary are

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684 Gass Interview I, supra note 596.

685 Beliles Interview, supra note 593; Gass Interview I, supra note 596; Goldin and Braslow Interview, supra note 578.

686 Gass Interview I, supra note 596.

687 Gass Interview I, supra note 596; Goldin and Braslow Interview, supra note 578.

688 Beliles Interview, supra note 593; Goldin and Braslow Interview, supra note 578.

taken on an ad hoc basis, and they can occur occasionally in the evolution of an important rule.[689]

(III). The Action Recommendation.

Whether or not the Regulation Team drafts separate risk and alternatives documents, it must summarize the contents of the Risk Analysis and Alternative Analysis in an Action Recommendation for the Regulation Review Committee and the Assistant Secretary.[690] The Action Recommendation is a key document in the OSHA decisionmaking process; it is intended to be the primary decision document within the agency.[691] The Recommendation is intended to be comprehensive, but it should not be so lengthy that it cannot be assimilated by busy decisionmakers. The typical Action Recommendation is approximately 20 pages long, although some can be considerably longer than that.[692] The Action Recommendation summarizes the regulatory issues and the alternative approaches to resolving those issues. For health standards, for example, the Action Recommendation summarizes the health effects of the toxic substance at issue, the extend of exposure, the technologies available to reduce exposure, the cost and economic impacts of those technologies, and alternative devices for reducing exposure such as worker education and respirators.[693] It also contains

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689 Gass Interview I, supra note 596.

690 If necessary, a revised Workplan must also be submitted and approved [OSHA Instruction RUL.1, supra note 586, at III-13].

691 Strobel Interview, supra note 595.

692 Strobel Interview, supra note 595.

693 Goldin and Braslow Interview, supra note 578.

the Regulation Team's initial recommendation of which alternative the agency should adopt.[694]

Before the Assistant Secretary reads the Action Recommendation, the Regulation Review Committee reads and discusses the document. Since most of the institutional entities that are represented on the Regulation Review Committee have a representative on the team, the meeting of the Committee to discuss the Action Recommendation for a particular rule could be a vehicle for resolving intra-agency disputes about the rule that resulted from the Team's deliberations. The Committee, however, apparently is not an intra-agency appellate body in this sense. As we have seen, unresolvable disputes on the teams are elevated through the management hierarchy to the Assistant Secretary on an ad hoc basis as they arise. The role of the Committee appears to be limited to reviewing the Action Recommendation and suggesting changes. In the view of at least one mid-level official in the Health Standards Directorate, the Committee's comments are usually uninformed and not especially helpful.[695]

ii. The First Options Memorandum.

At the same time that it is drafting the Action Recommendation, the team must draw upon the Risk Analysis and the Alternatives Analysis to prepare an Options Memorandum for Departmental review. Since the contents of the Options Memorandum, which have already been detailed,[696] are almost

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694 Beiiles Interview, supra note 593.

695 See, note 628, supra.

696 See, text accompanying note 647, supra.

identical to the contents of the Action Recommendation, this task is not especially burdensome. Like the Action Recommendation, the Options Memorandum must be reviewed by the Regulation Review Committee and approved by the Assistant Secretary.[697]

The Policy Review Coordinating Committee must review the Options Memorandum and determine whether the rulemaking effort should go forward as the agency proposed. The meeting on the Options Memorandum is the point at which the upper level Departmental officials have an opportunity to interject broad Departmental policy considerations into the internal decisionmaking process. By this time, however, the agency has achieved consensus on the technical and policy issues that the rulemaking effort raised, and the agency staff is not inclined to make changes without compelling reasons. Any significant demands from members of the Policy Review Coordinating Committee that the agency consider new options or undertake additional analysis would require a rescheduling of the entire effort. In practice, a staff attorney from the Departmental Office of the Solicitor attempts to keep track of all rules as they evolve in the agencies within the Department, and he or she can become involved in the agencies' internal deliberations for important rule.[698] The agency staff can thereby acquire a feel for the direction that the Departmental decisionmakers are likely to take on particular issues in the rulemaking

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697 OSHA Instruction RUL.1, supra note 586, at III-13.

698 Telephone Interview with Ms. Dianne Burkley, formerly Special Assistant to the Solicitor for Regulatory Affairs, Office of the Solicitor, DOL, May 19, 1983.

effort, and the agency consensus usually reflects earlier informal Departmental input.

In many cases, the Policy Review Coordinating Committee meeting is largely informational at this point. The Secretary and the other members of the committee do not often attempt to second guess the agency on technical questions; they do not suggest additional options for the agency to consider at this late date; and they rarely disagree with the agency's proposed choice from among the available options. Usually, the upper level Departmental decisionmakers simply want to be informed of the options that the agency considered and the ones that it chose so that they can be prepared to answer any questions that might arise about the proposal.

In other cases, however, the Assistant Secretary for Policy raises economic issues for the Committee's consideration. Several proposed standards have had to be reexamined as a result of Policy Review Coordinating Committee Meetings in order to gain the support of the Assistant Secretary. In some cases the agency responded by providing additional analysis. In others, the agency altered the proposed regulatory provisions.[699]

iii. The Notice of Proposed Rulemaking.

If the Regulation Review Committee and the Assistant Secretary approve the Action Recommendation and if the Policy Review Coordinating Committee approves the Options Memorandum, the Regulation Team must proceed in accordance with the (possibly amended) Workplan to draft the Notice of

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699 Goldin and Braslow Comments, supra note 591.

Proposed Rulemaking under the direction of the relevant Standards Director. By this time most of the Regulation Team's preliminary analytical work has been accomplished, and the team leader must assign to a member or members of the Team the task of incorporating all of the information that the Team has considered into a Preamble for the Notice of Proposed Rulemaking. How the task of drafting the Notice of Proposed Rulemaking is assigned varies from team to team. Sometimes the team leader will draft the Notice, and sometimes he or she will divide up the task among members with expertise in the particular areas that the rule addresses.[700] The Regulation Team then submits its draft for review to OSHA technical experts, the Office of Information and Consumer Affairs, the Standards Director, State Programs, and external technical commentors before it is submitted to the Regulation Review Committee and the Assistant Secretary for final approval.[701]

iv. The Preliminary Regulatory Analysis Document.

During the same time period that the Regulation Team is deliberating over the contents of the proposed rule, the representative to the Team from the Office of Regulatory Analysis in the Policy Directorate must draft the preliminary regulatory analysis documents.[702] The OSHA procedural directive does not elaborate on the content of the regulatory analysis documents; nor does it suggest the source of information for preparing the documents. The directive further fails to specify how the Regulation Team

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700 Beliles Interview, supra note 593.

701 OSHA Instruction RUL.1, supra note 586, at III-14.

702 Beliles Interview, supra note 593.

should use the regulatory analysis document or its contents. The directive apparently envisions that the regulatory analysis documents will be completed at about the same time as the Notice of Proposed Rulemaking.

The Office of Regulatory Analysis begins to think about the contents of the preliminary regulatory analysis document at least as early as the Research and Analysis Plan, when the Office may suggest studies that the agency should undertake to support the future rulemaking effort. In addition, as previously discussed, the Office of Regulatory Analysis commissions and drafts cost and economic impact studies during the Team's deliberations. The regulatory analyst, however, does not begin serious work on the actual regulatory analysis document until after the Team has narrowed down the regulatory options considerably. The Office of Regulatory Analysis does not have sufficient resources to analyze too many marginal options.[703]

The regulatory analyst makes the contractor's reports and the regulatory analyst's analyses available to the Team as soon as they become available. Any member of the Team is free to comment on those documents, but most members of the Team regard economic analysis as the primary domain of the Office of Regulatory Analysis. At the end of the Team's deliberations, after it has narrowed down the regulatory options and has decided upon a preferred option, the regulatory analyst drafts the preliminary regulatory analysis document based upon the contractors'

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703 Goldin and Braslow Interview, supra note 578; Strobel Interview, supra note 595.

reports, any of his or her own analyses, and the comments of Team members.[704]

The preliminary regulatory analysis document is completed at about the same time that the Notice of Proposed Rulemaking is finished. It is generally written to support the option that the Assistant Secretary decided to propose.[705] This does not generally pose any professional difficulties for the analysts, because they are present at the Team meetings in which the options are being debated and selected, and are therefore familiar with the arguments for and against the various options. Given the consensual mode that most team leaders adopt, and given the large uncertainties that usually surround the analysis of the options, the analyst can usually craft an analysis that both supports the proposal and satisfies the analyst's professional integrity.

v. The Draft Preliminary Implementation Plan and the Draft Evaluation Plan.

Before the Team sends its draft Notice of Proposed Rulemaking to the Assistant Secretary for approval, the Team must draft a "Preliminary Implementation Plan" and a "Draft Evaluation Plan."[706] The "Preliminary

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704 Goldin and Braslow Interview, supra note 578. The regulatory analyst can begin drafting the preliminary regulatory analysis document at any time after the Team has narrowed down the options and focused upon a preferred option. Usually, this point in the Team's deliberations is reached just prior to the time that it drafts its Action Recommendation. However, if there is significant doubt about whether the Assistant Secretary will approve the Action Recommendation, the regulatory analyst may wait until after the Assistant Secretary has settled upon a definite option [Strobel Interview, supra note 578].

705 Beliles Interview, supra note 593.

706 OSHA Instruction RUL.1, supra note 586, at III-15.

Implementation Plan" is an outline of how the rule will be implemented in the field. It sets out the Team's thoughts on the timing of the rule's implementation, suggesting "phasing" schedules if appropriate. The Plan also includes proposed instructions to enforcement officials on how the rule will be implemented in the field.[707] This is especially important in the case of "performance standards," which by their nature give a great deal of discretion to the enforcement official.[708]

The "Preliminary Evaluation Plan" is the first step in the reevaluation of the rule that is required at ten year intervals by the Regulatory Flexibility Act. The Plan provides a structured mechanism for retrospective evaluation of the rule that it about to be proposed. Through the Evaluation Plan, the agency can later ascertain whether the rule is having the effect that the agency intended.[709]

vi. The Second Options Memorandum.

The Team must finally draft a second Options Memorandum to accompany the rulemaking package through Departmental Review.[710] Since the Policy Review Coordinating Committee has by now already had an opportunity to examine the rulemaking effort, and since the agency's effort is virtually

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707 Strobel Interview, supra note 595.

708 Strobel Interview, supra note 595. OSHA inspectors desire further guidance on how to enforce performance standards, because they are otherwise not confident of prevailing against employers in proceedings before the Occupational Safety and Health Review Commission. Gass Interview II, supra note 669.

709 Strobel Interview, supra note 595.

710 OSHA Instruction RUL.1, supra note 586, at III-15.

complete, only minor changes to the rulemaking documents are usually necessary at this point. The Notice of Proposed Rulemaking Package and these related documents are then reviewed by the Regulation Review Committee, the Assistant Secretary, the Policy Review and Coordination Committee, and sent to OMB for further review.[711]

3. Interagency Review of Proposed Rules and Preliminary Regulatory Analysis Documents.

a. Departmental Procedures.

The Office of the Solicitor is the official Departmental liaison between agencies within the Department and the Office of Management and Budget for all major rules.[712] The Solicitor's Office plays a largely procedural role in this regard, much like the role played by the Office of General Counsel in the Department of Transportation.[713] Substantive discussions are carried on between the technical personnel and regulatory analysts in the agencies and the desk officers and regulatory analysts in OMB. For those rules for which the regulatory analysts in the Departmental Office of Policy draft regulatory analysis documents, that office is, of course, also included in inter-agency discussions of the contents of those documents.[714]

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711 OSHA Instruction RUL.1, supra note 586, at III-15.

712 Departmental Procedures Memo, supra note 583, at 2.

713 See part III, supra.

714 Connerton Interview, supra note 572.

b. The Occupational Safety and Health Administration.

The acrimonious relationship between OSHA and OMB has been detailed at considerable length in the press,[715] and it has been the subject of Congressional Hearings.[716] This Report will therefore not dwell at length on the many disputes that those two agencies have had with one another. Instead, it will concentrate upon the perceptions that personnel from each agency have of the inter-agency review process that is the procedural vehicle for those disputes.

During the first two years that Executive Order 12291 applied to the OSHA rulemaking process, there was very little communication between OMB and agency personnel at the staff level.[717] Most of the contacts occurred at the Departmental level or at very high levels within OSHA. The only significant contact between OMB and lower level personnel occurred in the Office of Regulatory Analysis, the office that drafts the agency's RIAs. More recently, however, OMB personnel have begun to interact with OSHA staff at all levels.[718] OMB personnel may offer comments and suggestions to individual members of the OSHA team that develops a rule.

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715 See, e.g., Washington Post, Nov. 11, 1984, at A15, col. 3; [Current Reports] O.S.H. Rep. (BNA) 211 (Aug.4, 1983).

716 Office of Management and Budget Control of OSHA Rulemaking: Hearings Before a Subcomm. of the House Comm. on Government Operations, 97th Cong., 2d Sess. (1982).

717 The staff official in the Office of Information and Regulatory Affairs in OMB complained that "the [agency] staff is willing to talk to the press and to the Hill, but not to me." Personal Interview with Mr. John Morrall, Office of Information and Regulatory Affairs, OMB, May 17, 1983 [hereinafter cited as Morrall Interview I].

718 Telephone Interview with Mr. John Morrall, Office of Information and Regulatory Affairs, OMB, September 24, 1984 [hereinafter cited as Morrall Interview II].

OSHA and Departmental employees interviewed in connection with this Report were almost universal in their negative opinions of the quality of OMB review of agency analyses and decisions.[719] The complaints of agency and Departmental officials about the role that OMB plays in agency decisionmaking parallels those of employees in other agencies studied in connection with this Report.[720] Agency employees who expressed a view on the subject generally felt that the regulatory analysts in OMB often attempted to usurp the agency's decisionmaking authority under the guise of reviewing regulatory analysis documents. OMB can, in this view, accomplish this result in a variety of ways including delaying its review of rulemaking proposals, finding gaps in the analysis of the agency's regulatory analysis documents, and remanding the rule to the agency as "inconsistent with the Executive Order." Agency employees and representatives of beneficiary groups have been especially critical of perceived OMB attempts to affect the substance of rules by threatening to delay them indefinitely.[721]

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719 The Director of the Directorate of Policy had kind words for OMB and expressed support for OMB's external review function. In his opinion, the agency has a good relationship with OMB: "We consider them helpful in our process." Goldin and Braslow Interview, supra note 578 (Goldin).

720 Many of the employees interviewed in connection with this Report were unwilling to have their comments regarding OMB review attributed to them. Therefore, the description that follows will for the most part not attribute the observations of agency employees.

721 See, OMB Delay of Grain Elevator Standard Act, Washington Post, November 11, 1984, A15, col. 3; OSHA's Grain Elevator Rule Delayed, Washington Post, August 1, 1983, A12, col. 1; Unneeded OMB Review has Delayed Rule, Migrant Workers' Representatives Charge, BNA Occupational Safety and Health Rpt'r, Current Developments, February 16, 1984, at 993; OMB to Continue 'Extended Review' of OSHA Hearing Conservation Rules, BNA Occupational Safety and Health Rpt'r, Current Developments, November 4, 1982, at 438. See generally, OMB

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Most of the agency employees believed that OMB's input was not normally of high enough quality to be useful to the agency in choosing from among various options. Terms like "terrible" and "off-the-wall" characterized their comments on the quality of OMB review. In one mid-level employee's opinion, "they [OMB personnel] don't know what they are talking about, and they don't care." In addition, there is a belief among some agency employees that OMB's views of agency rulemaking efforts are strongly biased against regulatory solutions to workplace health and safety problems. Finally, some employees feel that OMB personnel do not realize that the agency is acting under statutory constraints that preclude some of the market-oriented solutions that OMB typically suggests.

The staff official in OMB who is responsible for reviewing OSHA rules responds that agency personnel are required to bias the assumptions in the regulatory analysis documents in favor of the regulatory option that the agency management settled upon prior to drafting the document. This bias is particularly strong on the benefits side of the cost-benefit calculus, for which health scientists and other non-economists are primarily responsible.[722] He believes that agencies have a bias in favor of regulatory solutions to societal problems and that they need to be "reigned

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721 Interference with OSHA Rulemaking, Thirtieth Report by the Committee on Government Operations, 98th Cong., 1st Sess. (1983). The former head of OSHA, however, testified that "in all but a few cases OMB review was completed within the time frames set forth in the Executive Order and without creating any significant delay in the rulemaking process. Hearings on H.R. 2327 Before the Subcomm. on Administrative Law and Governmental Relations of the House Comm. on the Judiciary, 98th Cong., 1st Sess. 455 (1983) (testimony of Mr. Thorne Auchter).

722 Morrall Interview II, supra note 718.

in" by some centralized authority.[723] The regulatory analysts in OMB approach regulatory problems from an "efficiency perspective," and tend to be critical of regulations and the documents that support them.[724] Similarly, a former Deputy Administrator for Regulatory and Statistical Analysis in the Office of Information and Regulatory Affairs believes that OMB analysts should advocate elevating efficiency to a higher priority in agencies such as OSHA. He believes that OMB has had only limited success in advancing the cause of efficiency in OSHA.[725]

It is fair to conclude that OMB's review of OSHA regulatory analysis documents during the first two years of the current OMB review process resulted in few important changes in the agency's analysis of the problems that it addressed in its rulemaking proceedings. OMB likewise had limited success in influencing the substantive direction of OSHA rulemaking activities. When the agency decided to "go to the mat" with OMB, it rarely lost a substantive battle. It is quite possible, however, that the prospect of having to do battle with OMB had an in terrorum effect on the staff and regulatory analysts in the agency that moved them in the direction of more thorough analysis and more "efficient" regulatory decisions. The Director of Policy believes that the knowledge that the regulation and its analysis will be carefully scrutinized by OMB has had the effects of intensifying the

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723 Morrall Interview I, supra note 717.

724 Morrall Interview I, supra note 717.

725 Personal Interview with Mr. Thomas Hopkins, Deputy Administrator for Regulatory and Statistical Analysis, Office of Information and Regulatory Affairs, OMB, May 17, 1983 [hereinafter cited as Hopkins Interview].

agency's analytical efforts and of forcing the agency to reconsider rules that are not cost-effective.[726]

In the last two years, it appears that OMB review has had a larger impact on agency decisionmaking. While OMB written submissions are now routinely placed in the rulemaking docket, OMB personnel make oral contact by telephone with agency staff at all levels.[727] While the frequency of major battles between OSHA and OMB varies, there is little doubt that they have induced changes in the substance of proposed rules. The lengthy comments that OMB occasionally submits for the rulemaking records can also have an important impact on the final rules that the agency issues. For example, in one recent rulemaking an OMB submission highly critical of the agency's Preliminary RIA resulted in the agency writing a new contract with another company to work on the Final RIA.[728] In another proceeding, OMB comments on a proposed rule lead the agency to include a new issue in the preamble to that rule and to solicit public comment on that issue.[729] Still, it is unclear how much influence OMB has had on the agency's substantive output.

4. Agency Response to Public Comment.

While OSHA accepts written public comments from anyone during the designated comment period, it usually holds semi-formal hearings where

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726 Goldin and Braslow Comments, supra note 591.

727 Morrall Interview II, supra note 718.

728 Morrall Interview II, supra note 718.

729 Morrall Interview II, supra note 718.

witnesses can testify orally and be cross-examined by counsel for OSHA and other parties. Since technological and economic feasibility are central issues to the validity of most proposed standards, comments routinely address the regulatory analysis documents, which are placed in the docket.[730] The regulatory analysts in the Office of Regulatory Analysis are usually witnesses in the hearings when, as is frequently the case, one of the parties attacks the agency's regulatory analysis. The regulatory analysts must respond to questions about those documents.[731]

The regulatory analysts and some technical staffs in OSHA believe that the regulatory analysis document plays a very valuable role in the comment process by forcing the commenters to respond to explicit quantitative assessments of the risks that the standards address and to the feasible alternatives for reducing those risks.[732] If the regulated industry or other members of the public believe that the agency's quantitative estimates are erroneous, they are obliged to produce better estimates.[733] It also forces the regulatees to suggest reasons why the agency's estimates are erroneous.[734] The net result is that opponents of the rule must bear a greater responsibility for the quality of the agency's final analysis.[735]

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730 Goldin and Braslow Interview, supra note 578.

731 Goldin and Braslow Interview, supra note 578. See, e.g., Further Questioning of Consultants on Economic Analyses Urged by Two Groups,
(Continued on page 239)

732 Goldin and Braslow Interview, supra note 578; Wentzler Interview, supra note 674; Silk Interview, supra note 673.

733 Wentzler Interview, supra note 674.

734 Wentzler Interview, supra note 674.

735 Wentzler Interview, supra note 674.

The regulatory analysts also feel that the RIA enhances the quality of the public debate over a rulemaking effort, because it suggests alternative regulatory approaches that the public may not have envisioned.[736] It also makes the public aware of the probable effect of the agency's action in time to comment upon those effects.[737]

Personnel in the program offices tend to agree that the regulatory analysis documents enhance the quality of public comment on the feasibility aspects of OSHA rules.[738] The comments on the regulatory analysis documents have helped shape the agency's thinking about rules as it proceeded to promulgate final rules.[739] Still, for many rules the bulk of the comments go to the technical aspects of the Preamble, rather than to the regulatory analysis.

After the hearing, the agency leaves the record open for further comment and then divides the comments up by issue. Comments directed toward the economic analysis in the RIA are routed to the regulatory analysts in the Office of Regulatory Analysis. The Team then begins the difficult process of "weighing the record." This requires the Team members to reach conclusions about which facts, judgments, and assumptions have sufficient support in the record to survive judicial review. Not surprisingly, the

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731 14 BNA Occupational Safety and Health Rpt'r [Current Developments] 37 (June 21, 1984) (opponents of grain elevator rule urge in hearing that the agency adopt a different analytical approach to cost assessment).

736 Goldin and Braslow Interview, supra note 578.

737 Goldin and Braslow Interview, supra note 578.

738 Beliles Interview, supra note 593.

739 Beliles Interview, supra note 593.

Team representative from the Solicitor's Office plays a large role in this effort.[740]

As with the proposed rule, the team attempts to reach consensus on the content of the final rule. Any disputes are elevated through the hierarchy on an ad hoc basis and may ultimately have to be resolved by the Assistant Secretary. The upper level agency officials can and do interject policy considerations at any stage of the Team's deliberations over the final rule, but they rarely have much to say about the weight of evidence in the record.[741] Thus, to the extent that technical facts or scientific and engineering judgments dominate the rulemaking effort, the Team absorbs a great deal of the agency's decisionmaking power.

After the Team has weighed the evidence and drafted a final rule, and after the regulatory analyst has drafted the final regulatory analysis document, the entire package is forwarded to the Regulation Review Committee for comment and on to the Assistant Secretary for final approval. Finally, the rulemaking package is forwarded to the Departmental Policy Review Coordinating Committee for comment and policy input.

5. Interagency Review of the Final Rule and Final Regulatory Analysis Document.

Of the very few OSHA rules that have gone through both the proposed and final stages since the promulgation of Executive Order 12291, OMB review has not been as intensive at the final stage as it was at the proposal stage. More recently, OMB review of the final rule has intensified in at least one

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740 Silk Interview, supra note 673.

741 Belilles Interview, supra note 593; Wentzler Interview, supra note 674.

rulemaking proceding concerning worker exposure to ethylene oxide. Aside from some delay problems, the interagency review process appears to function more smoothly at the final rule stage. However, given the very slight experience with OMB review of OSHA final rules, any general conclusions are probably unwarranted.

6. Retrospective Analysis.

OSHA does not routinely undertake to analyze retrospectively the accuracy of the predictions made in its regulatory analysis documents.[742] The Director of the Policy Analysis Directorate believes that the agency does not have sufficient analytical resources to undertake retrospective analysis of its existing rules. He also observed that one recent attempt to review retrospectively the standard for acrylonitrite did not gain enough industry cooperation to lead to definitive findings.[743] When asked whether the agency worked such retrospective analysis into its evaluation plans, the Special Assistant to the Administrator for Regulatory Affairs replied that analysis of the predictions of regulatory analysis documents was not currently a part of the agency's scheme for evaluation plans, but he thought that it might be a good idea for the future.[744] The agency long ago conducted a retrospective study on the costs imposed by its 1974 vinyl chloride standard. The study concluded that the agency had greatly

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742 Strobel Interview, supra note 595; Goldin and Braslow Interview, supra note 578; Beliles Interview, supra note 593.

743 Goldin and Braslow Interview, supra note 578; Goldin and Braslow Comments, supra note 591.

744 Strobel Interview, supra note 595.

overestimated the costs that the standard would impose on the vinyl chloride industry.[745]

C. Level of Analysis in Regulatory Analysis Documents.

Although the regulatory analysts in the Directorate of Policy of the Occupational Safety and Health Administration would prefer to adhere to the requirement of Executive Order 12291 that agencies use cost-benefit analysis as a tool for evaluating major rules,[746] the agency has concluded that it is precluded by law from using cost-benefit analysis in promulgating health standards.[747] Instead, the agency uses cost-effectiveness analysis in the decisionmaking process. Nevertheless, the agency prepares a cost and a benefit analysis for all major rules.

The analyses that the agency does prepare tend to be very comprehensive analyses of the costs of complying with the enumerated alternatives and of the impact of those costs on the affected industries. In addition, the agency has more recently attempted to assess the cost-effectiveness of most health regulations by calculating the implicit cost-per-life-saved or cost-per-illness-avoided of the various regulatory alternatives.[748] Nevertheless, the agency has done little in the way of monetizing the benefits of most health regulations because of the statutory prohibition

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745 Belilles Interview, supra note 593.

746 Goldin and Braslow Interview, supra note 578.

747 See, American Textile Manufacturers Institute v. Donovan, 452 U.S. 490 (1981).

748 Goldin and Braslow Interview, supra note 578.

against cost-benefit analysis. The cost-benefit analyses for safety regulations, however, generally examine monetized benefits.[749]

The regulatory analysis documents attempt to characterize uncertainties in the quantitative analysis in two ways. First, the regulatory analysts use "sensitivity analysis" to probe the sensitivity of the quantitative predictions to various assumptions in the quantitative models. Second, the regulatory analysis documents attempt to "bound" the uncertainties in the quantitative predictions by estimating the high and low extremes. Pursuant to OMB's request, the agency attempts to predict a "best estimate" as well.

Some of the Occupational Safety and Health Administration's regulatory analysis documents explore alternatives to regulation over which the agency has no statutory authority. In particular, RIAs might explore nonregulatory alternatives such as relying on state agencies, workers compensation, or tort liability.[750]

D. The Impact of Regulatory Analysis on the Decisionmaking Process.

1. The Impact of the Regulatory Analysis Documents.

As in the other regulatory agencies studied in connection with this Report, its seems clear that the formal regulatory analysis documents do not play a major role in the decisionmaking process of the staff teams that identify and examine alternative regulatory approaches and draft rulemaking documents. Although other members of the Regulation Team attempt to comment

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749 Goldin and Braslow Interview, supra note 578; Goldin and Braslow Comments, supra note 591.

750 Wentzler Interview, supra note 674.

on the quantitative analysis that the regulatory analysis office produces, the formal documents arrive too late in the decisionmaking process to have much impact on the Team's deliberations. The documents are generally not changed much as a result of suggestions of members of the Team.[751] There is usually little conflict over the content of the regulatory analysis documents, because the members of the team generally have an ample opportunity to critique the contents of the contractors' reports that the regulatory analysis office staff uses in drafting the those documents.

The information that goes into the regulatory analysis documents can be very influential to the working groups' deliberations. The representative from the Office of Regulatory Analysis on the Regulation Team usually briefs the other members of the Team on the contractors' studies that that Office commissions, and the economic analyses can play an important role in the Teams' deliberations, especially on the issue of feasibility. In addition, early drafts of the regulatory analysis document for a rule are often relied upon by the Director of Policy and other senior officials in upper level policy deliberations. The contents of these early drafts have been useful in bringing about significant changes to proposed rules. This is especially true for final rules, because the regulatory analysis documents incorporate the staff's response to public comments.[752]

2. The Impact of the Regulatory Analysis Office.

The Occupational Safety and Health Administration is one of very few

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751 Gass Interview I, supra note 596.

752 Goldin and Braslow Comments, supra note 591.

agencies within the Department to have a separate office of regulatory analysts. A representative from that office sits on all important Regulation Teams, and that representative is usually one of the more active team participants.[753]

The Office of Regulatory Analysis in the Directorate of Policy has been assigned the task of preparing regulatory analysis documents for virtually all rules that the agency promulgates. That office supervises the economic impact assessment contracts, and translates the results of those contracts into memoranda for the use of the other members of the teams and for the Director of Policy. While it is clear that the representatives from the regulatory analysis office actively participate in the identification of options, they by no means dominate that process. Most of the options that the teams consider are suggested by the representatives of the technical offices.[754]

It appears that the representatives from the program offices generally respect the regulatory analysts in the the Office of Regulatory Analysis and attempt to take their efforts into account in identifying options and selecting preferred alternatives.[755] The technical staff do not believe that the regulatory analysts come to the team meetings with preconceived

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753 Goldin and Braslow Interview, supra note 578; Wentzler Interview, supra note 674.

754 Silk Interview, supra note 673.

755 Silk Interview, supra note 673; Beliles Interview, supra note 593; Gass Interview I, supra note 596.

notions about how regulations should be crafted or about whether the agency should be promulgating regulations at all.[756]

The Director of the Directorate of Policy, however, believes that the Office of Regulatory Analysis has a role beyond that of helping to identify and "cost out" regulatory options. He believes that the office should attempt to "force" (in a non-pejorative sense) the consideration of less costly alternatives through data analysis, modeling, and other ways of assessing the costs and benefits of compliance with alternative regulatory approaches.[757] The representative from the Office of Regulatory Analysis should make the team aware of these concerns, and the Director of the Policy Directorate is responsible for raising them at Regulatory Management Committee deliberations and to the Assistant Secretary when the teams do not adequately deal with them.[758]

The Director of Policy feels that he has problems with the receptivity of other institutional actors within OSHA to regulatory analysis, particularly with respect to the economic effects of a regulatory option. He believes that health scientists and safety engineers bring a particular perspective to the rulemaking process. Their raison d'etre is to write regulations. They emphasize technology and technological feasibility, and they are generally unreceptive to economics and concepts like cost-benefit analysis.[759] At least one member of the technical staff in OSHA agrees

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756 Silk Interview, supra note 673.

757 Goldin and Braslow Interview, supra note 578.

758 Goldin and Braslow Interview, supra note 578.

759 Goldin and Braslow Interview, supra note 578.

that employees from the program office tend to emphasize health effects over monetary considerations.[760] He believes that regulatory analysts are less biased in the sense that they are not entirely "wrapped up in the health effects."[761] The technical staff personnel tend to emphasize "worst case" risk analysis, and they behave more like prosecutors. Sometimes they are pleasantly surprised when the regulatory analysts demonstrate that the problem before the agency is not as severe as the program office technical staff thought.[762]

According to the Director of Policy, the regulatory analysts apparently were generally ignored during the preceding Administration, because the upper level managers were not receptive to economic analysis. In the current Administration, however, economic analysis is a more important input into the decisionmaking process. He believes that the agency's regulatory analysts are currently important contributors to the substance of agency policy on large rulemaking efforts.

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760 Gass Interview I, supra note 596.

761 Gass Interview I, supra note 596.

762 Gass Interview I, supra note 596.

V. The Role of Regulatory Analysis in the Environmental Protection Agency.

The Environmental Protection Agency (EPA) is a federal agency that is not associated with any cabinet department. Reporting directly to the President, it is responsible for administering eight important environmental statutes[763] and portions of several other statutes. EPA regulations can cut across several industries and can have profound impacts on whole sectors of the economy. Hence, EPA has always been intimately involved in regulatory analysis efforts. Indeed, the first regulatory analysis review program, the Quality of Life Review in the Nixon Administration, was aimed almost exclusively at this single agency.[764] EPA is currently one of the most prolific producers of regulatory analysis documents.[765] It also has

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763 These include National Environmental Policy Act of 1969, 42 U.S.C. § 4321 et seq. (1982); Clean Air Act, 42 U.S.C. § 7401 et seq. (1982); Federal Water Pollution Control Act, 33 U.S.C. § 1251 et seq. (1982); Resource Conservation and Recovery Act of 1976, 42 U.S.C. § 6901 et seq. (1982); Toxic Substances Control Act, 15 U.S.C. § 2601 et seq. (1982); Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. § 136 et seq. (1982); Safe Drinking Water Act, 42 U.S.C. § 300F et seq. (1982); and Comprehensive Environmental Response, Compensation, and Liability Act of 1980, 42 U.S.C. § 9601 et seq. (1982).

764 See ch.2, supra at II-8.

765 In the Summer of 1983, then Deputy Administrator Alvin Alm assembled a small task force of agency employees to examine the conduct and use of economic analysis in EPA. This task force was named the Task Force on Analytic Resources. The task force was charged with examining the integration of economic analysis into regulatory decisionmaking and the distribution of staff and extramural resources devoted to economic analysis. The task force adopted two approaches to fulfilling its tasks. First, it prepared four case studies of the use of economic analysis in regulatory decisionmaking in four agency offices. Second, it conducted an inventory of the resources devoted to economic analysis in the agency.

The task force reported back to the Deputy Administrator in September,

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the most systematic approach to rulemaking and regulatory analysis of any agency studied in connection with this Report.[766]

A. Agency Structure and Heirarchy.

The organizational chart set out in Table 3-4 demonstrates that EPA is primarily a regulatory agency.[767] The Administrator and Deputy Administrator of EPA are appointed by the President, with the advice and consent of the Senate, and they serve at his pleasure. The Associate Administrators for International Activities and Regional Operations are also political appointees, but they have very little responsibility for

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765 1983. Its report consisted of: (1) a five-page memorandum to the Deputy Administrator [hereinafter cited as Task Force Memo]; (2) a seven-page "Analysis of the Inventory of EPA Economic Analytical Resources" [hereinafter cited as Task Force Inventory]; (3) four lengthy case studies of the use of analysis in individual agency rulemakings prepared by various agency employees [hereinafter cited as Task Force Case Study on _____]; (4) an Overview of the Case Studies prepared by Rebecca A. Barclay of the Program Evaluation Division of the Office of Management Structure and Evaluation of the Office of Policy, Planning and Evaluation [hereinafter cited as Task Force Case Study Overview]; (5) the transcripts of a series of "roundtable" discussions by a panel of employees drawn from the Office of Policy and Resource Management (now Office of Policy, Planning and Evaluation [hereinafter cited as Task Force Panel Transcripts]; (6) a document entitled "Background on Range of Economic Analysis in Regulatory Decision-Making in Pesticide Programs by by Arnold L. Aspelin; and (7) a document entitled "The Role of Economic Analysis in the Office of Toxic Substances," [hereinafter cited as Toxic Substances Appendix to Task Force Report]. Although the task force report is somewhat dated, this Report will occasionally draw on it.

766 One high level staff employee at EPA who had been in six different agencies over a nine year period commented that EPA has the most systematic process for issuing major rules that he had ever seen. Personal Interview with Mr. John M. Campbell, Deputy Assistant Administrator for Policy, Planning and Evaluation, EPA, June 29, 1984.

767 The agency does undertake some research and development functions that are not immediately related to its regulatory efforts in the Office of Research and Development.

promulgating agency rules. Nine Assistant Administrators, who are appointed by the President with the advice and consent of the Senate, also serve directly under the Administrator and Deputy Administrator. Four of the Assistant Administrators -- the Assistant Administrator for Air and Radiation, the Assistant Administrator for Pesticides and Toxic Substances, the Assistant Administrator for Solid Waste and Emergency Response, and the Assistant Administrator for Water -- bear responsibility for implementing the agency's regulatory programs. All of the substantive regulations that the agency promulgates must have the approval of one of these four Assistant Administrators, and all of the regulatory program offices fall under the jurisdiction of one or another of these Assistant Administrators.

The Assistant Administrator for Policy, Planning and Evaluation is responsible for centralized regulatory analysis and overall program evaluation. The Assistant Administrator for Enforcement and Compliance Monitoring is responsible for enforcing agency regulations and coordinating enforcement actions with the states and the Department of Justice. The Assistant Administrator for Research and Development supervises agency-sponsored research and oversees several agency laboratories. The Assistant Administrator for Administration and Resources Management is primarily responsible for budgetary and management functions, and the Assistant Administrator for External Affairs oversees the agency's relations with Congress, the public, and other agencies in the executive branch.[768]

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768 During a large part of the time that the agency was being studied for this Report, the agency had two Associate Administrators who were not subject to the advice and consent of the Senate and who played important roles in the rulemaking process. From late 1981 until mid-1983, the Associate Administrator for Legal and Enforcement Counsel was responsible for both enforcement and legal advice. In 1983 the legal advice function was shifted to the Office of General

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1. The Program Offices.

Each of the four program offices -- the Office of Air and Radiation, the Office of Pesticides and Toxic Substances, the Office of Solid Waste and Emergency Response, and the Office of Water -- is composed of several "suboffices," serving under Office Directors, that are responsible for particular regulatory programs. The Office of Air and Radiation includes the Office of Air Quality Planning and Standards,[769] the Office of Mobile Sources,[770] and the Office of Radiation Programs.[771] The Office of

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768 Counsel, which now serves directly under the Administrator. The enforcement functions were placed under the Assistant Administrator for Enforcement and Compliance Monitoring. The Associate Administrator for Policy and Resource Management was responsible for budget management, program evaluation, and regulatory analysis. These functions have since been transferred to the Assistant Administrator for Administration and Resources Management and the Assistant Administrator for Policy, Planning and Evaluation. The Assistant Administrators were independent of the Associate Administrators, but the two Associate Administrators were important contributors to the decisionmaking process. In particular, the Associate Administrator for Policy and Resource Management had a virtual veto power over any proposals of the Assistant Administrators. Personal Interview with Mr. Joseph Cannon, formerly Associate Administrator for Policy and Resource Management, Radiation, EPA, May 18, 1984 [hereinafter cited as Cannon Interview]. Although the agency's new organizational structure has been in place for over a year, some of the descriptions of the role that regulatory analysis has played in the rulemaking process will necessarily hark back to the previous regime in which the regulatory analysis function may have had a somewhat higher profile in the agency.

769 The Office of Air Quality Planning and Standards is responsible for promulgating national air quality standards, administering the approval process for State Implementation Plans (which must ensure that the ambient air quality standards are not exceeded), promulgating

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770 The Office of Mobile Sources is responsible for promulgating standards for mobile sources of pollution, such as automobiles, trucks, and airplanes.

771 The Office of Radiation Programs is responsible for promulgating criteria and standards for human and environmental exposure to

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Pesticides and Toxic Substances includes the Office of Pesticide Programs and the Office of Toxic Substances.[772] The Office of Solid Waste and Emergency Response includes the Office of Emergency and Remedial Response[773] and the Office of Solid Waste.[774] The Office of Water includes the Office of Drinking Water,[775] the Office of Water Program Operations,[776] and the Office of Water Regulations and Standards.[777]

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769 performance standards for new stationary sources of pollution, and promulgating standards for hazardous pollutant emissions.

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771 radiation. The standards are usually enforced by other agencies, such as the Nuclear Regulatory Commission.

772 The Office of Pesticide Programs is responsible for approving new pesticides and canceling the registrations of existing pesticides that pose an unreasonable risk to the environment. The Office of Toxic Substances is responsible for administering the Toxic Substances Control Act, a comprehensive statute that requires manufacturers of new chemicals to notify EPA prior to marketing such chemicals and to test such chemicals for toxicity if EPA so requires. In addition, EPA may remove or place restrictions on existing chemicals if they pose an unreasonable risk to man or the environment.

773 The Office of Emergency and Remedial Response is responsible for cleaning up existing hazardous waste facilities and assessing responsibility for cleanup costs. The Office administers a large "superfund" to pay for cleanup costs when a financially viable responsible party cannot be located.

774 The Office of Solid Waste promulgates standards for new and existing hazardous waste facilities, administers a permitting system for such facilities, and promulgates standards for ensuring the financial responsibility of those facilities.

775 The Office of Drinking Water is responsible for promulgating interim and final standards for drinking water quality.

776 The Office of Water Program Operations administers grants to municipalities for sewage treatment plants and oversees the several statutory programs that call for regional and state water quality plans.

777 The Office of Water Regulations and Standards promulgates technology-based standards for new and existing sources of water

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Because regulatory analysis is only of tangential concern to several of the "suboffices," the description and analysis that follows will focus on the rulemaking process in the following suboffices:

-- the Office of Air Quality Planning and Standards;
-- the Office of Toxic Substances;
-- the Office of Solid Waste;
-- the Office of Drinking Water; and
-- the Office of Water Regulations and Standards.

Each of the five program offices listed above has its own regulatory analysts, and at least one has two separate groups of regulatory analysts.[778] The regulatory analysis process, however, varies from program to program.[779]

a. The Office of Air Quality Planning and Standards.

The Office of Air Quality Planning and Standards has three groups of regulatory analysts. The Ambient Standards Branch of the Strategies and Air Standards Division has a staff of two full-time regulatory analysts and several other analysts who devote time to preparing portions of regulatory analysis documents for National Ambient Air Quality Standards.[780] This

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777 pollutants, promulgates water quality-based standards for sources of hazardous pollutants, oversees state water quality standards, and plays a role in overseeing the National Pollution Discharge Elimination System permit process.

778 Only two rulemaking offices lack a separate regulatory analysis staff -- the Office of Emergency Response in the Office of Solid Waste and Emergency Response and the Office of Mobile Sources in the Office of Air and Radiation. Task Force Memo, supra note 765, at 3.

779 See Task Force Memo, supra note 765, at 2.

780 Telephone Interview with Mr. Henry Thomas, Ambient Standards Branch, Strategies and Air Standards Division, Office of Air Quality Planning

(Continued on page 254)

staff devotes approximately four man-years to regulatory impact assessment efforts.

Six cost engineers and financial analysts in the Cost and Economics Section of the Economic Analysis Branch of the Strategies of Air Standards Division prepare cost analyses and economic impact analyses for New Source Performance Standards and National Emission Standards for Hazardous Air Pollutants.[781] The Cost and Economics section devotes approximately $1 million to contractor efforts.[782] Since the Standards Development Branch of the Emission Standards and Engineering Division, which is the program office for these standards, does not have a separate staff of economists or regulatory analysts, all of the economic analysis is done in the Economic Analysis Branch.

Finally, the Regulatory Impact Section of the Economic Analysis Branch of the Strategies and Air Standards Division contains four analysts who help prepare regulatory analysis documents for all three of the Division's regulatory functions (National Ambient Air Quality Standards, New Source Performance Standards, and National Emission Standards for Hazardous Air

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780 and Standards, Office of Air and Radiation, EPA, May 25, 1984 [hereinafter cited as Thomas Interview I] and July 24, 1984 [hereinafter cited as Thomas Interview II]. One of the current regulatory analysts in the Ambient Standards Branch is not a professional economist; he is a public health specialist with training in economics.

781 Comments of Mr. Allen Basala, Chief, Regulatory Impact Section, Economic Analysis Branch, Strategies and Air Standards Division, Office of Air Quality Planning and Standards, Office of Air and Radiation, EPA, on an earlier draft of this Report, August 21, 1984; Telephone Interview with Mr. Al Wehe, Cost and Economics Section, Economic Analysis Branch, Strategies and Air Standards Division, Office of Air Quality Planning and Standards, Office of Air and Radiation, EPA, July 26, 1984 [hereinafter cited as Wehe Interview].

782 Wehe Interview, supra note 781.

Pollutants).[783] This section is the exclusive source of benefits analyses for the entire Office.[784]

b. The Office of Toxic Substances.

The Regulatory Impacts Branch of the Economics and Technology Division of the Office of Toxic Substances is responsible for preparing regulatory analysis documents for that Office. That Branch has fourteen analysts who manage contracts and draft cost and benefit analyses for regulatory analysis documents. During the last fiscal year, that office was allocated $1.9 million for contracts relevant to regulatory analysis.[785] At one time each analyst was assigned to a particular aspect of the toxics regulatory program, but in more recent years any analyst may be assigned a task relevant to any of the regulatory programs that the Office of Toxic Substances administers.[786] This is intended to encourage a cross-fertilization of ideas within the Division.[787]

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783 In addition, this staff represents the Office of Air Quality Planning and Standards on the intra-agency Work Group that prepares agency guidelines for regulatory analysis document preparation. Basala Interview, supra note 781. More recently, the staff has been given the task of preparing regulatory analyses for the air emissions of hazardous waste facilities in connection with the implementation of the Resource Conservation and Recovery Act. Telephone Interview with Mr. Allen Basala, Chief, Regulatory Impact Section, Economic Analysis Branch, Strategies and Air Standards Division, Office of Air Quality Planning and Standards, Office of Air and Radiation, EPA, May 1, 1985.

784 See text accompanying note 1042, infra.

785 Telephone Interview with Mr. Michael Shapiro, Acting Director, Economics and Technology Division, Office of Toxic Substances, Office of Pesticides and Toxic Substances, EPA, May 23 and 24, 1984 [hereinafter cited as Shapiro Interview].

786 Shapiro Interview, supra note 785.

787 Shapiro Interview, supra note 785.

c. The Office of Solid Waste.

Most of the regulatory analysts in the Office of Solid Waste are located in the Economic Analysis Branch of the Waste Management and Economics Division.[788] Many of the Office's standard-setting functions are located in other branches of that Division. The Branch employs nine regulatory analysts and has approximately $3 million for contractor support.[789]

d. The Office of Drinking Water.

The Economic and Policy Analysis Branch of the Office of Program Development and Evaluation is responsible for regulatory analysis in the Office of Drinking Water. That branch devotes three regulatory analysts to this effort.[790] The Director of the Office of Program Development and Evaluation takes a keen interest in regulatory analysis and participates actively in the drafting of regulatory analysis documents.[791] The Branch has a small budget of $300,000 to $600,000 per year for contractors.[792]

e. The Office of Water Regulations and Standards.

The Office of Water Regulation and Standards has an Economic Analysis

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788 Telephone Interview with Mr. Dale Ruhter, Chief, Economic Analysis Branch, Waste Management and Economics Division, Office of Solid Waste, Office of Solid Waste and Emergency Response, EPA, July 10, 1984 [hereinafter cited as Ruhter Interview].

789 Ruhter Interview, supra note 788.

790 Telephone Interview with Mr. Arnold Kuzmack, Director, Office of Program Development and Evaluation, Office of Drinking Water, Office of Water, EPA, May 22, 1984 [hereinafter cited as Kuzmak Interview].

791 Kuzmack Interview, supra note 790.

792 Kuzmack Interview, supra note 790.

Staff of ten economists in the Office of Analysis and Evaluation. These economists write the economic impact analysis and cost-effective analyses for technology-based standards for new and existing sources of pollution.[793] The Economic Analysis Staff has approximately $1.4 million available for contractor support.[794] Recently, the agency has attempted to analyze the benefits of these standards in accordance with the requirements of Executive Order 12291. The Economic Analysis Staff, however, has delegated this task to regulatory analysts in the Economic Analysis Division of the Office of Policy Analysis in the Office of Policy, Planning and Evaluation.[795]

2. The Office of Policy, Planning and Evaluation.

The Office of Policy, Planning and Evaluation performs a centralized regulatory analysis review function for the agency. In addition, it manages the agency decisionmaking process to ensure that agency actions remain on schedule and reflect upper level policy input. The Office is composed of three "suboffices" -- the Office of Management Systems and Evaluation, the Office of Policy Analysis, and the Office of Standards and Regulations. The Office of Management Systems and Evaluation is responsible for the agency's planning, evaluation, accountability and management system. One Division of that Office evaluates the performance of the agency's programs; another division keeps close track of each program's progress toward predetermined

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793 Telephone Interview with Mr. Lewis DuPuis, Chief, Economic Analysis Staff, Office of Analysis and Evaluation, Office of Water Regulations and Standards, Office of Water, EPA, May 31, 1984 [hereinafter cited as DuPuis Interview].

794 DuPuis Interview, supra note 793.

795 DuPuis Interview, supra note 793.

milestones. The Office plays no role in the day-to-day rulemaking process.[796]

a. The Office of Policy Analysis.

The Office of Policy Analysis provides centralized guidance on policy analysis in general and on the content of regulatory analysis documents in particular.[797] The Office also plays an advocacy role, representing the Assistant Administrator for Policy, Planning and Evaluation in intra-agency debates over the substantive content of rules.[798] It attempts to interject cost and efficiency considerations into the decisionmaking process at every level.[799] This may require the representative of the Office to engage in extensive debates with program office staff at the Work Group level and at higher levels as upper level decisionmakers resolve remaining issues.

The office occasionally drafts a regulatory analysis document for an overburdened program office or for a program office that does not have an independent regulatory analysis staff. It also conducts special studies related to regulatory analysis and focuses particularly upon benefits

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796 Telephone Interview with Ms. Eileen Sheehan, Program Evaluation Division, Office of Management Systems and Evaluation, Office of Policy, Planning and Evaluation, EPA, July 26, 1984.

797 Telephone Interview with Mr. Thomas Kelly, Program Evaluation Division, Office of Systems and Evaluation, Office of Policy Planning and Evaluation, EPA, May 21, 1984 [hereinafter cited as Kelly Interview].

798 Telephone Interview with Mr. Daniel Fiorino, Acting Director, Regulation and Enforcement Management Division, Office of Standards and Regulations, Office of Policy, Planning and Evaluation, EPA, May 23, 1984 [hereinafter cited as Fiorino Interview II].

799 See text accompanying note 1381, infra.

analysis. But its primary functions are to review regulatory analysis documents that the analysts in the program offices have drafted and to offer analytical guidance to program offices and Work Groups. The Office of Policy Analysis is in turn divided into three Divisions, two of which have duties directly related to the regulatory process.[800]

The Regulatory Policy Division consists of twenty-three analysts and support staff.[801] This Division is the primary contact with the program offices for regulatory matters.[802] It provides the "lead analysts" that sit on all Work Groups and brief the Assistant Administrator for Policy Planning and Evaluation for his meetings with high level agency decisionmakers. The three branches in the Division are divided along programmatic lines into the Air Branch, the Water Branch and the Hazardous Wastes Branch. Lead analysts in each Branch interact with the scientists and engineers in the program offices on the Work Groups as the Work Groups resolve substantive issues and explore regulatory alternatives. They also interact with the regulatory analysts in the program office in the process of reviewing regulatory analysis documents.[803]

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800 The Integrated Environmental Management Division examines issues that cut across two or more media in an attempt to avoid the not infrequent problems that arise when environmental controls that are intended to protect one medium (e.g. scrubbers to remove sulfur dioxide from air emissions) have unanticipated impacts on other media (e.g. land disposal of the scrubbers wastes).

801 Telephone Interview with Mr. Stuart Sessions, Acting Director, Regulatory Policy Division, Office of Policy Analysis, Office of
(Continued on page 260)

802 Sessions Interview, supra note 801; Telephone Interview with Mr. Ralph Luken, Benefits Grants Chief, Economic Analysis Division, Office of
(Continued on page 260)

803 Sessions Interview, supra note 801; Telephone Interview with Mr. Alexander Cristofaro, Air Branch Chief, Regulatory Policy Division,
(Continued on page 260)

The Economic Analysis Division does not interact on a routine basis with the program offices, and personnel from that division generally do not sit on agency Work Groups.[804] It largely devotes its efforts to long range exploratory projects and projects that cut across two or more programs. The twenty-five professionals in that Division are divided into three Branches:[805] the Strategic Studies Branch, the Economic Studies Branch, and the Benefits Branch. The Strategic Studies Branch, which contains five professionals, examines broad long-term issues such as the "greenhouse effect" and the role of chlorofluorocarbons in reducing the protection afforded by the ozone layer in the upper atmosphere.[806]

The Economic Studies Branch -- which includes a half-dozen professionals with backgrounds in economics, business, and financial analysis -- undertakes a variety of analyses, most of which involve financial or industry issues. These include enforcement-related financial analyses, both for individual cases and for general policy making. The Branch also deals with cross-cutting economic issues, such as the overall

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(Continued from page 259)
801 Policy, Planning and Evaluation, EPA, May 29, 1984 [hereinafter cited as Sessions Interview]

(Continued from page 259)
802 Policy Analysis, Office of Policy and Program Evaluation, EPA, May 25, 1984 [hereinafter cited as Luken Interview II].

(Continued from page 259)
803 Office of Policy Analysis, Office of Policy, Planning and Evaluation, EPA, May 24, 25, 1984 [hereinafter cited as Cristofaro Interview].

804 Telephone Interview with Mr. Albert Nichols, Acting Director, Economic Analysis Division, Office of Policy Analysis, Office of Policy, Planning and Evaluation, May 22, 1984 [hereinafter cited as Nichols Interview].

805 Nichols Interview, supra note 804.

806 Nichols Interview, supra note 804.

impacts of EPA regulations on the economy. Groundwater issues are becoming a special focus of the Branch's work. Although often involved in analyzing specific aspects of regulatory programs, this Branch rarely has the lead in preparing regulatory analyses. The recently proposed rule on lead in gasoline is an important exception to this general rule; members of this Branch were responsible for virtually all of the analysis behind the rule, including estimates of health effects as well as costs. The Branch played this unusual role in part because the program office did not have the necessary analytical resources and in part because members of the Branch are knowledgeable about both the refining industry and about lead.

The Benefits Branch is probably the most active with respect to regulatory analysis. The thirteen economists in that Branch work on assessing the benefits of health and environmental regulations. The Branch is the primary agency resource for benefits analysis for regulatory analysis documents. Indeed, some program offices have on occasion transferred funds to the Benefits Branch to prepare benefits analysis for their regulatory analysis documents.[807] In addition, the Benefits Branch was the primary author of the agency-wide guidelines for preparing Regulatory Impact Analyses.[808] Finally, the Benefits Branch includes a group that has been transferred from the Office of Research and Development that sponsors long term research on environmental economics.[809]

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807 Telephone Interview with Mr. Allen Basala, Chief, Regulatory Impact Section, Economic Analysis Branch, Strategies and Air Standards Division, Office of Air Quality Planning and Standards, Office of Air and Radiation, EPA, May 29, 1984.

808 Nichols Interview, supra note 804.

809 Nichols Interview, supra note 804.

b. The Office of Standards and Regulations.

With one exception,[810] The Office of Standards and Regulations does not generally play a direct role in regulatory analysis drafting and review.[811] The Office is, however, intimately involved in the regulatory process in a management capacity.[812] The Office is subdivided into two large Divisions--the Regulation and Information Management Division and the Chemicals and Statistical Policy Division.

The primary function of the Regulations and Information Management Division is "decision management."[813] The thirty professionals in that Division attempt to ensure that the internal process of rule generation and review functions smoothly. In addition to its largely ministerial function of seeing to it that the various agency actors perform their duties in a timely fashion, the Division also performs the more substantive function of determining whether the regulatory analysis and rulemaking documents examine all of the relevant issues and present all of the alternatives in a clear fashion.[814] This latter function overlaps somewhat with the regulatory analysis review function of the Office of Policy Analysis. Unlike the Office of Policy Analysis, however, the Regulation and Information Management Division does not take a position on substantive issues and does

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810 The Office of Standards and Regulations provides the "lead analyst" for Work Groups considering rules that the Office of Pesticides and Toxic Substances generates. See, note 821, infra.

811 Fiorino Interview II, supra note 798.

812 Kelly Interview, supra note 797.

813 Telephone Interview with Mr. Daniel Fiorino, Acting Director, Regulation and Enforcement Management Division, Office of Standards and Regulations, Office of Policy, Planning and Evaluation, EPA, February 8, 1983 [hereinafter cited as Fiorino Interview I].

814 Fiorino Interview II, supra note 798.

not overtly participate in internal agency debates.[815] This attempted neutrality allows the Division to manage the high level "Red Border Review" process[816] and to play the role of rapporteur at the very high level "Options Selection/Rejection" process for important agency rules[817] without raising concerns in the program offices that those processes are biased in favor of the Office of Policy, Planning and Evaluation.[818] Finally, the Office of Standards and Regulations is the formal agency liaison with OMB.[819]

The Chemicals and Statistical Policy Division manages statistics and other information relevant to agency rulemakings. In that capacity, the Division also provides a quality control function.[820] For historical reasons, the Division also performs a regulatory analysis review function for rules that the Office of Pesticides and Toxic Substances generates,[821]

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815 Fiorino Interview II, supra note 798.

816 See, text accompanying notes 1141-1143, infra.

817 See, text accompanying note 1023, infra.

818 Campbell Interview, supra note 766.

819 Fiorino Interview I, supra note 813; Kelly Interview, supra note 797.

820 Kelly Interview, supra note 797. For example, that division played a very prominent role in the development of the recently proposed National Ambient Air Quality Standard for particulate matter. That proposal depended heavily upon statistical epidemiology studies that were interpreted both in the air program office and in the Chemicals and Statistical Policy Division, and that Division participated heavily in the internal agency debates over the validity of various statistical approaches to the epidemiological data. Personal Interview with Mr. Al Jennings, Director, Chemicals and Statistical Policy Division, Office of Standards and Regulations, Office of Policy and Program Planning, EPA, May 18, 1983 [hereinafter cited as Jennings Interview].

821 Kelly Interview, supra note 797. The personnel most familiar with the pesticides and toxic substances programs have been associated with the

(Continued on page 264)

a function that one would expect to find in the Regulatory Policy Division of the Office of Policy Analysis. Finally, the Office of Standards and Regulations also has a small "Regulatory Reform" staff that is responsible for developing innovative regulatory alternatives to existing regulatory approaches.

B. The Formal Regulatory Process.

EPA has promulgated formal agency-wide procedures for developing and reviewing regulations.[822] The Procedures Memorandum specifies in detail the roles of all of the offices that are directly involved in the rulemaking process. In addition, the agency has provided guidance for writing and reviewing rulemaking documents in a separate Criteria and Guidelines Memorandum.[823] Finally, the agency has prepared formal Regulatory Impact

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821 Office of Standards and Regulations as they have evolved through several agency reorganizations. To avoid disrupting the association between the statisticians and the persons with expertise in chemical control, the latest reorganization effort left those analysts in the Chemicals and Statistical Policy Division, rather than transferring them to the Regulatory Policy Division of the Office of Policy Analysis where they fit organizationally. Kelly Interview, supra note 797; Fiorino Interview I, supra note 813. Consequently, the agency regulatory analysts that sit on working groups and advise the Assistant Administrator for Policy, Planning and Evaluation for pesticides and toxic substances rules are located in the Chemicals and Statistical Policy Division of the Office of Standards and Regulations.

822 Memorandum on Procedures for Regulation Development and Review from Alvin L. Alm, Deputy Administrator to Assistant Administrators, General Counsel, Inspector General, Associate Administrators, Regional Administrators, and Staff Office Directors, February 21, 1984 [hereinafter cited as Procedures Memo].

823 Memorandum on Criteria and Guidelines for Review of Agency Actions from Alvin L. Alm, Deputy Administrator to Assistant Administrators, General Counsel, Inspector General, Associate Administrators, Regional Administrators, and Staff Office Directors, January 30, 1984 [hereinafter cited as Criteria and Guidelines Memo].

Analysis Guidelines for the program offices and their consultants.[824] These three documents provide substantial guidance to agency employees on virtually every aspect of the rulemaking and regulatory analysis process.

1. Origin and Threshold Analysis.

The most frequent source of EPA rules is the agency's statutes, which often provide that the agency must promulgate a particular rule by a specific deadline.[825] A somewhat less frequent source of EPA rules is petitions for rulemaking from environmental group and industry. Since citizen petitioners may invoke judicial sanctions if the agency arbitrarily rejects a petition, a petition can generate a fair amount of technical and analytical effort in the agency, even if the agency ultimately rejects the petition.

Rules originate in "lead offices" under the four Assistant Administrators with rulemaking responsibility.[826] For example, the "lead office" for the Lead Phasedown rulemaking detailed in Appendix B to this Report was the Office of Mobile Sources in the Office of Air and Radiation.[827] The lead office is the primary source of technical expertise concerning the regulatory action, although it may draw on other

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824 Environmental Protection Agency, Guidelines for Performing Regulatory Impact Analysis (December, 1983) [hereinafter cited as EPA RIA Guidelines].

825 See, e.g., Resource Conservation and Recovery Act of 1976, 42 U.S.C. § 6921(b)(3)(C) (1982) (180 days); Clean Air Act, as amended, 42 U.S.C. § 7412(b)(1)(B) (1982) (180 days).

826 Procedures Memo, supra note 822, at 2.

827 See Lead Phasedown Case Study, Appendix B to this Report.

offices within the agency to complement its analytical resources.[828] In addition to technical expertise, nearly all of the lead offices have expertise in regulatory analysis.[829] The regulatory analysts in the lead offices supervise independent contractors who do the bulk of the economic data gathering for the program offices,[830] prepare regulatory analysis documents, and occasionally sponsor independent research on issues relevant to their programs. The lead office is also responsible for organizing and chairing the Work Group, setting the schedule for the rulemaking process, and eliciting the participation of other agency offices and the public.[831] The Assistant Administrator for the Office that includes the lead office must designate a "project officer" in the lead office to manage each regulation's development as it moves through the internal agency procedures.[832]

a. The Lead Offices.

i. The Office of Air Quality Planning and Standards.

The Office of Air Quality Planning and Standards promulgates three

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828 Procedures Memo, supra note 822, at 3.

829 The Office of Mobile Sources in the Office of Air and Radiation and the Office of Emergency and Remedial Response in the Office of Solid Waste and Emergency Response do not employ regulatory analysts, because they very rarely promulgate rules. On the rare occasions in which they do promulgate major rules, the offices delegate their regulatory analysis drafting responsibilities to regulatory analysts in the Office of Policy Analysis in the Office of Policy, Planning and Evaluation.

830 Task Force Memo, supra note 765, at 3.

831 Task Force Memo, supra note 765, at 3.

832 Procedures Memo, supra note 822, at 3.

kinds of rules -- National Ambient Air Quality Standards, New Source Performance Standards, and National Emission Standards for Hazardous Air Pollutants.

(I). National Ambient Air Quality Standards.

National Ambient Air Quality Standards are media-quality-based standards for ubiquitous air pollutants. The primary standards specify a level of pollutant in the ambient air that is sufficiently low to protect the public health with an adequate margin of safety. The secondary standards specify a level capable of protecting the public welfare (plants, animals, materials). This regulatory function is lodged in the Strategies and Air Standards Division of the Office of Air Quality Planning and Standards. The standards do not have to specify how society should go about achieving the National Ambient Air Quality Standards. Implementation of sufficient control techniques is a matter that is left largely to the states, which must promulgate State Implementation Plans, subject to EPA approval. Headquarters staff and the Regional Offices give guidance to the states for drafting acceptable plans.

The origin of the National Ambient Air Quality Standards is the Clean Air Act itself. The agency must promulgate a standard for any pollutant that "causes or contributes to air pollution that may reasonably be anticipated to endanger public health or welfare" and which "results from numerous or diverse mobile or stationary sources."[833] A citizen group may petition the agency to make these findings and may secure judicial review of

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833 42 U.S.C. § 7408(a)(1) (1982).

the agency's determination.[834] Once the agency has added a pollutant to the list of pollutants that meet this test, it must promulgate the standard in accordance with a strict statutory timetable. In addition, the statute requires that every National Ambient Air Quality Standard be reexamined for possible revision every five years.[835] The Office of Air Quality Planning and Standards is therefore constantly in the process of revising old standards and promulgating new standards.

The rulemaking process begins when the agency-wide Office of Research and Development prepares a "criteria document" for a pollutant for which the agency will promulgate or revise a National Ambient Air Quality Standard.[836] The criteria document must review the literature on the health and welfare effects and analytical chemistry of the pollutant and survey possible pollution control techniques.

After the criteria document is completed, the technical staff and regulatory analysts in the Ambient Standards Branch of the Strategies and Air Standards Division prepare a "staff paper" for upper level agency decisionmakers and the Clean Air Scientific Advisory Committee.[837] The staff paper presents the staff's interpretation of key studies and identifies the critical issues that will arise in the standard setting

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834 See, Natural Resource Defense Council, Inc. v. Train, 545 F.2d 320 (2d Cir 1976) (lead listing).

835 42 U.S.C. § 7409(d)(1) (1982)

836 42 U.S.C. § 7408 (1982).

837 The Clean Air Scientific Advisory Committee is a scientific Advisory Committee established by the Clean Air Act to review the scientific and technical documents that the agency prepares in connection with promulgating National Ambient Air Quality Standards. 42 U.S.C. § 7409(d)(2) (1982).

process."[838] The staff paper averages 100-200 pages in length.[839] The regulatory analysts in the Economic Analysis Branch of the Office of Air Quality Planning and Standards generally do not participate in drafting the staff paper,[840] because the staff paper does not contain any information on the costs of implementing alternative standards.[841] The agency is currently of the opinion that, under the Clean Air Act, it cannot consider costs in determining the level at which it sets National Ambient Air Quality Standards.[842] Whether quantitative benefits may be considered in establishing National Ambient Air Quality Standards is currently an open question in the agency.[843] To the extent, however, that benefits analysis can play a role in the standard setting process, the Economic Analysis Branch may participate in drafting the staff paper.[844] Until very

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838 Thomas, Use of Quantitative Analysis in the NAAQS Review Process, paper presented at the 77th Annual Meeting of the Air Pollution Control Association, San Francisco, June, 1984; Thomas Interview I, supra note 780.

839 Thomas Interview I, supra note 780.

840 Basala Interview, supra note 807.

841 Thomas Interview I, supra note 780.

842 Thomas Interview I, supra note 780. General Accounting Office, Cost-Benefit Analysis Can Be Useful in Assessing Environmental Regulations, Despite Limitations 15-16 (1984) [hereinafter cited as GAO Cost-Benefit Report]. Preamble, Proposed Revisions to the National Ambient Air Quality Standards for Particulate Matter, 49 Fed. Reg. 10408, 10409 (March 20, 1984) [hereinafter cited as Preamble]. See, American Petroleum Inst. v. Costle, 665 F.2d 1176, 1185 (D.C. Cir. 1981), cert. denied, 102 S. Ct. 1737 (1982); Lead Industries Ass'n v. EPA, 647 F.2d 1130 (D.C. Cir.), cert. denied, 101 S. Ct. 621 (1980).

843 Thomas Interview I, supra note 780. Preamble, supra note 842, at 10409.

844 At this point it is unclear whether benefits analysis will play a role in setting future National Ambient Air Quality Standards. In the past

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recently, the staff paper has not attempted to quantify the benefits of proposed alternatives.[845] The staff paper does, however, contain a quantitative analysis of the effects of the pollutant on sensitive populations.[846]

(II). New Source Performance Standards.

New Source Performance Standards are limitations applicable to the emissions of new sources of pollutants. In promulgating New Source Performance Standards the Emissions Standards and Engineering Division of the Office of Air Quality Planning and Standards divides an industry into categories and subcategories, surveys existing sources and pilot plants for workable pollution control technologies, and prescribes emissions limitations for new sources reflecting the best available demonstrated control technology.[847] While cost considerations play a large role in setting New Source Performance Standards, they must be set without regard to the quality of the air in the areas in which the new sources will be built. This task calls for a healthy dose of "engineering judgment."

The important initiating event for a New Source Performance Standard is when the agency places a category of sources on its list of sources that causes or contributes significantly to air pollution which "may reasonably

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844 it has played no role in that process, but the agency may change its posture on this issue.

845 Thomas Interview I, supra note 780.

846 Thomas Interview I, supra note 780.

847 42 U.S.C. § 7411 (1982).

be anticipated to endanger public health or welfare."[848] The agency promulgated a list of categories in 1978, and it has slowly been working its way down that list.[849] The entire decisionmaking process takes approximately four years for each rule.[850]

(III). National Emissions Standards for Hazardous Air Pollutants.

National Emission Standards for Hazardous Air Pollutants are emissions limitations applicable to new and existing sources of hazardous air pollutants. The agency first promulgates a list of hazardous air pollutants. Next, it promulgates standards for all sources of pollutants on the list that are sufficient to protect the public health with an ample margin of safety.[851] Engineering, cost, and risk considerations are all relevant to the promulgation of these standards. Although the standards are not strictly technology-based, engineering and cost considerations have historically played an important role in their promulgation.[852] Like the New Source Performance Standards, the National Emission Standards for

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848 42 U.S.C. § 7411(b)(1)(A) (1982).

849 Telephone Interview with Mr. Robert L. Ajax, Chief, Standards Development Branch, Emissions Standards and Engineering Division, Office of Air Quality Planning and Standards, Office of Air and Radiation, EPA, July 13, 1984 [hereinafter cited as Ajax Interview].

850 Ajax Interview, supra note 849.

851 42 U.S.C. § 7412(b)(1)(B) (1982).

852 McGarity, Media Quality, Technology and Cost-Benefit Balancing Strategies for Health and Environmental Regulation, 46 L. & Contemp. Prob. 159, 202 (1983). The agency's liberal reliance on cost considerations in setting emissions standards for hazardous pollutants probably violates the Clean Air Act (see GAO Cost-Benefit Report, supra note 842), but the issue has not been litigated thus far.

Hazardous Air Pollutants are initially developed in the Emission Standards and Engineering Division.

For National Emission Standards for Hazardous Air Pollutants, the triggering event is when the agency places a particular pollutant on its list of "hazardous air pollutants.[853] Once a pollutant is placed on this list, the agency has 180 days to promulgate standards.[854] Since this trigger precipitates an extremely lengthy and complicated rulemaking effort, the agency studies the relevant pollutants very carefully before placing one on the list. Once it places a pollutant on the list, the agency has very little discretion to delay the rulemaking process for further study.

ii. The Office of Toxic Substances.

A rule can originate in the Office of Toxic Substances in any one of a number of ways. The agency has compiled an inventory of all existing chemical substances. Under section 5 of the Toxic Substances Control Act, any manufacturer of a new chemical substance (any chemical not on the inventory) must notify EPA of that fact,[855] and EPA has 90 days to decide whether to promulgate a rule prohibiting or limiting the manufacture of the substance until adequate data are available to determine whether it poses an unreasonable risk to humans or the environment.[856] In order to manufacture or process an existing chemical for a significant new use, the

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853 A "hazardous air pollutant" is defined as one which causes or contributes to air pollution which "may reasonably be anticipated to result in an increase of mortality or an increase in serious irreversible, or incapacitating reversible, illness."

854 42 U.S.C. § 7412(b)(1)(B) (1982).

855 15 U.S.C. § 2604 (1982)

856 Id. The 90 days may be extended to 180 days.

manufacturer or processor must submit a similar notice to the agency. The agency may then decide whether to prohibit or limit the new use pending the completion of additional testing.[857] Under section 4 of the Act, the agency can by rule require that existing chemicals be tested. An interagency committee is responsible for suggesting a priority for testing existing chemicals, and the agency must act on that priority list within one year.[858] The agency also has a continuing program of evaluating the health effects of existing chemicals on the basis of existing health and safety studies.[859] If the agency determines that a new or existing chemical will cause "unreasonable adverse effects" on humans or the environment, it may, under section 6 of the Act, promulgate a rule prohibiting, limiting, or otherwise regulating the manufacture, distribution, or use of the chemical.[860]

Much of the Office of Toxic Substance's activity for new chemicals is stimulated by premanufacture notifications from industry or by petitions from industry and environmental groups.[861] In addition, the statute allows the agency to gather a wide variety of hazard and exposure information on existing chemicals. Freshly generated information on

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857 18 U.S.C. § 2604(e) (1982). If adequate data are available and the agency determines that the substance would pose an unreasonable risk, it may limit or prohibit the manufacture or use of the chemical or take other actions described in section 6(a) of TSCA. 15 U.S.C. § 2604(f) (1982).

858 15 U.S.C. § 2603(e) (1982).

859 Telephone Interview with Ms. Margaret Stasikowski, Acting Director, Chemical Control Division, Office of Toxic Substances, Office of Pesticides and Toxic Substances, EPA, July 11, 1984 [hereinafter cited as Stasikowski Interview].

860 15 U.S.C. § 2605 (1982).

861 Stasikowski Interview, supra note 859.

existing chemicals can also stimulate a rulemaking effort. The Office frequently faces the "chemical-of-the-month syndrome" whereby a great deal of media attention to a particular chemical precipitates pressure on the agency to deal with the problems that the chemical has caused or may cause.

iii. The Office of Solid Waste.

The Resource Conservation and Recovery Act requires the agency to promulgate standards relating to hazardous waste management. The statute required the agency to promulgate regulations identifying the characteristics of hazardous waste and listing particular hazardous wastes.[862] The criteria and list must be revised "from time to time," and in practice they are in a constant state of revision. The agency must also promulgate and revise standards for the generation, transportation, storage, and disposal of hazardous wastes.[863] Although these standards were to have been promulgated by the late 1970s, they were not in fact promulgated until the early 1980s, and many were promulgated on an interim basis. The agency is therefore still completing this initial effort. Finally, the agency must promulgate standards for permits for the treatment, storage and disposal of hazardous wastes.[864]

Many of the regulations that the agency has promulgated in the last five years have been promulgated in response to court orders that required

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862 42 U.S.C. s 6921 (1982).

863 42 U.S.C. §§ 6922-24 (1982).

864 42 U.S.C. § 6925 (1982).

the agency to follow fixed rulemaking timetables.[865] As the agency has slipped behind the timetables, states and environmental groups have returned to court to secure further orders to hurry up the process.[866] Hence, the rulemaking process in the Office of Solid Waste has gone forward under considerable pressure from the public and the courts, and many of its activities were exempted from the regulatory analysis requirements of Executive Order 12291.

iv. The Office of Drinking Water.

The Office of Drinking Water is responsible for promulgating interim and revised primary and secondary standards for contaminants in drinking water.[867] The Safe Drinking Water Act requires the agency to promulgate revised national primary drinking water standards.[868] The revised national primary drinking water regulations must be amended whenever changes in technology permit greater protection of public health, and they must be reviewed every three years.[869] As new drinking water contaminants are

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865 Telephone Interview with Mr. Robert Tonetti, Land Disposal Branch, Waste Management and Economics Division, Office of Solid Waste, Office of Solid Waste and Emergency Response, July 26, 1984 [hereinafter cited as Tonetti interview].

866 Ruhter Interview, supra note 788. Illinois v. Costle, 12 ERC 1597 (D.D.C. 1979); Illinois v. Gorsuch, 530 F. Supp. 340 (D.D.C. 1981) [litigation to force EPA to promulgate regulations under the Resource Conservation and Recovery Act of 1976].

867 Primary standards are standards necessary to protect the public health. Secondary standards protect the public welfare. 42 U.S.C. § 300f(1)(2) (1982).

868 42 U.S.C. § 300g-1 (1982).

869 42 U.S.C. § 300g-1(b)(4) (1982).

discovered, national primary drinking water standards must be promulgated for them.[870]

The Office of Drinking Water has an informal "intelligence network" in the field that is constantly on the lookout for new contaminants and new technologies.[871] If a scientist or local public health official discovers a new contaminant in a drinking water supply, they will usually report that discovery to the agency. If the agency receives a sufficient number of such reports, it will initiate the rulemaking planning process.[872] In addition to relying upon its "intelligence network" to initiate rulemaking efforts, the Office will occasionally receive petitions from outside groups to begin the process.

v. The Office of Water Regulations and Standards.

The Office of Water Regulations and Standards devotes the bulk of its regulatory resources to promulgating technology-based Effluent Guidelines and Limitations for categories and subcategories of industries that discharge effluent into the navigable waters. This function is very similar to that of the Office of Air Quality Planning and Standards when it promulgates technology-based New Source Performance Standards.[873] The major difference is that water standards must be promulgated for both new and existing sources. In addition, the Effluent Guidelines Division of the

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870 42 U.S.C. § 300g-1(e) (1982).

871 Kuzmack Interview, supra note 790; Telephone Interview with Mr. Craig Vogt, Deputy Director, Criteria and Standards Division, Office of Drinking Water, Office of Water, EPA, June 26, 1984 [hereinafter cited as Vogt Interview].

872 Kuzmack Interview, supra note 790.

873 See text accompanying notes 847-50, supra.

Office of Water Regulations and Standards has less discretion than the Office of Air Quality Planning and Standards in determining which categories of sources to regulate. The Clean Water Act lists the sources to which the agency must give priority in establishing guidelines and limitations.[874] So far, the agency has not undertaken to expand its work load by including additional categories on the list, and it has not received petitions to include new industries on the list.

The Effluent Guidelines Division begins the standard-setting process by hiring contractors to "categorize" the relevant industry, identify pollution control technologies in that industry and industries with similar effluents, and assess the costs of installing available pollution control technologies. The economic analysis staff then undertakes a "gross screening" of the technically feasible options in an attempt to exclude any options that are obviously beyond the range of reasonable options. The economic analysis staff then directs a contractor to compile necessary economic and financial data, to conduct economic impact assessments, to prepare cost-effectiveness analyses, and (in the case of major rules) to prepare benefits analyses.[875] When the contractor reports are completed, an engineer in the Effluent Guidelines Division will be assigned the task of assembling a Work Group and drafting a federal register notice.

The statute provides that "best available technology" standards for existing sources be reviewed every five years and, if appropriate,

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874 33 U.S.C. § 1316(b)(1)(A) (1982). Technically, the list is applicable only to new source performance standards. Since the agency promulgates new source performance standards at the same time that it promulgates standards for existing sources, the list effectively dictates the rule-initiation process for both types of rules.

875 Task Force Case Study in the Inorganic Chemicals Industry Effluent Guideline (Phase I), supra note 765, at V-4.

revised.[876] New Source Performance Standards must be reviewed and revised "from time to time, as technology and alternatives change."[877] Hence, as in the case of National Ambient Air Quality Standards and New Source Performance Standards for air pollutants, the agency is in a constant state of reviewing and revising regulations.

b. The Start Action Request.

When the lead office is ready to initiate the rulemaking process with respect to a particular subject matter, it must first prepare a "Start Action Request" and submit it to the Office of Standards and Regulations in the Office of Policy, Planning and Evaluation. The Start Action Request must:

-- describe the proposed action and its purpose;

-- state the statutory authority for the action and propose its classification as either major, significant, or minor;

-- explain the reason(s) for proposing to initiate the action, and the consequences of not doing so;

-- certify that the action's relation to other relevant programs has been investigated, and justify any projected conflict, duplication, or failure to pursue possibilities for integration;

-- explain why developing the action now will be an appropriate use of [agency] time and resources.[878]

Although the regulatory analysts in the individual program offices

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876 33 U.S.C. § 1311(d) (1982).

877 33 U.S.C. § 1316(b)(1)(B) (1982).

878 Procedures Memo, supra note 822, at 5.

rarely participate in the preparation of Start Action Requests,[879] they often participate in informal teams within the program office prior to drafting the Start Action Request.[880] Occasionally, the regulatory analysts will have already done some background work on the regulatory issue prior to the time that the technical staff drafts the Start Action Request.[881] Most regulatory analysts in the agency believe that if the analysts do not become involved in a rule's development at the very early planning and research stage prior to the Start Action Request, they cannot be very influential in the rulemaking process that follows.[882]

The Office of Standards and Regulations in the Office of Policy, Planning and Evaluation reviews the Start Action Request and circulates it to the regulatory analysts in the Regulatory Policy Division of the Office of Policy Analysis for review.[883] The Director of the Regulation and Information Management Division of the Office of Standards and Regulations

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879 Basala Interview, supra note 807; Shapiro Interview, supra note 785; Tonetti Interview, supra note 865; Kuzmack Interview, supra note 790; DuPuis Interview, supra note 793.

880 Shapiro Interview, supra note 785; Kuzmack Interview, supra note 790; Tonetti Interview, supra note 865; Ajax Interview, supra note 849; Wehe Interview, supra note 781. An exception is the Office of Air Quality Planning and Standards. In that office the engineers and regulatory analysts in the Ambient Standards Branch of the Strategies and Air Standards Division meet regularly to draft the staff paper for National Ambient Air Quality Standards, but they do not usually include the regulatory analysts from the Economic Analysis Branch of that same Division. Basala Interview, supra note 807.

881 Shapiro Interview, supra note 785; Tonetti Interview, supra note 865; Ajax Interview, supra note 849.

882 Shapiro Interview, supra note 785; Basala Interview, supra note 807; Kuzmack Interview, supra note 790.

883 Telephone Interview with Mr. Sam Napolitano, Chief, Hazardous Waste Branch, Regulatory Policy Division, Office of Policy Analysis, Office of Policy, Planning and Evaluation, EPA, May 24, 1984 [hereinafter cited as Napolitano Interview].

then assigns the rule to one of his or her rulemaking managers, and that manager will take responsibility for seeing the rule through to the final agency action.[884]

The Start Action Request is next reviewed by the Steering Committee.[885] The Steering Committee is the primary collective agency decisionmaking entity. It is composed of representatives of each of the nine Assistant Administrators, the General Counsel, and the two Associate Administrators.[886] The Director of the Office of Standards and Regulations chairs the Steering Committee. The Steering Committee meets regularly at biweekly intervals and more often as necessary, but much of its business is conducted on the "consent calendar" under which documents are circulated to the Steering Committee and approved by members without a formal meeting.[887] Most Start Action Requests are decided on the consent calendar.

The purpose of circulating the Start Action request to the Steering Committee is to inform all relevant institutional units of an Office's intent to propose a regulation and to afford them an opportunity to

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884 Fiorino Interview I, supra note 813. There is some degree of specialization within the Division; two or three people within the Division deal with each substantive program area. But current workload is considered in making assignments as well as program expertise. Fiorino Interview II, supra note 798.

885 Procedures Memo, supra note 822, at 4.

886 These representatives must be at or above the Office Director level and have responsibilities covering the entire range of regulatory issues within the offices that they represent. Procedures Memo, supra note 822, at 4. The representatives are typically on the staff of an Office Director, rather than a Branch Chief or some other person below the Office Director of more senior status than the Office Director's staff.

887 See Procedures Memo, supra note 822, at Appendix ii, p. 2.

participate in the rulemaking process. A second purpose is to avoid duplication. If one Office is aware that another Office is working on a regulatory problem of interest to both offices, they can coordinate their efforts. The Offices represented on the Steering Committee may respond in writing to the Start Action Request or they may communicate directly with the originating office and request to be put on the Work Group that develops the rule.[888] Because the purpose of the Start Action request is informational rather than functional, members of the Steering Committee almost never object to the action itself.

After the Office of Standards and Regulations has reviewed the Start Action Request and received the input of those members of the Steering Committee who have comments, that office makes a recommendation to the Assistant Administrator for Policy, Planning and Evaluation. The Criteria and Guidelines Memorandum identifies the following criteria for evaluating a Start Action Request:

1. The action responds to a clearly defined problem that requires regulatory action.

2. The action will be consistent with, and adequate to, the statutory mandate.

3. The action is not likely to duplicate or conflict with other regulatory programs, either at EPA or at other Federal agencies, without adequate justification.

4. The action will coordinate its approach with that of other relevant Federal and State programs that affect the same prospective regulated community.

5. This is the appropriate time to develop the action, and the effort will make the best use of our resources in view of competing priorities.

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888 Fiorino Interview II, supra note 798.

In deciding what to recommend to the Assistant Administrator, the Office of Standards and Regulations consults with the Regulatory Policy Division of the Office of Policy Analysis[889] At this point, the Regulatory Policy Division will assign to a staff member the task of "lead analyst" for the rule.[890] The lead analyst and the relevant staff person from the Office of Standards and Regulations then meet to decide upon the appropriate recommendation to the Assistant Administrator.[891] In performing this function, they will rely almost exclusively upon information provided by the lead office.[892] In addition, the staffers might make some telephone calls to knowledgeable persons.[893]

The Office of Standards and Regulations only very rarely recommends that a Start Action Request be denied.[894] Before the staff in that office go to this extreme length, they meet with the personnel in the program

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889 Usually the staff official in the Office of Standards and Regulations interacts with the Regulatory Policy Division of the Office of Policy Analysis in performing this function. However, for Start Action Requests coming from the Office of Pesticides and Toxic Substances, the Regulation and Information Management Division consults with the Chemicals and Statistical Policy Division of the same office, because the latter division has historically had the responsibility for sitting on Work Groups for rules originating in the Office of Pesticides and Toxic Substances. See note 821, supra.

890 Fiorino Interview II, supra note 798.

891 Fiorino Interview II, supra note 798; Cristofaro Interview, supra note 803.

892 Fiorino Interview II, supra note 798.

893 Fiorino Interview II, supra note 798.

894 Fiorino Interview II, supra note 798; Napolitano Interview, supra note 883; Sessions Interview, supra note 801 ("We don't advise that they get rejected.") The Office of Standards and Regulations has never recommended to the Assistant Administrator that a Start Action Request Originating in the Office of Air and Radiation or the Office of Toxic Substances be denied. Cristofaro Interview, supra note 803; Vogt Interview, supra note 871.

office who drafted the request and attempt to reach an accommodation.[895] Often this accommodation results in the Office of Standards and Regulations' recommending approval, but attaching certain conditions to its recommendation.[896] If one of the conditions goes unfulfilled, the Office will feel free to raise its objections at any stage of the process. In those extremely rare instances in which no accommodation can be reached, the Office of Standards and Regulations will recommend to the Assistant Administrator for Policy, Planning and Evaluation that the request be denied, and the program office can present its case to the Assistant Administrator. For extremely difficult matters, the Assistant Administrator for Policy, Planning and Evaluation may meet with the Assistant Administrator for the relevant program office and attempt to work out the disagreement.[897] The ultimate authority to approve or reject a Start Action Request, however, resides in the Assistant Administrator for Policy, Planning and Evaluation. No rulemaking action may enter the internal agency review process without an approved Start Action Request.

The Office of Standards and Regulations so rarely recommends that a Start Action Request be denied that it is ignored by some program offices[898] and treated on a pro forma basis by many others.[899] The

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895 Fiorino Interview II, supra note 798.

896 Fiorino Interview II, supra note 798; Cannon Interview, supra note 768.

897 Fiorino Interview II, supra note 798.

898 The Office of Water Regulations and Standards skips the Start Action Request for Effluent Guidelines and Limitations, because the rules are required by statute. DuPuis Interview, supra note 793.

899 Ajax Interview, supra note 849; Kuzmack Interview, supra note 790; Vogt Interview, supra note 871; Ruhter Interview, supra note 788;

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Office of Standards and Regulations will recommend approval even when the discussion of the five required issues is incomplete. The Office does screen out requests that are very poorly thought out, but the primary function of the Start Action Request is to make the other interested institutional entities aware of the fact that a rule is germinating so that they may make personnel and resource decisions relevant to the upcoming rulemaking process.[900]

c. The Threshold Determination.

At the same time that it is reviewing the Start Action Request, the Office of Standards and Regulations must make the first of two threshold determinations. Since the standard form for the Start Action Request has a place for the program office to state its opinion on the threshold issue, the Office of Standards and Regulations has the program office's input prior to making its decision. The Office must determine whether the action identified in the Start Action Request is "major," "significant," or "minor."

Major rules are those meeting the definition of "major" in Executive Order 12291. A rule is significant if it is not major but nonetheless will have important effects on the environment, public health, or the economy, will present intermedia issues, or will affect the administration or operation of several Agency offices. Minor rules are those that are neither major nor significant. They include the more specialized and routine rules

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899 Tonetti Interview, supra note 865; Fiorino Interview II, supra note 798; Thomas Interview I, supra note 780.

900 Fiorino Interview II, supra note 798.

that affect only one program or sector of the economy, or that simply implement established Agency policy.

For several programs, these distinctions are relatively unimportant, because the program office prepares a regulatory analysis document for virtually every rule of any consequence that it promulgates.[901] Nevertheless, the intensity of the analysis and the care with which it is undertaken will increase if a rule is formally designated "major".[902] It seems clear, however, that in the absence of the cost-benefit mandate of Executive Order 12291, many of the programs would not put as much effort into benefits analysis for major rules.[903] Many of the offices that do not prepare formal RIAs for every rule nevertheless prepare thorough economic impact analyses. These documents, which accompany all minor rules of any consequence, differ from formal RIAs primarily in their lack of a benefits analysis.[904]

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901 Kuzmack Interview, supra note 790 (drinking water rules); Vogt Interview, supra note 871 (same); Shapiro Interview, supra note 785 (rules under section 6 of TSCA); Stasikowski Interview, supra note 859 (same); Basala Interview, supra note 807 (National Ambient Air Quality Standards); Ajax Interview, supra note 849 (New Source Performance Standards, National Emission Standards for Hazardous Air Pollutants); Cristofaro Interview, supra note 803 (hazardous waste standards).

902 Shapiro Interview, supra note 785; Kuzmack Interview, supra note 790; Jennings Interview, supra note 820; Cristofaro Interview, supra note 803.

903 Personal Interview with Mr. Ralph Luken, Benefits Grants Chief, Economic Analysis Division, Office of Policy Analysis, Office of Policy and Program Evaluation, EPA, May 18, 1983 [hereinafter cited as Luken Interview I]; Thomas Interview I, supra note 780; Telephone Interview with Mr. Jeff Kolb, Benefits Branch, Economic Analysis Division, Office of Policy Analysis, Office of Policy, Planning and Evaluation, EPA, July 28, 1983. Because the substantive mandate of
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904 Ajax Interview, supra note 849 (New Source Performance Standards under the Clean Air Act); Ruhter Interview, supra note 788 (Hazardous Waste
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The memoranda detailing the agency's rulemaking procedures do not suggest how the Office of Standards and Regulations should go about making the initial threshold determinations. In actual practice, the threshold determination is made very informally. After he or she receives the Start Action Request, the rulemaking manager in the Regulation and Information Management division of the Office of Standards and Regulations usually contacts a regulatory analyst in the program office,[905] who has usually already reached a tentative conclusion on the threshold issue.[906] The Office of Standards and Regulations also consults informally with regulatory analysts in the Office of Policy Analysis on the threshold issue.[907]

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903 the Office of Toxic Substances generally requires the agency to balance risks against benefits on promulgating rules, that program engages in substantial benefits analysis (risk analysis) for nearly all of its rules, irrespective of the requirements of Executive Order 12291.

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904 Standards); DuPuis Interview, supra note 793 (Water Effluent Limitations and Guidelines); Shapiro Interview, supra note 785 (TSCA §§ 4, 5, 8); Fiorino Interview I, supra note 813.

905 Since nearly all of the program offices have regulatory analysts on their staffs, the initial contact is generally with a regulatory analyst in the program office. If engineering costs are relevant to the threshold determination, however, an informal contact might also be made with a technical person in the program office.

906 Basala Interview, supra note 807; Shapiro Interview, supra note 785; Stasikowski Interview, supra note 859; Kuzmack Interview, supra note 790; Ruhter Interview, supra note 788; DuPuis Interview, supra note 793. Sometimes, however, the regulatory analysts and the technical personnel in the program office have not reached agreement on the issue, and the Office of Standards and Regulations can resolve the question. Fiorino Interview II, supra note 798.

907 The lead analyst in the Regulatory Policy Division of the Office of Policy Analysis who sits on the Work Group for the rule has the responsibility to make a recommendation on the threshold issue. The lead analyst may in turn consult with analysts in the Economic Analysis Division on the threshold issue, although this does not

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The agency's procedural memoranda also fail to specify sources of data for the threshold analysis. The findings that must accompany the Start Action Request are entirely unrelated to the threshold issue, and the Project Officer in the Lead Office will not generally have gathered this sort of information in preparing the Start Action Request. Thus, the threshold determination at this point is largely a matter of educated guesswork.[908]

Given the lack of relevant data at this point, the lead analyst usually makes a "back-of-the-envelope" calculation, which is subject to change when better information becomes available.[909] In many cases, for example, the analysts in the program office will have an inventory of sources affected by a particular rule and a rough approximation of the cost per source. This can be used to make a very rough approximation of the cost of the rule.[910] The agency has, however, been criticized for failing to consider the costs to predictable new sources in calculating anticipated compliance costs.[911]

In many cases, the analysts in the program office have already undertaken a sufficient cost analysis upon which to base a rough cost

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907 happen very often. Luken Interview II, supra note 802; Nichols Interview, supra note 804.

908 Fiorino Interview II, supra note 798. See GAO Cost-Benefit Report, supra note 842, at 24-25.

909 Cristofaro Interview, supra note 803.

910 DuPuis Interview, supra note 793; Basala Interview, supra note 807; Sessions Interview, supra note 801.

911 GAO found that two of sixteen effluent limitations guidelines examined in connection with that report would have been major rules if predicted new source compliance costs had been considered. GAO Cost-Benefit Report, supra note 842, at 23.

estimate for purposes of the threshold determination.[912] On the other hand, the regulatory analysts in the program office and in the Office of Policy Analysis can agree to postpone the threshold determination until a later date when more complete data will be available.[913]

For the "majorness" determination, the agency focuses almost exclusively on the $100 million threshold.[914] In addition, the focus is almost exclusively upon the regulation's costs, and not its projected benefits.[915] Even the cost assessment, however, can be very difficult, because it is hard to tell at this early stage how the agency will resolve important regulatory issues. For example, a very lenient option for solving a regulatory problem may impose $10 thousand in costs upon the regulated industry, while a very stringent option might cost $500 million. Similarly, it is often very difficult to tell at the Start Action Request stage whether a rule will have a significant impact on a substantial number of small businesses for purposes of the Regulatory Flexibility Act. The Office of Standards and Regulations is inclined to be overinclusive at this point to

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912 DuPuis Interview, supra note 793; Sessions Interview, supra note 801; Napolitano Interview, supra note 883.

913 Napolitano Interview, supra note 883.

914 Fiorino Interview II, supra note 798; Cannon Interview, supra note 768; Sessions Interview, supra note 801. Basala Interview, supra note 807; Kuzmack Interview, supra note 790; Ruhter Interview, supra note 788.

915 In one case a regulatory analyst in the Office of Air Quality Planning and Standards evaluated the predicted economic impacts of three options -- (1) control through economic incentives; (2) control through monitoring only; and (3) no regulatory action. The analyst predicted that the first two options would impose more than $100 million in costs on the regulated industry and the third option would impose social costs of greater than $100 million on the population protected by the standard. Basala Interview, supra note 807. The EPA analyst was told by OMB analysts that OMB did not consider social costs for purposes of threshold determinations.

avoid delaying the rulemaking process while the agency prepares a formal RIA or RFA later in the process.[916] In any event, the process is sufficiently flexible that if it becomes apparent at some later point that the original designation was mistaken, the analysts can change that designation.[917]

The "significance" determination is more subjective than the "majorness" determination. To make this determination the analysts in the Office of Standards and Regulations examine the "controversialness" of the rulemaking action and the amenability of the rule to analysis. For example, the regulatory analysts in the Regulatory Policy Division of the Office of Policy Analysis can easily predict that any air standard related to sulfur dioxide will be sufficiently controversial to warrant the preparation of a regulatory analysis document, because that pollutant is a precursor to the atmosphere sulfates that cause acid rain, a very controversial subject.[918]

d. The Options Selection/Rejection Designation.

Superimposed upon the regulatory analysis classification scheme is a recently developed "Options Selection/Rejection Process," which is designed to facilitate high level input into the low level decisionmaking process.[919] All major and significant rules must go through this options

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916 Fiorino Interview II, supra note 798; Thomas Interview I, supra note 780; Shapiro Interview, supra note 785; Vogt Interview, supra note 871.

917 DuPuis Interview, supra note 793; Fiorino Interview II, supra note 798.

918 Cristofaro Interview, supra note 803.

919 At least one regulatory program in EPA does not observe the Options Selection/Rejection Process. The Office of Water Regulations and Standards has not generally followed the process when it has promulgated effluent limitations and guidelines for new and existing

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review process.[920] Early in the development of a major or significant regulation, the Deputy Administrator designates it for either Level I or Level II options review.[921] These designations are made independently of the "major" and "significance" determinations; major rules can be designated for Level II review while significant rules can be designated for Level I Review. In this sense, the "majorness" determination is a measure of the intensity of the formal analysis that a rule will receive internally and from OMB, whereas the Level I determination is a measure of the intensity of the upper level scrutiny that a rule will receive internally.

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919 sources of water pollution. A recent exception to this is the proposed effluent limitations and guidelines for the organic chemical point source category. Whether the exceptions become the rule remains to be seen.

The process for promulgating these regulations also bypasses many of the procedures, such as steering committee review, that are designed to incorporate the participation of all segments of the agency. Largely for historical reasons having to do with the requirements of a consent decree with an environmental group, these regulations follow a very hierarchical pattern. A working group composed of an engineer, an economist, a statistician, and environmental specialists from the Office of Water Regulations and Standards, an attorney from the Office of General Counsel, and a regulatory analyst from the Office of Policy, Planning and Evaluation prepares the rulemaking documents and the regulatory analysis documents. The working group then presents options and a recommendation to the Director of the Office of Water Regulations and Standards in a single meeting. After this, the same group meets with the Assistant Administrator for Water, the Assistant Administrator for Policy, Planning and Evaluation, and the General Counsel to work out any disagreements remaining from the preceding meeting. In some rare cases this high level meeting cannot resolve all disagreements and they are left to the Administrator for resolution. DuPuis Interview, supra note 793. Like the Options Selection/Rejection Process, this procedure allows high level input at relatively early stages in the development of rules.

920 Procedures Memo, supra note 822, at 2.

921 Memorandum on Options Selection/Rejection Process from Alvin L. Alm, Deputy Administrator to Assistant Administrators and General Counsel, November 4, 1983 [hereinafter cited as Options Selection/Rejection Memo].

The Assistant Administrators for the regulatory programs nominate candidates for Level I Options Review. Although the Assistant Administrator and his or her immediate staff will draw upon lower level staff for suggestions and information, the decision whether to nominate a rule for Level I Options Review is made at a very high level within the program office.[922] The staffs of the Office of Standards and Regulations and the Office of Policy Analysis in the Office of Policy, Planning and Evaluation also nominate rules to their Assistant Administrator, who makes the final determination.[923]

Agency memoranda do not suggest criteria for designating rules for Level I or Level II review, but they do suggest that only about 20-30 rules per year should be designated for Level I review while 40-50 rules per year should be designated for Level II review. In practice the Assistant Administrators use much the same criteria for nominating rules for Level I Review that they use for classifying regulations "major" or "significant." They look to the cost of the rule, the likelihood that it will cause public controversy, and the importance of the rule to the program. They also look to the precedential value of the rule for future agency rulemakings.[924] In addition, the Assistant Administrators and the Staff in the Office of Policy, Planning and Evaluation look to the probability that the rule will

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922 DuPuis Interview, supra note 793; Shapiro Interview, supra note 785; Ruhter Interview, supra note 788; Basala Interview, supra note 807.

923 Fiorino Interview I, supra note 813; Sessions Interview, supra note 801; Cristofaro Interview, supra note 803; Napolitano Interview, supra note 883.

924 For example, virtually all of the Office of Toxic Substances' section 6 rules were initially designated for Level I review because the agency had never promulgated a rule under that standard. Stasikowski Interview, supra note 859.

require the agency to resolve a major policy issue that may have impacts on more than a single program.[925] As a practical matter, however, there is a fairly strong correspondence between major regulations and regulations chosen for Level I Options Review,[926] and the Assistant Administrators rarely differ as to which regulations ought to receive such review.[927]

The Options Selection/Rejection Process for Level I rules is implemented through quarterly planning meetings and more frequent options review meetings.[928] The Deputy Administrator chairs the quarterly planning meetings. The purposes of these meetings are: (1) to give a status overview of all Level I rules; (2) to provide advance notice of rules that will be ripe for an options selection/rejection review during the quarter; and (3) to decide which Assistant Administrators and Regional Administrators should participate in particular Options Selection/Rejection review meetings.[929] The agency memoranda do not specify who should attend the

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925 Sessions Interview supra note 801; Cristofaro Interview, supra note 803; Fiorino Interview I, supra note 813. For example, a recent rulemaking dealing with the disposal of sludge in the oceans did not have a sufficient dollar impact to trigger the preparation of an RIA, but it was clear that in the process of promulgating the regulation, the agency would have to resolve a major issue regarding its posture toward protecting the water quality of oceans. On the other hand, if the agency decided to be very protective of oceans, the sludge would have to be placed in landfills. This possibility raised concerns with the program regulating on-land solid waste disposal. Hence, even though the regulation would not have a major cost impact, it was an ideal candidate for Level I Options Review. Sessions Interview, supra note 801.

926 Sessions Interview, supra note 801.

927 Fiorino Interview I, supra note 813.

928 Personal Interview with Mr. Rob Wolcott, Special Assistant to the Deputy Administrator, EPA, June 27, 1984 [hereinafter cited as Wolcott Interview].

929 Options Selection/Rejection Memo, supra note 921, at 2.

quarterly planning meetings. The options review meetings are held for individual regulations at crucial decision points. The Deputy Administrator has had a strong preference for resolving potential intra-agency disputes at a very early stage.[930]

The purpose of the Options Selection/Rejection process is five-fold. First, upper level decisionmakers view the Level I options selection/rejection process as "an institutional mechanism for forcing consideration of a much broader spectrum of approaches to the regulatory problem."[931] Having forced lower level staff to identify a broad range of options, a second purpose of the process is to allow high level policymakers to narrow the range of options that the Work Group considers and, as the rulemaking process progresses toward completion, to select the option that will go forward to OMB and the Administrator as the agency's preferred option.[932] Third, by forcing mid-level management to consider the implications of many options for all institutionally important decisions, the process was intended to make mid-level (career) management more accountable to high level (politically appointed) management.[933] Fourth, the process was intended to eliminate the perception on the part of the technical staff in the program offices that the regulatory analysts in the Office of Policy Analysis were officious intermeddlers in the decisionmaking process. Those analysts are fully participating members of the Options

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930 Fiorino Interview I, supra note 813; Campbell Interview, supra note 766.

931 Wolcott Interview, supra note 928.

932 Criteria and Guidelines Memo, supra note 823, at 5.

933 Wolcott Interview, supra note 928.

Selection/Rejection Process, which makes many of the most important regulatory decisions in the evolution of a Level I rule.[934]

Finally, the Options Selection/Rejection Process was intended to give upper level management a greater role in the subtle policymaking that goes on at low levels in the bureaucracy when options are examined and rejected as the Work Group members attempt to reach consensus. The new management team that came to the agency with the appointment of William Ruckelshaus as Administrator believed that high level policymakers were able to play only a small role in the real decisionmaking process, because the consensus building process in the Work Groups eliminated most available options. In most cases the Work Group process effectively lined up all of the relevant institutional entities behind a single recommendation to the Administrator. The Administrator in reality had only two options -- he could accept the recommendation or he could send everyone back to "square one." The practical effect of this process was that much agency policy was often made at the Branch Chief level.[935] The new Administration created the Options Selection/Rejection Process as a mechanism to retain the benefits of the team approach (such as information-sharing and a multi-disciplinary perspective) while at the same time enhancing the role of the politically appointed upper level management in the decisionmaking process.[936]

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934 Wolcott Interview, supra note 928.

935 Fiorino Interview I, supra note 813.

936 Fiorino Interview I, supra note 813.

2. The Proposed Rule and the Preliminary Regulatory Analysis Documents.

a. Internal Program Office Deliberations.

By the time that a Start Action Request is approved, the program office has usually defined the regulatory "problem" with some precision and has often arrived at one or more "solutions" to the problem. The regulatory analysts and the scientists and engineers within the program office often debate about how to define the problem and how to identify the available options for solving the problem.[937] In several offices, a representative from the Office of Policy, Planning and Evaluation is invited to attend the internal meetings, to enable that office to become involved very early in the planning process. That Office, however, rarely sends a representative to an internal meeting prior to the time that a Work Group is formed.[938]

In many offices the interaction between the regulatory analysts and technical staff is conducted on an informal give-and-take basis.[939] In the Office of Drinking Water, for example, the regulatory analysts are regarded as the "resident intellectuals," and the technical staff and management of the Office actively seek out their advice on an informal basis.[940] The technical staff further believes that the regulatory

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937 Ruhter Interview, supra note 788; Shapiro Interview, supra note 785; Kuzmack Interview, supra note 790.

938 Kuzmack Interview, supra note 790; Ajax Interview, supra note 849; Tonetti Interview, supra note 865; Shapiro Interview, supra note 785.

939 Kuzmack Interview, supra note 790; Stasikowski Interview, supra note 859.

940 Vogt Interview, supra note 871; Kuzmack Interview, supra note 790.

analysts can help identify useful options for resolving some kinds of issues.[941]

In some cases, the Division Director who supervises both the regulatory analysts and the technical staff may formalize their interaction by appointing an internal team to formulate the positions that the program office will take when it interacts with other offices in the agency and with upper level management. In the Office of Toxic Substances, for example, the internal rulemaking process begins when the Division Director asks the technical staff to prepare a risk assessment of a particular use or uses of a chemical.[942] If the risk assessment persuades the Division Director that the Division should explore the possibility of regulatory action, he or she will recommend to the Director of the Office of Toxic Substances that he or she appoint a "staff team" to formulate the position of the office for Work Group and Steering Committee meetings. The staff team usually includes a chemical engineer, a hazard assessment expert, an economist, and an attorney from the Office of General Counsel. This staff team does most of the actual work on rules, and it identifies most of the relevant regulatory options. The rare disputes that survive team efforts at compromise can be elevated to the Branch Chief or Division Director Level.[943]

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941 Vogt Interview, supra note 871.

942 Stasikowski Interview, supra note 859. The risk assessment is in turn composed of a hazard assessment based on animal studies or epidemiological data and an exposure assessment.

943 Stasikowski Interview, supra note 859.

The Emissions Standards and Engineering Division of the Office of Air Quality Planning and Standards follows a similar internal team approach. At the very beginning of the rulemaking process, when the Division selects an industry from the list of industries to be regulated, the Division Director appoints a team of engineers, emissions testing experts, economists, and others from the Office of Air Quality Planning and Standards.[944] The Office of Policy Analysis in the Office of Policy, Planning and Evaluation is invited to send a representative to these internal team meetings, but it very rarely does so.[945] The team begins by deciding what data and analyses are necessary. It then commissions contractor studies on the availability, cost, and effectiveness of technologies. As these data come in over a two-year period the team digests and analyzes them and debates regulatory options.[946]

The Office of Solid Waste also uses the internal team approach.[947] Disputes within the Office do not occur often. When they do, the Director of the Waste Management and Economics Division resolves them. Once he or she has resolved a dispute, his or her determination becomes the Division's position in interactions with other agency offices, and the technical staff and regulatory analysts must fall in line behind that decision. The

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944 Ajax Interview, supra note 849; Wehe Interview, supra note 781.

945 Even if it does not send a representative to the team meetings, the Office of Policy Analysis receives copies of all of the teams working documents. Ajax Interview, supra note 849.

946 Ajax Interview, supra note 849.

947 Tonetti Interview, supra note 865.

technical staff has come to value the input of the regulatory analysis office, because one of the roles of that office is to prevent the Division from being "blind-sided" by the regulatory analysts in the Office of Policy, Planning and Evaluation in meetings with high level decisionmakers.[948]

In other programs, however, the technical staff is not as receptive to the input of the regulatory analysts. In the opinion of the chief regulatory analyst in the Regulatory Impact Section of the Economic Analysis Branch of the Strategies and Air Standards Division, the regulatory analysts and technical staff in the Ambient Standards Branch of that division do not regard regulatory analysis as a very important aspect of their job, because the Clean Air Act does not explicitly allow the agency to consider costs and benefits in setting National Ambient Air Quality Standards.[949] Historically, regulatory analysts in the Regulatory Impact Section have believed that their role is limited to providing benefits information to the analysts in the Ambient Standards Branch, who rework it and put it in the regulatory analysis documents without seriously considering it in drafting the standard.[950] Similarly, the regulatory analysts and technical staff in the Ambient Standards Branch are not, in the opinion of the economists in the Economic Impact Section, favorably disposed toward the alternatives that the regulatory analysts suggest.[951] The regulatory analysts in the

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948 Ruhter Interview, supra note 788.

949 Basala Interview, supra note 807.

950 Basala Interview, supra note 807.

951 Basala Interview, supra note 807.

Economic Impact Section have often felt left out of the decisionmaking process.

One policy analyst in the Ambient Quality Standards Branch does not agree that that Branch denigrates regulatory analysis.[952] In his opinion, the technical staff in the Ambient Standards Branch value regulatory analysis in general, but they do not necessarily agree with the approach to regulatory analysis taken in Executive Order 12291. He feels that the agency has an obligation to Congress and the public to provide a credible cost assessment, so that they will know what the absolutist approach of the Clean Air Act costs society. But so long as the statute precludes cost considerations, the health scientists in the Branch feel that they should not consider costs in determining what levels of exposure to pollutants protect the public health with an adequate margin of safety.[953] Personnel in the Ambient Standards Branch generally believe that since it cannot consider costs, it should not consume a large amount of resources in extensive cost analyses.[954] Benefits analysis, in their opinion, is useful in the standard setting process, and they believe that greater efforts should be made to incorporate it into the decisionmaking process.[955]

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952 Thomas Interview II, supra note 780.

953 Thomas Interview II, supra note 780.

954 Thomas Interview II, supra note 780.

955 Thomas Interview II, supra note 780.

With the recent advent of new leadership in the Office of Air Quality Planning and Standards, the role of regulatory analysts in the Economic Impact Section has expanded. The recently appointed Director of the Strategies and Air Standards Division, who was at one time the head of the Economic Analysis Branch of that Division, is committed to expanding the role of regulatory analysis in the decisionmaking process with respect to National Ambient Air Quality Standards.[956] Recognizing that cost considerations can play no role in setting National Ambient Air Quality Standards, the Division Director believes that benefits analysis does have an important role to play. Although the efforts to incorporate benefits analysis into the staff papers for past ambient air quality standards revisions have not been entirely successful, he is confident that benefits analysis and, consequently, the Regulatory Impact Section of the Economic Analysis Branch will play a larger role in the standard-setting process.[957] Analysts in both the Regulatory Impact Section and the Ambient Standards Branch apparently share this optimistic view.[958] Further, the Division Director believes that analysts in the Strategies and Air Quality Division should work more closely with analyst in the Office of Policy, Planning and Evaluation to improve the quality of the analysis that

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956 Telephone Interview with Mr. John O'Connor, Director, Strategies and Air Standards Division, Office of Air Quality Planning and Standards, Office of Air and Radiation, EPA, August 24, 1984 [hereinafter cited as O'Connor Interview].

957 O'Connor Interview, supra note 956.

958 Basala Interview, supra note 807; Thomas Interview II, supra note 780.

the Division produces.[959] The Division Director has a high regard for the quality of the participation of personnel from the Office of Policy, Planning and Evaluation in the standard setting process.[960] This respect is reciprocated by analysts in the Office of Policy, Planning and Evaluation, who believe that the Strategies and Air Quality Division has devoted more attention and resources to good regulatory analysis than almost any other office in the agency.[961]

b. The Work Group.

Shortly after the Assistant Administrator for Policy, Planning and Evaluation has approved a Start Action Request, the Project Officer in the Lead Office must convene a "Work Group."[962] The Work Group is composed of the Project Officer from the Lead Office,[963] the lead analyst from the

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959 O'Connor Interview, supra note 956.

960 O'Connor Interview, supra note 956.

961 Comments of Mr. Ralph Luken, Benefits Grants Chief, Economic Analysis Division, Office of Policy Analysis, Office of Policy and Program Evaluation, EPA, on an earlier draft of this Report, August 22, 1984 [hereinafter cited as Luken Comments].

962 Procedures Memo, supra note 822, at 4. This pattern may vary in some programs. For example, the Work Groups for National Ambient Air Quality Standards are formed long before the Start Action Requests are prepared. Since the standards must be reviewed on a five year basis, a Work Group is essentially a permanent entity. It begins to meet very early in the process, prior to the time that the technical staff drafts the staff paper for upper level and scientific advisory committee review. Thomas Interview I, supra note 780.

963 Usually, the Project Officer is from the technical staff of the lead office rather than from the regulatory analysis staff. The lead office regulatory analysts, however, generally attend the Work Group

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Regulatory Policy Division of the Office of Policy Analysis,[964] a staff attorney from the Office of General Counsel, and usually staff representatives of the Office of Research and Development, the Office of Enforcement and Compliance Monitoring, and at least one regional office. Other offices may send representatives when the Work Group will be addressing issues that concern them.[965] The Project Officer generally chairs the Work Group.[966]

Attendance at Work Group meetings for unexciting rules can be erratic. For example, the Office of Policy Analysis does not have sufficient personnel to send a lead analyst to every Work Group meeting for every regulatory program.[967] The Branch Chiefs in the Regulatory Policy Division of that Office therefore attempt to assign staff to the Work Groups in which the regulatory analyst's perspective is likely to make a difference. This can, however, lead to friction between the program office and the regulatory analysis office when the Office of Policy Analysis raises

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963 meetings. Basala Interview, supra note 807; Shapiro Interview, supra note 785; Ruhter Interview, supra note 788. One exception is the Office of Drinking Water, whose regulatory analysts rarely attend Work Group meetings. Kuzmack Interview, supra note 790.

964 Napolitano Interview, supra note 883; Cristofaro Interview, supra note 803; Fiorino Interview II, supra note 798. In the case of rules originating in the Office of Pesticides and Toxic Substances, the lead analyst will come from the Office of Standards and Regulations. See note 821, supra.

965 Procedures Memo, supra note 822, at 4; Fiorino Interview II, supra note 798.

966 Nichols Interview, supra note 804; Kuzmack Interview, supra note 790.

967 Cristofaro Interview, supra note 803.

objections or identifies fresh options at the "sign-off" stage very late in the standard-development process. The lead offices, with some justification, complain that the Office of Policy Analysis should have raised its objection at the Work Group level.[968] The lead offices are especially reluctant to undertake further analysis at the request of the Office of Policy Analysis at this late stage, where any additional analysis means additional delay.[969]

The Work Group is the primary working unit for the development of regulations in EPA. The group meets regularly throughout the life cycle of a rule. The meetings are intended to "provide a forum for sharing expertise" and to help "resolve conflicts at the start, thus enhancing the quality of Steering Committee review."[970] Two other purposes of the Work Group are to "ensure that all necessary analyses are integrated and that resources are efficiently allocated."[971] Another very important function of the Work Group is to facilitate an exchange of information among the various offices in the agency.[972] A final unarticulated, but very real

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968 Cristofaro Interview, supra note 803; Ajax Interview, supra note 849; DuPuis Interview, supra note 793.

969 Cristofaro Interview, supra note 803; Ajax Interview, supra note 849; DuPuis Interview, supra note 793. This seems to be a problem more with large technology-based standards than with other rules that the agency promulgates. It may be that the Office of Policy Analysis generally assigns a relatively low priority to these rules, which germinate in the program offices for many years before emerging at the Work Group level.

970 Procedures Memo, supra note 822, at 4.

971 Procedures Memo, supra note 822, at 4.

972 Cristofaro Interview, supra note 803.

function of the Work Group is to bring together professionals with different perspectives to focus their attention on a regulatory problem and debate about the appropriate ways to address that problem. Hence, the agency procedural guidelines provide that a representative from the Office of Policy Analysis should be assigned to every Work Group.[973] Ideally, the interchange of perspectives helps achieve a "synthesis" that goes beyond the outlook or observations of any individual group member.[974] Obviously, the likelihood that such a creative synthesis will occur depends upon the level of energy that the Work Group members put into the effort.[975] Members of the Work Groups do not actually engage in gathering data and drafting documents, tasks that are normally the responsibility of the lead office. Instead, Work Group members comment upon and critique documents that others draft.[976]

Some Work Groups are more active than others. For example, the Work Groups that prepare the decision packages for the National Ambient Air Quality Standards meet very infrequently. Most of the real drafting and analytical work is done by informal groups composed of staff from the Ambient Standards Branch and personnel from other parts of the agency who may or may not be members of the Work Group. Several of these informal

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973 Procedures Memo, supra note 822, at 4.

974 Kuzmack Interview, supra note 790.

975 Kuzmack Interview, supra note 790.

976 Comments of Mr. Arnold Kuzmack, Director, Office of Program Development and Evaluation, Office of Drinking Water, Office of Water, EPA, on an earlier draft of this Report, August 27, 1984 [hereinafter cited as Kuzmack Comments].

groups may be assembled to work on different aspects of a single rule. Official Work Group meetings are called largely to ratify the work of the informal groups.[977]

Similarly, the Work Groups that meet on New Source Performance Standards and National Emissions Standards for Hazardous Air Pollutants are not very active. The Work Group for a standard does not meet until after the program office has studied the available technologies and reached a preliminary conclusion. The Work Groups provide little policy input and they do not provide options beyond those already identified by the program office. The Work Groups are useful, however, in identifying potential conflicts among programs and thereby avoiding unnecessary inconsistencies.[978] Work Group meetings for the technology-based Effluent Guidelines and Limitations that the Office of Water Regulations and Standards promulgate follow a similar sporatic pattern.[979] The Work Groups for these standards may lack influence because the standards apparently lack a high priority with the Office of Policy, Planning and Evaluation. That Office rarely sends a participant to the Work Group meetings until after the program office has nearly completed the drafting and analysis.[980]

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977 Thomas Interview I, supra note 780.

978 Ajax Interview, supra note 849.

979 DuPuis Interview, supra note 793.

980 Ajax Interview, supra note 849.

c. The Development Plan.

For all major and significant regulations, the first task of the Work Group is to draft a "Development Plan."[981] Although the Development Plan is the responsibility of the Work Group, the lead office actually drafts it and makes most of the important decisions that go into it. [982] The drafters must ensure that:

(1) the plan states the need for the regulation and identifies its goals and objectives;[983]

(2) the plan discusses the prima facie reasonable, legal, and technically feasible options;[984]

(3) the plan identifies any alternatives that may be environmentally or administratively preferable, or more cost-effective, but that currently cannot be considered because they are precluded under existing law;

(4) the plan specifies any generic decision rules drawn from current or historical Agency policy that will be used to choose among the options;[985]

(5) The plan presents a work plan for developing the regulation that outlines, as appropriate:

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981 Procedures Memo, supra note 822, at 6.

982 Fiorino Interview I, supra note 813.

983 Guidelines Memo, supra note 823, at 4.

984 The options discussed must include (a) no action; (b) alternatives to Federal regulation, including market, judicial, or state or local regulatory mechanisms; and (c) alternatives within the scope of the action's legislative provision, including degree of control, effective compliance dates, and methods of ensuring compliance. Criteria and Guidelines Memo, supra note 823, at 4.

985 The memorandum cites as an example the fact that certain generic forms of regulations have historically been compared on the basis of the cost per pound of pollutants reduced. Criteria and Guidelines Memo, supra note 823, at 4.

-- the areas that projected analyses will cover, including, as applicable: health and environmental risks, benefits, economic impacts, effects on small entities, paperwork and recordkeeping burdens, and the potential for fraud, waste, or mismanagement;

-- the major areas of technical uncertainty, and how [the agency] plan[s] to resolve them;

-- the major tasks that will be performed -- from the first Work Group meeting to the final promulgation of the regulation -- and milestones for each task;

-- the Agency offices -- including EPA Regional Offices -- that will participate in developing the rule, and the choice of the Work Group chairperson;

-- other agencies, States, and others that will be involved in developing the regulation, and the nature of their involvement;

-- the mechanisms for communicating with participants external to the Agency, other affected parties, and the general public during the regulatory development process; and

-- the Agency personnel and contract resources that will be necessary to develop the regulation.[986]

The Procedures Memorandum stresses that "[i]t is especially important that the plan present a broad array of options for management to consider in determining the most effective way to meet [the agency's] regulatory obligations."[987]

Since the implementation of the Options Selection/Rejection Process, the Development Plan is not viewed as critical documents by the Office of Policy, Planning and Evaluation.[988] The Development Plan is now viewed as

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986 Criteria and Guidelines Memo, supra note 823, at 4-5.

987 Procedures Memo, supra note 822, at 6.

988 Sessions Interview, supra note 801.

a vehicle for raising relatively minor issues that require familiarity with technical details, rather than as a place to raise and discuss broad policy options. Although the lead analyst from the Office of Policy Analysis reviews the Development Plan, only about twenty percent of the Development Plans get much serious attention from that Office.[989] By contrast, all of the Options Selection/Rejection Memoranda receive considerable attention in the Office of Policy Analysis.[990]

After the Work Group has completed the Development Plan, it must submit it to the Steering Committee for review and approval. Although consensus in the Steering Committee is not necessary to approve a Development Plan, it must be approved by the Committee's chairman, who is normally the Director of the Office of Standards and Regulations in the Office of Policy, Planning and Evaluation. In addition, Development Plans for "major" rules must be approved by the Assistant Administrator for Policy, Planning and Evaluation. Yet while a member of the Steering Committee occasionally requests the lead office to consider a particular issue or option,[991] Development Plans are almost never disapproved.[992] Like the Start Action Request, the Development Plan appears to be a procedural device for informing other program offices and upper level decisionmakers, rather than a substantive decisionmaking tool.

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989 Sessions Interview, supra note 801.

990 Sessions Interview, supra note 801.

991 Fiorino Interview I, supra note 813.

992 Fiorino Interview I, supra note 813.

d. The First Options Review Meeting.

For all Level I rules the lead office must prepare an Options Memorandum for the first Level I Options Review Meeting and circulate it to the members of the committee at least ten days prior to the scheduled options review meeting. The precise timing of the first Options Review Meeting is somewhat flexible. It must occur early enough in the rulemaking process that options are realistically available to the program office. Yet it must not occur until after the Work Group has had an opportunity to analyze the problem and the existing data sufficiently to crystallize the thinking of its members. There may, in addition, be more than one Options Review Meeting prior to the promulgation of the proposed rule if other issues needing high level input arise during the Work Group's deliberations.[993]

The Options Memorandum must analyze each of the options identified in the development plan. The lead office must, to the extent possible, ensure that:

1. The analyses are based on the best data available within the constraints of the decision schedules, taking into consideration:
   -- uncertainties in the data;
   -- other technically sound scientific studies based on adequate peer review;
   -- anticipated requirements for further research; and
   -- adequate and appropriate statistical data.
2. The analyses consider all relevant health and environmental impacts, including primary and secondary impacts, cumulative

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993 Sessions Interview, supra note 801.

impacts, and short and long term impacts. Especially for major rules, the analyses should consider these impacts not only in qualitative terms, but -- where possible -- in quantitative and monetized terms as well.

3. The analyses consider the relevant economic impacts, such as:

   -- the effect on product prices, and overall economic output;

   -- the impact on foreign trade and competition;

   -- potentially disproportionate effects on small businesses; and

   -- potential effects on plant closures or employment.

4. The analyses take account of the reporting and recordkeeping burdens that the option entails.

5. The analyses consider the following issues related to implementation:

   -- the resources required for implementation and enforcement;

   -- the enforceability of the option;

   -- the degree to which the option allows for flexibility in achieving compliance and

   -- the potential inherent in the option for fraud, waste, or mismanagement in practice.

6. The analyses assess impacts on other regulatory programs -- both within and beyond the Agency -- and overall consistency with Agency policy and regulatory strategy.[994]

The goal of the options identification process is to identify several options (perhaps six or seven) that the upper level policymakers can narrow to a smaller range of options (perhaps three or four) for consideration in detail prior to the publication of the Notice of Proposed Rulemaking.[995]

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994 Criteria and Guidelines Memo, supra note 823, at 5-6.

995 Fiorino Interview I, supra note 813.

The program office staff attempts to identify and explain a broad range of options without going into such an extensive explanation of any particular option that the upper level decisionmakers get bogged down in the details.[996] On some occasions, however, the available range of options is quite limited, and the Options Review Meeting is essentially limited to choosing between the option of going forward with a proposed rule and the option of doing nothing.

Although any member of the Work Group may suggest options for the Options Memorandum, the lead office staff in practice identifies most of the options. Since the drafter of the Options Memorandum is almost always a member of the lead office technical staff, that person has the first opportunity to identify options. This first cut at options identification is generally based upon the judgment and prior experience of the scientists and engineers on the technical staff.[997] Additional options may arise out of formal or informal interchanges between the technical lead office staff and the regulatory analysts in the lead office.[998] The regulatory analysts attempt to make the technical staff aware of the kinds of options and arguments that the Office of Policy Analysis will raise at the Work Group meetings.[999]

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996 Ruhter Interview, supra note 788.

997 Tonetti Interview, supra note 865; Ruhter Interview, supra note 788.

998 Shapiro Interview, supra note 785; Ruhter Interview, supra note 788; Kuzmack Interview, supra note 790.

999 Ruhter Interview, supra note 788.

The analysts in the lead office can come up with new ways of examining a problem or of looking at options that the scientists and engineers in the office did not envision.[1000] In the Office of Hazardous Waste, for example, the regulatory analysts suggested that the technical staff make more explicit use of risk assessment techniques and benefits analysis.[1001] In the Office of Toxic Substances, where the lead office staff meets as a team to formulate the lead office's position on issues, the team meetings can serve as brainstorming sessions for coming up with new options and ideas.[1002] In the Office of Air Quality Planning and Standards, where the relationship between the regulatory analysts and the technical staff is somewhat distant, the lead office regulatory analysts play very little role in identifying options.[1003] Although the lead office regulatory analysts interviewed for this report could think of one or more instances in which they identified unique options that had escaped the attention of the

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1000 Shapiro interview, supra note 785; Tonetti Interview, supra note 865; Ruhter Interview, supra note 788.

1001 Ruhter Interview, supra note 788. In another case the regulatory analysts suggested that a particular standard for hazardous waste facilities be tailored to individual facilities through the permit process, so as to afford maximum flexibility for considerations of location, nature of waste, etc. Tonetti Interview, supra note 865.

1002 Shapiro Interview, supra note 785. For example, at the suggestion of its regulatory analysts, the Office considered a "marketable permit" approach for phasing out asbestos use. Shapiro Interview, supra note 785; Stasikowski Interview, supra note 859.

1003 Basala Interview, supra note 807. Once again, the relative absence of regulatory analysis office input in the options identification process for National Ambient Air Quality Standards may stem from the fact that the agency is probably not empowered to consider options that are dictated by control cost or other economic considerations.

technical staff, in most cases technical judgment and experience seem to dominate the options identification effort.

Once the lead office has identified a set of options, it shares them with the Work Group and encourages its members to comment upon those options and to suggest further options. In practice, the members of the Work Group are more useful in reviewing the options that have already been identified than in identifying fresh options.[1004] The representative from the Office of Policy, Planning and Evaluation on the Work Group will occasionally suggest an option that the lead office had not identified.[1005] The extent to which the lead analyst on the working group will expend time and intellectual effort searching for additional options depends upon the importance of the rule and the speed with which the agency must proceed with the rulemaking process.[1006] Since the lead analysts have a limited amount of time to devote to any single rule, they tend to focus their efforts on persuading the lead offices to think in broader terms and to identify more options, rather than suggesting their own options to the Work Group.[1007]

The regulatory analyst in the Office of Policy, Planning and Evaluation can play a very large role in identifying and analyzing options for rules

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1004 Fiorino Interview I, supra note 813; Kuzmack Interview, supra note 790. ("Options get argued about in the working group; they rarely get introduced into the working group.")

1005 Cristofaro Interview, supra note 803; Nichols Interview, supra note 804.

1006 Napolitano Interview, supra note 883.

1007 Fiorino Interview I, supra note 813, Kuzmack Interview, supra note 790.

that originate in programs that do not have a separate staff of regulatory analysts. Since the Office of Mobile Sources in the Office of Air and Radiation, for example, lacks a separate regulatory analysis staff, the lead analyst on the Working Group from the Office of Policy, Planning and Evaluation of necessity played a major role in suggesting options for the lead phasedown regulation.[1008]

After all of the Offices that are represented on the Work Group have had an opportunity to comment on the advantages and disadvantages of the available options, the lead office drafts the Options Memorandum. This document lists the options, summarizes the arguments for and against each option, and states the position of each office on each option.[1009] Occasionally, however, a program will not be receptive to options that the Office of Policy Analysis suggests and will omit it from the Options Memorandum.[1010] When this happens, the Office of Policy Analysis may write its own options memorandum to use at the Steering Committee or the Level I Options Review Committee.[1011] This happens approximately ten percent of the time.[1012]

1008 See Lead Phasedown Case Study, Appendix B. Other offices that lack an independent regulatory analysis capability include the Office of Radiation Programs and the Office of Emergency Response.

1009 Sessions Interview, supra note 801.

1010 For example, the Office of Air Quality Planning and Standards is fairly protective of its right to draft the options paper and, in the
(Continued on page 315)

1011 Cristofaro Interview, supra note 803; Sessions Interview, supra note 801.

1012 Sessions Interview, supra note 801.

At the Options Review Meeting, the high level participants "attempt to agree on which options to retain for further development and which to reject."[1013] The Options Review Meeting is also an appropriate place for an Office to suggest an option that the program office rejected or otherwise failed to include in the options memorandum.[1014] The participants at the meeting, which include the relevant Assistant Administrators and the Deputy Administrator, can then decide whether the lead office should analyze and consider the neglected option. Before the Assistant Administrators commit themselves to engage in a debate before the Deputy Administrator over the failure of the lead office to include an option in the Options Memorandum, they will usually instruct their staffs to attempt to work out their differences, and the Assistant Administrators themselves may meet with each other to arrive at a solution. At this stage of the process, compromise is not normally difficult, because a decision to include an option in the Options Memorandum merely allows the Deputy Administrator to consider the option; the lead office may still argue that the option should be rejected.

The more serious discussion at the first Options Review Meeting concerns the selection of three or four options from among the options

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(Continued from page 314)
1010 opinion of the Office of Policy Analysis, generally unreceptive to listing innovative options from the Office of Policy Analysis. Cristofaro Interview, supra note 803.

1013 Procedures Memo, supra note 822, at 7.

1014 Fiorino Interview II, supra note 798.

listed in the Options Memorandum.[1015] This meeting is one early forum in which the Office of Policy Analysis, which is designed to be the institutional skeptic, can raise questions about the substantive advantages and disadvantages of the regulatory options that the program office selects. Since "do nothing" is nearly always one of the options this meeting also presents an opportunity for the Office of Policy Analysis to question the need for any regulation at all.

In approximately fifty percent of the meetings, the Office of Policy Analysis will take a position that varies from that of the program office in "some fairly major way."[1016] If the disagreement is strong enough, the staff of the Office of Policy Analysis will draft a separate memorandum for the meeting that sets out the nature of the disagreement.[1017] The debate, however, is rarely acrimonious at this stage. A decision to consider an option further is merely a decision to devote analytical resources to the study of that option; it is not a decision that the agency should select that particular option.[1018] Debates about whether to pursue an option further are most likely to arise when the program office maintains that it

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1015 Cristofaro Interview, supra note 803; Sessions Interview, supra note 801. See. e.g., Policy Hits Air Office Plan to Try State/TSLA Controls on Acrilonitrile, Inside EPA, June 8, 1984, at 11 (detailing dispute between policy office and program office on options for reducing airborne exposure to acrilonitrile).

1016 Sessions Interview, supra note 801.

1017 Sessions Interview, supra note 801.

1018 The Acting Director of the Regulatory Policy Division of the Office of Policy Analysis estimates that the Office of Policy Analysis wins approximately half of the battles over the appropriate options to select and reject. Sessions Interview, supra note 801.

lacks the authority to choose that option. In such cases the program office is reluctant to expend analytical resources in a futile effort to study an impossible option.[1019]

By contrast, it is also possible that the lead office has so effectively managed the Work Group process that the Options Review Meeting becomes a "love-in" where no serious debate takes place about the options that should be rejected and those that should be pursued. This, however, does not happen very often.

If the Options Review Committee cannot reach consensus, the dissenters may present recommendations in writing to the Assistant Administrator for Policy and Planning and Evaluation within one week. The Assistant Administrator is responsible for drafting a "closure" memorandum to document the results of the meeting. The closure memorandum also serves as a vehicle for raising disagreements for resolution by the Deputy Administrator that were not resolved at the Options Review Meeting.[1020] There is some tendency among agency personnel to treat the closure memorandum as a "legal document" that seals the agency's position. Not surprisingly, this has on occasion shifted the nature of the dispute between two offices from one of policy and technical analysis to one of interpretation.

1019 See, e.g., Alm to Decide Risk Assessment Funding Squabble on Waste Tank Regs, Inside EPA, June 29, 1984, at 3 (debate between Office of Solid Waste and Emergency Response and Office of Policy, Planning and Evaluation over whether a risk assessment for technology-based regulations should be prepared and, if so, who should pay for it).

1020 Procedures Memo, supra note 822, at 7.

The agency has experienced a few problems with differing interpretations of closure memoranda. On some occasions, each side to a debate has read the closure memorandum to seal a victory for its point of view.[1021] On other occasions, one office disagrees with the closure memorandum's interpretation of the outcome of the meeting.[1022] The fact that the Office of Policy, Planning and Evaluation is charged with drafting the closure memorandum exacerbates the problem, because that office is often an active participant in the debates before the Options Review Committee. The Office attempts to reduce this potential conflict of interest by giving responsibility for drafting the closure memorandum to the Regulation and Information Management Division of the Office of Standards and Regulations in the Office of Policy, Planning and Evaluation. This Division rarely plays an advocacy role in agency deliberations. Its function is merely to ensure that the various agency rulemaking participants prepare the appropriate documents and that the various packages of documents are circulated properly. Assigning the job of drafting the closure memorandum to this purely ministerial Division reduces the potential for bias.[1023]

While the Options Review Meeting is very effective in selecting a few options from among the options suggested by the Working Group for more intense analysis, the participants at those meetings rarely identify new

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1021 Wolcott Interview, supra note 928.

1022 Wolcott Interview, supra note 928.

1023 Campbell Interview, supra note 766.

options that the Working Group participants had failed to find.[1024] The meeting can result in the selection of variations of one or more of the suggested options,[1025] but at times such variations are little more than "window dressing."[1026]

Occasionally, the Options Review Meeting can reveal gaps in the available information that are so substantial that the Deputy Administrator determines that the Work Group should make additional data gathering efforts before the upper level decisionmakers further narrow the options.[1027] In these relatively rare instances, the matter is "remanded" to the lead office, and the Options Selection/Rejection Process goes through another iteration after the Work Group has assembled further information.[1028]

The Work Group itself serves as the Options Review Committee for Level II rules. Since the Options Selection/Rejection Process is therefore an ongoing process, the Work Group does not prepare a formal Options Memorandum. When it submits its final decision package for Steering Committee and Red Border review,[1029] however, the lead office must include

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1024 Stasikowski Interview, supra note 859; Shapiro Interview, supra note 785.

1025 Wolcott Interview, supra note 928; Fiorino Interview I, supra note 813.

1026 Stasikowski Interview, supra note 859.

1027 Fiorino Interview I, supra note 813; Wolcott Interview, supra note 928.

1028 Fiorino Interview I, supra note 813; Wolcott, Interview, supra note 928.

1029 Red Border review is discussed at text accompanying notes 1141-1143, infra.

a summary of the options that the Work Group considered and rejected, stating when and why each was rejected.[1030] If a Work Group member believes that the group has prematurely rejected an option, he or she must first attempt to resolve the disagreement with the lead Assistant Administrator. Failing this, he or she must communicate the disagreement to the Steering Committee for resolution by that body.[1031] The Steering Committee will then hold an Options Review meeting and attempt to resolve the disagreement. If the Steering Committee fails to achieve consensus, it must refer the matter to the Deputy Administrator and the relevant Assistant Administrators for resolution.[1032]

Upper level agency management personnel believe that the Options Selection/Rejection Process has been successful in incorporating comprehensive analytical thinking into the agency decisionmaking process.[1033] By giving the regulatory analysts and the technical staff a "day in court" before the highest level agency decisionmaker early in the process while many options are still alive, it interjects a "creative" adversarial note into the agency deliberations. Mixing the Options Selection/Rejection Process with the team approach takes away some of the

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1030 Procedures Memo, supra note 822, at 7.

1031 The lead analyst for the rule from the Office of Policy Analysis is responsible for periodically reporting to the Steering Committee on the progress of the Level II rule, the options that the working group has considered, and the options that it has retained or rejected. Procedures Memo, supra note 822, at 7.

1032 Procedures Memo, supra note 822, at 7.

1033 Wolcott Interview, supra note 928; Campbell Interview, supra note 766.

pressure towards consensus that characterizes that approach without requiring much duplication of effort. The regulatory analysts in the Office of Policy Analysis can play their role of "institutional skeptic"[1034] without too great a risk of paralyzing the process.[1035]

The designers of the process also believe that it avoids the obvious risk of alienating the technical staff in the program offices in the agency, because the Deputy Administrator carefully hears both sides of all arguments before deciding one way or another. He often decides issues in the presence of the staff, and not later after an opportunity for "insider" lobbying.[1036] Finally, to the extent that the Deputy Administrator is a proponent of comprehensive analytical rationality, the Options Selection/Rejection Process can move the agency toward that way of thinking and away from techno-bureaucratic rationality.[1037] The essence of the Options Selection/Rejection Process is that it gives upper level decisionmakers greater input into the decisionmaking process at an early stage. The content of that input, which can obviously be very influential in the Work Group meetings that follow, depends upon the policy preferences of the Deputy Administrator.

1034 See text accompanying notes 1406-1412, infra.

1035 Wolcott Interview, supra note 928.

1036 Wolcott Interview, supra note 928. There is evidence in interviews with staff-level technical personnel that the effort that the Deputy Administrator puts into the process and its openness have thus far been successful in avoiding the risk of alienation.

1037 On the other hand, if the Deputy Administrator is more of a techno-bureaucratic thinker, the process can move the agency in that direction. Wolcott Interview, supra note 928.

e. The Preliminary Regulatory Analysis Document.

In those offices that have separate regulatory analysis staffs, the task of drafting the regulatory analysis documents usually devolves to that staff. It is unclear whether the agency created separate lead office regulatory analysis staffs in response to the regulatory analysis requirements of the Executive Orders or in response to an independent institutional desire to incorporate regulatory analysis and cost considerations more thoroughly into the decisionmaking process. In any event, the agency decided in the mid-1970s to decentralize the regulatory analysis staff and to give the program offices the primary responsibility for supervising regulatory analysis contracts and for drafting regulatory analysis documents. For program offices with more than one group of regulatory analysts, the task is split between the groups.

A very high proportion of the economic impact information that is used in regulatory analysis documents in EPA is produced by independent contractors working under the supervision of personnel in the regulatory analysis suboffices of the program offices.[1038] The agency relies less extensively, but still heavily, upon independent contractors for benefits analysis. The reason for this heavy reliance upon outside contractors appears to be the fact that "extramural dollars are easier to obtain than [full time equivalent staff]."[1039] The regulatory analysts in the program

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1038 Task Force Memo, supra note 765, at 3 ("EPA does virtually all economic analysis through contractors . . ."); Conflict of Interest Hearings, supra note 323, at 690 (testimony of Ms. Barbara Blum,

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1039 Task Force Memo, supra note 765, at 3.

offices incorporate the information from the contractors' reports into the agency's regulatory analysis documents.

i. The Office of Air Quality Planning and Standards.

(I). National Ambient Air Quality Standards.

The agency prepares a formal RIA for every National Ambient Air Quality Standard.[1040] By convention, each RIA for a National Ambient Air Quality Standard has seven parts -- (1) Statement of Need; (2) Alternatives; (3) Benefits; (4) Costs; (5) Economic Impacts; (6) Benefit-Cost Analysis; and (7) Rationale. While the regulatory analysts in the Ambient Standards Branch have the ultimate responsibility for the entire RIA,[1041] that staff actually drafts only sections (1), (2), (4) and (7). Regulatory analysts in the Regulatory Impact Section of the Economic Analysis Branch draft the remaining sections, subject to review by the regulatory analysts in the Ambient Standards Branch.[1042]

Historically, there has been a great debate within the agency over the extent to which it may explicitly consider costs, economic impacts, and benefits in promulgating National Ambient Air Quality Standards. With the

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1038 then-Deputy Administrator, EPA.) ("Almost 95% of these analyses have some consumer assistance.")

1040 Basala Interview, supra note 807.

1041 Thomas Interview I, supra note 780; Basala Interview, supra note 807.

1042 Basala Interview I, supra note 781; Thomas Interview I, supra note 807.

promulgation of the Executive Orders requiring Inflation Impact Statements and Regulatory Analyses, the agency began to attempt to calculate the costs and economic impacts of the standards. The engineers and economists in the Strategies and Air Standards Division have developed sophisticated models to predict the restrictions that the states will impose to meet the alternative standards and the costs of those controls.[1043] Another set of economists and financial analysts then takes the cost data and predicts the economic impact of the standard in terms of inflation, plant closings, and so on.

All of this economic impact analysis is done fairly late in the standard-setting process after the staff paper has been prepared and the Work Group has commenced its deliberations.[1044] Not surprisingly staff economists are not anxious to undertake the elaborate modeling effort that is required to obtain some sense of the costs of implementing regulatory options until the health scientists and upper level decisionmakers have narrowed down the range of options that must be analyzed.[1045]

1043 Thomas Interview I, supra note 780. One of these models for the recently proposed particulate matter standard relies upon elaborate inventories of all sources of a pollutant in thousands of counties across the country. This gives the agency an idea of how much the ambient levels of the pollutant will have to be reduced to meet various standards. The agency, however, has no way of knowing how individual states will attempt to implement the standards. It solves this problem with an elaborate model that assumes that each state will implement the least cost strategy in its State Implementation Plan. The model thus predicts for each source in the inventory the technology that will have to be implemented and the cost of installing
(Continued on page 325)

1044 Thomas Interview I, supra note 780.

1045 Comments of Mr. Henry Thomas, Ambient Standards Branch, Strategies and Air Standards Division, Office of Air Quality Planning and Standards,
(Continued on page 325)

With the advent of Executive Order 12291, the Office has expanded the regulatory analysis documents for National Ambient Air Quality Standards to include a benefits analysis and a cost-benefit comparison.[1046] For the two most recent standards revisions on particulates and sulfur dioxide, the Office of Air Quality Planning and Standards has attempted to regularize the process of analyzing the benefits of the proposed standards. This has lead to some internal dissatisfaction as the Regulatory Impact Section of the Economic Analysis Branch, which is responsible for preparing these analyses, has attempted to involve itself in the decisionmaking process at an early enough stage that it can have some say in the data-gathering process.[1047]

The staff of the Regulatory Impact Section feels severely handicapped by the fact that it does not become involved in the standard-setting process until a relatively late date, after the Ambient Standards Branch has already assembled most of the information relevant to the pollutant's health

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1043 that technology. Thomas Interview I, supra note 780. The agency has developed models of similar complexity for other ambient air quality standards.

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1045 Office of Air and Radiation, EPA on an earlier draft of this report, August 16, 1984 [hereinafter cited as Thomas Comments].

1046 Thomas Interview I, supra note 780. Because this change was implemented midway through the standard setting process for two of the most recent standard revisions, the agency did not attempt a thorough benefits and cost-benefit analysis for those standards. The agency relied instead upon "back-of-the-envelope" calculations. OMB approved this patchwork approach after EPA promised to undertake a more thorough benefits and cost-benefit analysis in the future. Basala Interview, supra note 807.

1047 Basala Interview, supra note 807.

effects.[1048] The Regulatory Impact Section feels that it is "cut out" of the early "problem characterization" stage of standard development, where it could have some input into the way that the agency goes about gathering data for standards and standard revisions.[1049] The net result is that the benefits and cost-benefit analyses are not generally available to the Work Group and the upper level decisionmakers in the Options Selection/Rejection Process until fairly late in the life of a standard when some options are already foreclosed.[1050]

It is not clear how much of this failure to integrate the regulatory analysts in the Regulatory Impact Section into the standard setting process is attributable to the ambiguity of its function and how much is attributable to the resistance of personnel in the Ambient Standards Branch to benefits analysis and cost-benefit analysis. One analyst in the Ambient Standards Branch denies that the personnel in the Ambient Standards Branch

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1048 Basala Interview, supra note 807.

1049 Basala Interview, supra note 807

1050 A panel discussion of personnel from the Office of Policy, Planning and Evaluation reached a similar conclusion in its report to the agency's Task Force on Analytical Resources:

> The panel observes that the pressure to get rules up to the Assistant Administrator on deadline, combined with the organizational segregation of the economic staff, leads to poorer integration of economic analysis into the reg[ulation] development process than is desirable. The most visible problem in this regard, in the panel's view, is that regulatory options are prepared without the counsel of economic analysis, forcing economic analysis of alternatives chosen on exclusively engineering criteria.

Task Force Panel Transcripts, supra note 765, at 1.

are opposed to using benefits analysis in setting Primary National Ambient Air Quality Standards.[1051] He does, however, acknowledge that much of the current disputes may be attributable to a "difference in outlook of health scientists and economists."[1052] The chief economist in the Regulatory Impact Section likewise attributes the poor relationship to a difference in perspective. He views cost-benefit analysis as an essential aspect of rational decisionmaking, while the health scientists in the program office, in his opinion, view analysis as a "necessary evil."[1053] It is, of course, possible that both parties to the dispute are correct, and they simply have different conceptions of the meaning of "regulatory analysis."

Drafts of the various sections of the RIAs are circulated to Work Group members as they are completed, and the Work Group and other informal groups are aware of their contents as they discuss the standard. The completed RIAs, however, are rarely finalized until after the Work Groups have essentially finished their deliberations.[1054] The staff feels no urgency

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1051 Thomas Interview II, supra note 780. The current agency policy appears to be that it cannot consider cost analysis and benefits analysis for either primary or secondary National Ambient Air Quality Standards. See text accompanying notes 1327-1330, infra. OMB and the Regulatory Impact Section of the Economic Analysis Branch believe that the agency may lawfully consider benefits in setting primary standards and costs and benefits in setting secondary standards. Basala Interview, supra note 807. One regulatory analyst in the Ambient Standards Branch believes that there is room for benefits analysis in
(Continued on page 328)

1052 Thomas Interview I, supra note 780.

1053 Basala Interview, supra note 807. As previously mentioned, the chief analyst in the Ambient Standards Branch feels that the technical
(Continued on page 328)

1054 Cristofaro Interview, supra note 803.

to complete the documents prior to the publication of the Notice of Proposed Rulemaking, because they know that the Administrator will not review that document.[1055]

(II). New Source Performance Standards.

The agency does not prepare a separate regulatory analysis document for any of its New Source Performance Standards, because very few of those standards cross the relevant thresholds.[1056] The agency does, however, prepare an economic impact assessment for all New Source Performance Standards.[1057] The engineers in the Emission Standards and Engineering Division do the surveys necessary to determine what pollution control technologies exist and to ascertain the costs of those technologies. The engineer economists in the Economic Analysis Branch of the Strategies and Air Standards Division then hire contractors to gather additional economic and financial information on the sources in the regulated categories and to

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1051 setting both primary and secondary National Ambient Air Quality Standards. Thomas Interview I, supra note 780.

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1053 personnel in that branch have a high opinion of regulatory analysis. Thomas Interview II, supra note 780.

1055 Cristofaro Interview, supra note 803. See text accompanying notes 1327-1330, infra.

1056 Ajax Interview, supra note 849.

1057 Ajax Interview, supra note 849.

assess general economic status of the industry.[1058] With the combined data, the Economic Analysis Branch prepares an economic analysis that assesses the impact of the standard on the profits and capital requirements of the regulated sources, employment effects, and other general economic impacts. This economic analysis becomes one of nine chapters in the large background document that the agency prepares to support the rule.[1059] The agency feels that the background document is the functional equivalent of an RIA or RFA, and OMB has not objected to this procedure.[1060]

Since its task is to identify feasible control technologies for new air pollution sources, economic impact analysis is clearly relevant to the decision. The engineers in the Standards Development Branch of the Emissions Standards and Engineering Division are therefore quite receptive to the input of the Economic Analysis Branch of the Strategies and Air Standards Division on the question of economic impact.[1061] But the statute does not require the agency to compare the costs of installing the technology to its benefits. Therefore, the agency does not routinely prepare a benefits analysis for New Source Performance Standards.

1058 Wehe Interview, supra note 781. For the most part the Economic Analysis Branch and its contractors can rely on existing economic studies in preparing economic impact assessments. In addition, the Branch coordinates at an early date with the Emission Standards and Engineering Division in drafting the questionnaires for the industry survey that the agency conducts for most New Source Performance Standards. Wehe Interview, supra note 781.

1059 Ajax Interview, supra note 849; Wehe Interview, supra note 781.

1060 Ajax Interview, supra note 849.

1061 Basala Interview, supra note 807; Ajax Interview, supra note 849.

Nevertheless, in the spirit of Executive Order 12291, the agency has prepared a benefit analysis for one of its forty pending New Source Performance Standards.[1062] In addition the Regulatory Impact Section of the Economic Analysis Branch is working together with the Benefits Branch of the Economic Analysis Division of the Office of Policy Analysis to provide "generic" benefits analyses that place a dollar value on the general benefit of removing a ton of a particular pollutant from any emissions source.[1063] It remains to be seen whether the agency will adopt this generic benefits analysis to guide its selection of pollution reduction technologies in the future.

(III). National Emissions Standards for Hazardous Air Pollutants.

The Standards Development Branch of the Emissions Standards and Engineering Division goes about setting National Emissions Standards for Hazardous Air Pollutants in much the same way that it goes about setting National Ambient Air Quality Standards, except that the standard setting process must include a risk analysis to support the agency's statutory finding that the standard will protect the public health with an ample

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1062 Ajax Interview, supra note 849. The standard for which the agency has decided to prepare a benefits analysis is the New Source Performance Standard for Industrial Boilers, one of the most expensive new source performance standards that EPA has ever promulgated. Luken Comments, supra note 961.

1063 Ajax Interview, supra note 849; Luken Interview I, supra note 903; Nichols Interview supra note 804. The agency has recently begun a similar quantitative effort with respect to the pollutants NOx and VOC. Luken Comments, supra note 961.

margin of safety.[1064] Although this risk analysis could be converted to a benefits analysis by monetizing the interests at risk, the agency has only very rarely prepared a benefits analysis.

(IV). Summary.

Although a cost-benefit analysis is required by Executive Order 12291, the Division has made very little attempt to incorporate benefits analysis into the decisionmaking process. A small staff in the Economics Analysis Branch has in the last four years begun to work on benefits analysis for National Ambient Air Quality Standards, New Source Performance Standards and National Emissions Standards for Hazardous Air Pollutants,[1065] but its input has historically been entirely ad hoc. The failure to prepare benefits analysis is attributable to at least five factors: (1) the relative novelty of the requirement; (2) the inherent analytical difficulties involved in calculating the benefits of a technology-based standard that can be implemented in hundreds of plants spread throughout the country; (3) the general unreceptivity of the engineers in the program office to such analysis; (4) the considerable doubts within the agency (and

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1064 Ajax Interview, supra note 849. The risk analysis has several components. First, the Standards Development Branch assembles data on the sources that emit the hazardous pollutant, including information on emission strength, stack height, and stack configuration. This information is fed into a dispersion model to arrive at exposure estimates. The information from the epidemiological and laboratory animal studies on the health effects of the chemical are then combined with the exposure estimates to arrive at an overall risk assessment. Ajax Interview, supra note 849.

1065 Ajax Interview, supra note 849; Basala Interview, supra note 807.

especially within the Office of General Counsel) about the extent to which benefits analysis can legally play a role in the decisionmaking process concerning air pollution control; and (5) the apparent split among top decisionmakers about the usefulness of such analysis.

ii. The Office of Toxic Substances.

Although the Office of Toxic Substances rarely promulgates a rule that meets the RIA or RFA threshold criteria,[1066] it prepares some kind of regulatory analysis document for all of its substantive rules.[1067] The Economics and Technology Division, one of six Divisions in the Office, does the regulatory analysis work for the entire office.[1068] The regulatory analysis document is usually an elaboration upon the documents that the Office has already prepared for purposes of internal review and the Options Selection/Rejection Process.[1069] This means that as a practical matter the agency begins gathering information for the regulatory analysis document at a very early stage in the process, often prior to the Start Action Request.[1070] Both the internal Office of Toxic Substances team and the external Working Group generally receive a continuous stream of memoranda

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1066 Toxic Substances Appendix to Task Force Report, supra note 765, at 2.

1067 Shapiro Interview, supra note 785; Jennings Interview, supra note 820.

1068 Shapiro Interview, supra note 785; Stasikowski Interview, supra note 859.

1069 Shapiro Interview, supra note 785.

1070 Shapiro Interview, supra note 785; Stasikowski Interview, supra note 859.

from the Economics and Technology Division on various economic aspects of regulatory alternatives.[1071] The formal preliminary regulatory analysis document is seldom completed prior to the time that the Work Group has finished with the proposed rule. Indeed, the preparation of the full-fledged regulatory analysis document is often the last part of the decision package to be completed, and it can delay the process of circulating the package.[1072]

For section 4 testing rules and section 5 orders, the information for the economic analysis comes largely from the manufacturers of the chemical at issue, supplemented by a variety of sources of market and economic data. For section 6 rules regulating aspects of the manufacture, processing or use of existing chemicals, the information can come from the manufacturers, outside sources (such as university and government laboratories), section 8(a) information-collection rules, and industry surveys. For larger rules, the Economics and Technology Division will frequently employ contractors to aid in its assessments of the cost of alternative regulatory approaches. When it relies on contractors, the Division usually begins working with the contractor prior to the Start Action Request.[1073]

iii. The Office of Solid Waste.

The Office of Solid Waste prepares a cost and economic impact

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1071 Shapiro Interview, supra note 785; Stasikowski Interview, supra note 859.

1072 Stasikowski Interview, supra note 859.

1073 Shapiro Interview, supra note 785.

assessment for virtually all of the rules that it promulgates, but it undertakes a full benefits analysis only for major rules as defined by Executive Order 12291.[1074] The Economic Analysis Branch of the Waste Management and Economics Division begins assembling information on costs and benefits at the same time that the engineers begin gathering information on feasible technologies. This is usually at about the time that the Start Action Request is prepared.[1075]

The economists in the Economic Analysis Branch have had great difficulty in estimating the benefits of the standards that the Office promulgates. Much of the necessary information is simply beyond the technical capacity of the scientists and engineers.[1076] The Economic Analysis Division attempts to estimate the dollars expended per tumor avoided for some rules,[1077] but the analyses do not approximate the sophistication of the benefits analyses prepared in the Office of Air Quality Planning and Standards.[1078]

1074 Ruhter Interview, supra note 788. The analysts do not cost out tiny technical amendments to existing rules that have essentially no costs.

1075 Ruhter Interview, supra note 788.

1076 For example, estimating the benefits of alternative liners for hazardous waste disposal facilities requires the analyst to estimate the likelihood that each would leach, the likelihood that the resulting leachate would migrate, the likelihood that the leachate would contaminate underground water, the likelihood that the underground water would be used for drinking water, and the likelihood that the contaminated drinking water would cause adverse health effects. Estimating the probabilities and consequences of each of

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1077 Ruhter Interview, supra note 788.

1078 Luken Comments, supra note 961.

Analysts in the Office of Policy, Planning and Evaluation believe that officials in the program and regulatory analysis offices in the Office of Solid Waste have effectively resisted benefits analysis. Analysts in the Office of Solid Waste respond that while they do not attempt to quantify the value of a human life, they do calculate the benefits of solid waste regulations and attempt to express the benefits as an "implicit-cost-per-unit-case (of cancer)-avoided" basis. These calculations are used in internal agency briefings, but they are not published for public consumption,[1079] and they are apparently not circulated to The Office of Policy, Planning and Evaluation.

The Division is more confident in its ability to estimate the costs of its regulations. This is accomplished by surveying the regulated entities -- generators, transporters, and disposers of hazardous wastes -- and using economic models to extrapolate the costs to the relevant industries.[1080] Information on existing hazardous waste facilities is also available in the agency's files as a result of thousands of interim status permit applications that the agency received in late 1980s.[1081] The agency generally hires contractors to do this very expensive work. The Office of

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1076 these occurrences is so difficult and so clouded by uncertainties that an accurate benefits analysis is impossible to produce.

1079 Telephone Interview with Mr. Dale Ruhter, Chief, Economic Analysis Branch, Waste Management and Economics Division, Office of Solid Waste, Office of Solid Waste and Emergency Response, EPA, January 8, 1985, [hereinafter cited as Ruhter Interview II].

1080 Ruhter Interview, supra note 788.

1081 Sessions Interview, supra note 801.

Solid Wastes has spent millions of dollars on regulatory impact assessment efforts for a single rule.[1082] As in the Office of Toxic Substances, the regulatory analysis document itself is seldom completed before the rulemaking documents are finished.[1083] Nevertheless, the Economic Analysis Branch attempts to keep the Work Groups informed by preparing memoranda to the project officers as information becomes available.[1084]

iv. The Office of Drinking Water.

The Economic and Policy Analysis Branch of the Office of Program Development and Evaluation in the Office of Drinking Water prepares some kind of regulatory analysis document for every substantive rule.[1085] The sophistication of the analysis depends upon the significance that the Office attaches to the rule.[1086] While the Office promulgates very few, if any, "major" rules for purposes of Executive Order 12291, it prepares the substantial equivalent of a full-fledged RIA for most of the rules that it considers important.[1087] The Office began analyzing the benefits of its rules even before Executive Order 12291, but it has not reached any firm

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1082 Regulatory Reform Act: Hearings Before the Subcomm. on Administrative Law and Governmental Relations of the House Comm. on the Judiciary, 98th Cong., 1st Sess. 1617 (1983) [hereinafter cited as Hall Hearings].

1083 Ruhter Interview, supra note 788; Tonetti Interview, supra note 865.

1084 Ruhter Interview, supra note 788; Tonetti Interview, supra note 865.

1085 Kuzmack Interview, supra note 790; Vogt Interview, supra note 871.

1086 Kuzmack Interview, supra note 790.

1087 Kuzmack Interview, supra note 790.

conclusions about how to use benefits analysis in the decisionmaking process.[1088] Recognizing the limitations of formal cost-benefit analysis, the Economic and Policy Analysis Branch does not explicitly quantify the dollar cost of saving statistical lives.[1089] That Branch also funds extramural studies on general issues, such as the cost of various novel control technologies and the willingness of consumers to pay to remove contaminants from their water, that are germane to the Office's regulatory functions.[1090]

When the Economics and Policy Analysis Branch begins to work on a rule, it has available to it the "Technology and Cost Document" that the engineers in the Criteria and Evaluation Division have prepared with contractor support.[1091] The contractors conduct surveys to estimate the costs of drinking water treatment technologies and financial surveys to determine how much expense public water systems can afford.[1092] Objectivity in the cost surveys is enhanced by surveying vendors of contaminant removal technologies.[1093] The regulatory analysts in the Economic and Policy Analysis Branch see a draft of the Technology and Cost Document and comment

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1088 Kuzmack Interview, supra note 790.

1089 Kuzmack Interview, supra note 790.

1090 The Office has also funded a study on how communities have responded to contaminants in their water supplies. Kuzmack Interview, supra note 790.

1091 Kuzmack Interview, supra note 790.

1092 Kuzmack interview, supra note 790; Vogt Interview, supra note 871.

1093 Vogt Interview, supra note 871.

upon it.[1094] The Economic and Policy Analysis Branch then factors the information in the Technology and Cost Document into models that it has generated on the water supply industry to determine the economic impact of the control technologies that the Technology and Cost Document has examined.[1095]

All of this work is being done while the Work Group is meeting and examining regulatory options. A representative from the Economic and Policy Analysis Branch reports the results of its analyses to the Work Group as they become available. The Office attempts to "phase" the process so that the documents are finished as they are needed. For example, the Economic and Policy Analysis Branch attempts to finish its analysis of the economic impacts of the options that the Work Group has identified prior to the time that the first Options Selection/Rejection Meeting is held for Level I rules.[1096] The formal regulatory analysis document that becomes part of the public record, however, is seldom completed prior to the completion of the other rulemaking documents.[1097]

v. The Office of Water Regulations and Standards.

For "nonmajor" water Effluent Limitations and Guidelines, the Office of Water Regulations and Standards prepares four documents: (1) an engineering

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1094 Kuzmack Interview, supra note 790.

1095 Kuzmack Interview, supra note 790.

1096 Kuzmack Interview, supra note 790.

1097 Kuzmack Interview, supra note 790.

document that describes the alternative technologies available; (2) an economic analysis that describes the impact of requiring the regulated sources (including small entities) to install the various technologies; (3) an environmental assessment that broadly examines the effect of implementing the technologies on water quality in general; and (4) a cost-effectiveness document that compares the cost per ton of pollutant removal for the technologies at issue with the cost per ton of the technologies imposed by other rules. For "major" rules, the Office prepares two additional documents: (5) a benefits analysis that attempts to assess the benefits to receiving streams of reducing pollutants through the use of the alternative technologies; and (6) a Regulatory Impact Analysis that summarizes the contents of the first five documents in a format that is acceptable to OMB.[1098]

Engineers in the Effluent Guidelines Division prepare the engineering document. That Division relies primarily upon an industry questionnaire and site visits where EPA engineers (or engineers working for EPA contractors) visit plants and undertake analyses of the pollution control technologies that are currently in use.[1099]

The Economic Analysis Staff of the Office of Analysis and Evaluation drafts the economics document. Often the Staff can draw upon information in several very large industry surveys that the agency conducted in the

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1098 DuPuis Interview, supra note 793. The agency has only proposed two major regulations for which it has prepared RIAs during the last three years. Therefore, its experience with the latter two documents is very limited. DuPuis Interview, supra note 793.

1099 DuPuis Interview, supra note 793.

mid-1970s.[1100] These surveys contain detailed financial information about individual companies that are subject to the regulation.

The Economic Analysis Staff also prepares the cost-effectiveness document which draws upon the information in the engineering document and the economic document.[1101] This 20-30 page document sets out the cost per ton of pollutant removed for the alternative technologies. For toxic chemicals the document also contains some toxicity information on the relative toxicity of the pollutants that are being removed. This information comes from independent existing data sources within the agency.[1102] The extent to which the agency may consider cost-effectiveness analysis in promulgating Effluent Guidelines and Limitations is unclear.[1103]

The benefits analyses that have accompanied the Office's two major rules have been prepared by the Benefits Branch of the Economic Analysis Division of the Office of Policy Analysis.[1104] The Benefits Branch does not engage in original research to obtain information for the benefits document. To a large extent it relies upon existing studies on the health and ecological effects of the chemicals that the relevant industry

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1100 Sessions Interview, supra note 801; DuPuis Interview, supra note 793.

1101 DuPuis Interview, supra note 793.

1102 DuPuis Interview, supra note 793.

1103 DuPuis Interview, supra note 793.

1104 DuPuis Interview, supra note 903; Luken Interview I, supra note 961.

discharges and upon models of how the chemicals are dispersed in aquatic ecosystems.[1105] None of these calculations are very precise.[1106]

The agency begins the analytical process 5-8 years prior to issuing the notice of proposed rulemaking.[1107] The first document to be prepared, the engineering document, identifies the widest possible range of control technologies. In many cases, however, there may only be 2-3 broad possibilities. The economic document then takes the technologically available options and examines their economic achievability. At this point the Work Group may reject one or more options as being too expensive.[1108] The rejected options, however, are carried through in the document so that upper level decisionmakers and the public can see what options the Work Group rejected and the reasons for rejection.[1109] The cost-effectiveness document gives the Work Group an idea of the relative cost per ton of pollutant removed for each of the remaining technologies. This process of analyzing and narrowing options continues as the Work Group receives draft

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1105 DuPuis Interview, supra note 793.

1106 In the RIA for the Effluent Limitations and Guidelines for the Iron and Steel Point Source Category, EPA undertook three case studies of the benefits of removing effluent from three stream segments. The three case studies produced accurate assessments of the increase in stream quality attributable to the new standards. The agency, however, faced great analytical difficulties in extrapolating from the three case studies to all stream segments that received effluent from point sources in the Iron and Steel category. Luken Comments, supra note 961.

1107 DuPuis Interview, supra note 793.

1108 DuPuis Interview, supra note 793.

1109 DuPuis Interview, supra note 793.

documents from the engineers and analysts until approximately eight months prior to the time that the agency issues its Notice of Proposed Rulemaking.[1110] While the full-blown regulatory analysis documents are not completed until after the Work Group's task is almost complete, the information in the drafts of those documents informs the Work Group throughout its deliberations.

After all of the documents have been completed and the Work Group has narrowed the possibilities down to two or three options, the Work Group prepares a 10-15 page options memorandum for the Division Director and other high level decisionmakers.[1111] After meeting with the Work Group, the Division Director selects the option that most appeals to him. For important rules, the options memorandum then goes to the Assistant Administrator for Water and the Deputy Administrator for further concurrence.[1112] This process substitutes for the Options Selection/Rejection Procedure described earlier.[1113] The Work Group then drafts a Federal Register notice reflecting the decisions made during the circulation of the options memorandum.[1114] This usually achieves a rapid concurrence from the relevant agency actors, because they have already been

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1110 Sessions Interview, supra note 801.

1111 DuPuis Interview, supra note 793.

1112 DuPuis Interview, supra note 793.

1113 See text accompanying notes 993-1037, supra.

1114 DuPuis Interview, supra note 793.

exposed to the issues during the process of reviewing the options memorandum.[1115]

vi. The Office of Policy Analysis.

The Office of Policy Analysis contributes to the preparation of the agency's regulatory analysis documents in at least two ways. First, the Benefits Branch of the Economic Analysis Division of that Office has prepared extensive guidelines for the preparation of regulatory analysis documents that aid the regulatory analysts in the program offices to prepare consistent documents.[1116]

Second, the Regulatory Policy Division of the Office of Policy Analysis assigns a "lead analyst" to all agency Work Groups.[1117] One of the primary contributions that the lead analyst makes to the Work Group deliberations is to review and comment upon the regulatory analysis documents.[1118] The Office of Policy Analysis will assign a lead analyst to every regulation, even though the analysts do not attend every Work Group meeting for every rule.[1119] The lead analyst will on relatively rare occasions assist the program office in planning the research agenda for a

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1115 DuPuis Interview, supra note 793.

1116 EPA RIA Guidelines, supra note 824. Since the Guidelines have only recently been finalized, it is unclear at this point how closely the regulatory analysts in the program office adhere to them.

1117 Sessions Interview, supra note 801.

1118 Fiorino Interview I, supra note 813.

1119 Sessions Interview, supra note 801.

rule, but the analyst usually does not begin to interact with the program office actively until the data are already being assembled.[1120] The lead analyst then reviews and comments upon drafts of the regulatory analysis documents and attempts to ensure that any options memoranda and summary documents represent the analysis accurately and characterize the options adequately.[1121]

For the very few offices that lack a regulatory analysis staff, the task of drafting regulatory analysis documents falls upon the Office of Policy, Planning and Evaluation.[1122] Policy analysts in the Office of Policy, Planning and Evaluation also draft portions of regulatory analysis documents for programs that request their aid.[1123] This can have the effect of co-opting criticism from the Office of Policy Analysis and of switching roles so that the program office is the critic of the regulatory analysis office.[1124] Finally, the Economic Analysis Division of the Office of Policy Analysis also supports research by contractors and universities on the benefits of pollution control. The results of this research are made available to the program offices.[1125]

1120 Sessions Interview, supra note 801.

1121 Sessions Interview, supra note 801.

1122 Luken Interview I, supra note 903; Luken Interview II, supra note 802.

1123 For example, since the Office of Mobile Source Pollution Control in the Office of Air Quality Planning and Standards has not historically devoted much effort to analyzing the benefits of emission reduction
(Continued on page 345)

1124 Basala Interview, supra note 807.

1125 Luken Interview II, supra note 802.

f. The Second Level I Options Review Meeting.

After the Work Group has finished its deliberation for Level I rules, it will prepare another Options Memorandum listing the advantages and disadvantages of the options that it studied following the first Level I Options Review Meeting.[1126] Since many rules were already in the "pipeline" when the Options Selection/Rejection Process was implemented, the first meeting for these rules did not occur until late in a rule's development, often just prior to publication of the Notice of Proposed Rulemaking. Input from the Deputy Administrator at this late stage has proved useful, and the Committee has begun to schedule a second Options Review Meeting for many Level I rules to choose a single option from among two or three possibilities. Whether the Committee will routinely schedule a second meeting to choose one of the two or three options that were selected at the first meeting remains to be seen. For Level II rules, the agency practice appears to be evolving toward allowing the Steering Committee Meeting that reviews the decision package to serve as the second Level II Options Review meeting.[1127]

(Continued from page 344)

1123 Standards, it has asked the Economic Analysis Division of the Office of Policy Analysis to aid in the preparation of the benefits section of the RIAs for those regulations. Basala Interview, supra note 807.

1126 The current agency memoranda describing the Level I Options Selection/Rejection Process do not provide for a second Level I Options Selection Meeting. Agency practice, however, appears to be evolving in this direction. Campbell Interview, supra note 766.

1127 Campbell Interview, supra note 766.

g. The Decision Package.

After the Development Plan has been approved and the Options Selection/Rejection Process has been completed, the Work Group settles down to the task of assembling the "Decision Package." The Decision Package includes the draft proposed rule, the draft preliminary regulatory analysis document, other required documents, and a decision memorandum outlining the options, detailing the pros and cons of each, and explaining why and when each option was rejected. The Work Group must "to the extent appropriate" ensure that:

1. The package includes a neutral discussion of the major options that were considered at the most recent decision point in the options selection process, including:

   -- the comments of any Assistant Administrators who were involved in the decision, reflecting their preference among the options;

   -- the pros and cons of each of these options.

2. The package very briefly summarizes the major options considered and rejected at earlier decision points, indicating (again, very briefly) the point at which each option was rejected and why.

3. The package very briefly summarizes any legally proscribed alternatives that were identified as environmentally or administratively preferable, or more cost-effective -- explaining in each case the legal restrictions that operate.

4. The package clearly presents:

   -- as appropriate, the comparable costs, risks and benefits of the options considered based on comparable assumptions; and

   -- a comparison of the action's cost-effectiveness with that of any similar regulatory actions.

5. The package adequately analyzes reporting and recordkeeping burdens burdens, including:

   -- the uses of the required information; and

-- effective means to control the quality of the information and data processing.

6. The package assesses resources for implementing the rule, including:

-- plans for enforcement, implementation, and follow-up actions; and

-- resource needs, particularly for regional requirements.

There is little evidence that the preparation of the regulatory analysis documents has delayed the preparation of decision packages.[1128] The regulatory analysts in the program offices generally attempt to coordinate the timing of RIA preparation to correspond to the timing of the other rulemaking documents.

The aim of the Work Group is to arrive at a consensus on the analysis of the options that go forward and, if possible, to agree upon a single option to recommend to upper level decisionmakers as the option to propose in the Notice of Proposed Rulemaking.[1129] The members of the Work Group feel some pressure from their superiors to reach consensus. Busy decisionmakers do not want to spend their time resolving minor disputes, and high level officials who are called upon to resolve disputes invariably inquire as to why the Work Group members were unable to resolve them on their own.[1130]

1128 Cristofaro Interview, supra note 803.

1129 Ruhter Interview, supra note 788; Vogt Interview, supra note 871; Kuzmack Interview, supra note 790.

1130 Ruhter Interview, supra note 788; Stasikowski Interview, supra note 859.

h. Steering Committee Review.

The chairman of the Work Group must circulate the Decision Package to all members of the Work Group and acquire the signature of the lead Assistant Administrator.[1131] The Decision Packages for major and significant rules are then sent to the Steering Committee for final review. The Steering Committee reviews all major rules and many significant rules at a regular meeting. Some significant rules may be disposed of through the consent calendar.[1132]

The Steering Committee Meeting performs the same function for Level II and other rules that the Options Review Meeting performs for Level I rules.[1133] It provides a forum for intra-agency debate over the appropriate options to pursue, and it provides an opportunity for high level input into the decisionmaking process. The primary difference is that the input comes from a somewhat lower level policymaker at the Office Director level, rather than at the Deputy Administrator and Assistant Administrator level. For Level I rules, the Steering Committee is, of course, not at liberty to reverse a decision made at an earlier Options Review Meeting. The Steering Committee does, however, have the responsibility to resolve inter-office disputes on secondary and tertiary issues that were not debated

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1131 Procedures Memo, supra note 822, at 8.

1132 Procedures Memo, supra note 822, at 8.

1133 Cristofaro Interview, supra note 803.

and resolved at the Options Review Meeting.[1134] The Steering Committee meeting can end with an "agreement to disagree" on an issue, in which case the issue will be resolved at the Red Border Review stage if the principals cannot work out their disagreements prior to that time.[1135]

Members of the Steering Committee rarely suggest options that have not already been identified at the Work Group level, except when an office that suggested an option that the lead office rejected raises the option again at the Steering Committee Meeting.[1136] The Steering Committee itself is composed of mid-level career management personnel who act as arbiters of disputes.[1137] The meeting is a forum for debating serious issues that have already been debated in the Work Group.[1138] The Steering Committee is thus more of a reviewing body than an institution for developing different solutions to regulatory problems.[1139] The Acting Director of the Regulatory Policy Division of the Office of Policy Analysis (the

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1134 Campbell Interview, supra note 766. It is possible that in the future, Steering Committee Review will be eliminated for Level I rules. Campbell Interview, supra note 766.

1135 Cristofaro Interview, supra note 803.

1136 Fiorino Interview I, supra note 813; Cristofaro Interview, supra note 803; Sessions Interview, supra note 801; Napolitano Interview, supra note 883; Ajax Interview, supra note 849; Shapiro Interview, supra note 785; Ruhter Interview, supra note 788.

1137 Cristofaro Interview, supra note 803; Napolitano Interview, supra note 883.

1138 Napolitano Interview, supra note 883; Stasikowski Interview, supra note 859; Kuzmack Interview, supra note 790.

1139 Sessions Interview, supra note 801; Ajax Interview, supra note 849; Ruhter Interview, supra note 788.

Division that provides the lead analysts for the Work Groups) estimates that in a decision package that raises 12-15 issues, the Steering Committee may play a significant role in resolving two or three.[1140]

i. Red Border Review.

After the Steering Committee has concluded its deliberations, the package is cleared for "Red Border" review. Usually at this point the parties to any remaining disputes attempt to resolve as many as possible in informal meetings, often at the Assistant Administrator level.[1141] The Office of Policy, Planning and Evaluation must prepare an action memorandum for Red Border review that summarizes the important issues, comments and agreements that arose in the Steering Committee review. In addition, the lead office must prepare a summary of important changes in the package since Steering Committee review.[1142] Red Border review is the formal senior management review of all decision packages, including those for minor rules. It is normally limited to the Assistant Administrator for Policy, Planning and Evaluation and the General Counsel.[1143] Other Assistant

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1140 Sessions Interview, supra note 801.

1141 DuPuis Interview, supra note 793.

1142 Procedures Memo, supra note 822, at 8-9.

1143 Procedures Memo, supra note 822, at 9. As a practical matter, Red Border Review is extended to all of the Assistant Administrators in most cases, because it is easier to send the package to everyone and avoid the risk of skipping one of the Assistant Administrators who has an interest in it. Kuzmack Comments, supra note 790.

Administrators can be included if they have identified issues or concerns at the Steering Committee stage and ask to participate.

3. Interagency Review.

After completing Red Border review the Regulation and Information Management Division of the Office of Standards and Regulations forwards the decision package to OMB for review.[1144] If OMB comments on the rule or deems it "inconsistent with the executive order" then the action memorandum must be "revised to explain the issues involved and detail any resulting changes to the package."[1145] The Decision Package is then presented to the Deputy Administrator and the Administrator for final review and sign-off.[1146]

If OMB has a significant problem with a proposed rule or preliminary analysis, the Office of Standards and Regulations will often facilitate a meeting between OMB staff and EPA staff.[1147] This meeting will normally include technical staff and regulatory analysts from the program

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1144 Fiorino Interview I, supra note 813. Normally, the agency forwards Decision Packages to OMB for review only after they have completed Red Border review, but Red Border and OMB reviews may sometimes proceed simultaneously if the Office of Policy, Planning and Evaluation determines that no significant issues remain unresolved. Procedures Memo, supra note 822, at 9. DuPuis Interview, supra note 793 (program office regulatory analyst attempts to send draft of proposed regulation and regulatory analysis document to OMB 2-4 weeks in advance of Red Border Review).

1145 Procedures Memo, supra note 822, at 9.

1146 Procedures Memo, supra note 822, at 9.

1147 Fiorino Interview I, supra note 813.

office,[1148] the lead analyst from the Office of Policy Analysis,[1149] mid-level management, and (for large disputes) the appropriate Assistant Administrator or the Deputy Administrator.[1150]

Although the Office of Standards and Regulations in the Office of Policy, Planning and Evaluation is the formal OMB liaison, OMB personnel interact informally with EPA at all levels.[1151] These informal contacts are invariably oral.[1152] For example, a desk officer or analyst at OMB might telephone a technical staff person or an analyst in the lead office directly to ask questions or make suggestions.[1153] On occasion, a suggestion to a lead office staffer has risen to the level of a demand that a document be written in a particular way, raising concerns among mid-level EPA management that their decisionmaking authority was being undermined by OMB interference.

1148 Not all program offices send their regulatory analysts to meetings with OMB. One program office regulatory analyst speculated that his program and OMB came to blows too often because the program sought to overwhelm OMB with engineering expertise, rather than allowing the economists in OMB to converse face-to-face with program office economists. Basala Interview, supra note 807. Other lead office regulatory analysts agree that it makes sense for economists in the agency to interact with economists in OMB. DuPuis Interview, supra note 793.

1149 Sessions Interview, supra note 801.

1150 Fiorino Interview I, supra note 813.

1151 Fiorino Interview I, supra note 813; Cristofaro Interview, supra note 803; Vogt Interview, supra note 871; Kuzmack Interview, supra note 790.

1152 Jennings Interview, supra note 820; Luken Interview I, supra note 903; Cannon Interview, supra note 768.

1153 Fiorino Interview I, supra note 813.

OMB review can be used by the regulatory analysts in the Office of Policy Analysis to wage anew battles that they lost in the agency decisionmaking process.[1154] OMB analysts frequently telephone the lead analysts in the Regulatory Policy Division of the Office of Policy Analysis for an independent view of the regulations,[1155] and it can use the insights gained from those conversations in its future discussions with the technical staff in the program office and with upper level decisionmakers.[1156]

The regulatory analysts in the Office of Policy Analysis are aware of the tension that exists between institutional loyalty and professional perspective.[1157] If they are too free in sharing their professional perspective with OMB analysts, they risk undermining the decisions of their

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1154 Wolcott Interview, supra note 928.

1155 Sessions Interview, supra note 801.

1156 For example, in the internal consideration of a recent rule, the regulatory analysts in the Office of Policy Analysis, the technical staff in the lead office and the attorneys in the Office of General Counsel engaged in a hearty debate over whether an innovative concept of effluent trading among polluters could be used in a particular rule. EPA's high level management was persuaded that trading would be inappropriate. OMB, however, raised the trading issue again in its review of the rule and requested that the agency amend the proposal to include that concept. Wolcott Interview, supra note 928. This raises the real possibility that the agency's regulatory analysts might arm their allies in OMB for battles with EPA's top management in the interagency review process. Wolcott Interview, supra note 928.

1157 Sessions Interview, supra note 801. The same tension exists in a lead agency regulatory analyst when an analyst in the Office of Policy Analysis asks him or her for views on a proposal that has been approved by the lead office Division Director and is being debated at a Work Group. A lead office analyst who has lost an internal battle may wage it once again through his or her professional comrade in the Office of Policy Analysis.

superiors.[1158] Since much agency decisionmaking in uncertainty-laden regulatory areas such as environmental protection are highly subjective judgment calls, however, this danger should not be overstated. If, as is nearly always the case, a thoroughgoing analysis of the data does not yield any firm regulatory conclusions, the outcome of the decision really depends upon who makes the policy-dominated judgment calls. While it may be irritating for upper level EPA officials to have to debate with OMB arguments that they have already rejected in internal discussions, the OMB debates should not change the outcome of a decision insofar as the agency decisionmakers are empowered to make the substantive decisions. Interestingly, EPA considered including a representative from OMB in the Options Selection/Rejection Process as a cure for this potential problem, but rejected that approach because it did not feel it appropriate to give a staff level OMB analyst such a predominant role in EPA's internal decisionmaking process.[1159]

The relationship between EPA and OMB has not been especially harmonious. Officials in the Office of Information and Regulatory Affairs in OMB view their duty as two-fold. First, they must ensure that the agency analysis comports with the requirements. In this connection OMB analysts read EPA regulatory analysis documents, challenge assumptions, critique analytical efforts, and suggest areas where EPA should seek more data before

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1158 Sessions Interview, supra note 801; Wolcott Interview, supra note 928.

1159 Wolcott Interview, supra note 928.

moving ahead with its regulatory efforts.[1160] Although EPA has had a reputation for being one of the most analytical agencies in the federal government, OMB personnel feel that too many important EPA decisions lack a sufficient analytical basis.[1161]

Agency analysts chafe at the implication that they are not performing their jobs well.[1162] They respond that to the extent that OMB's criticisms of the agency's regulatory analysis documents go to the lack of adequate data, the fault lies with OMB, not EPA. EPA could collect more data if it had more resources, but OMB has refused to request more resources for EPA's policy analysts[1163] and has consistently cut the agency's research and development budget. According to agency analysts, the OMB staffers in the Office of Information and Regulatory Affairs should communicate their concerns about the adequacy of supporting data to the budget officers in OMB, not to EPA regulatory analysts.[1164] In short, agency analysts believe that they are getting mixed signals from OMB.[1165]

1160 Personal Interview with Mr. Arthur Fraas, Office of Information and Regulatory Affairs, OMB, May 19, 1984 [hereinafter cited as Fraas Interview].

1161 Luken Interview I, supra note 903; Fraas Interview, supra note 1160.

1162 Luken Interview I, supra note 903.

1163 GAO Cost-Benefit Report, supra note 842, at 29-30.

1164 Luken Interview I, supra note 903.

1165 Luken Interview I, supra note 903.

Agency analysts further argue that OMB's input has not often contributed to the quality of the agency's analysis.[1166] One agency analyst believes that the failure of OMB to contribute substantially to the quality of EPA analytical work stems from the fact that OMB analysts spend too little time with any single regulation to become sufficiently educated to contribute much to the agency's analytical effort.[1167] Other analysts suggest that OMB does not contribute much to the quality of EPA's regulatory analysis documents because OMB is more concerned with affecting the substance of the rules themselves than with improving the quality of the agency's analysis. They note that OMB concerns more often go to the agency's substantive policy choices than to the content of the regulatory analysis documents.[1168] As in other Departments, there is some sense in EPA that a good analysis will not save a decision with which OMB disagrees and a poor analysis will not slow down a decision with which OMB agrees. The OMB regulatory analyst responsible for reviewing EPA rules agrees that the dominant aspect of OMB's review role is determining "whether the [agency's substantive] decision is sensible."[1169] Agency regulatory

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1166 Thomas Interview I, supra note 780; Ruhter Interview, supra note 788; Kuzmack Interview, supra note 790; Cannon Interview, supra note 768; Luken Interview I, supra note 903.

1167 Kuzmack Interview, supra note 790.

1168 Sessions Interview, supra note 801; Ajax Interview, supra note 849; Ruhter Interview, supra note 788; Cannon Interview, supra note 768; Luken Interview I, supra note 903.

1169 Fraas Interview, supra note 1160.

analysts have a strong impression that OMB uses regulatory analysis as an excuse to deregulate.

The technical staff in the lead offices have generally found OMB's substantive input to be unhelpful.[1170] Many program office officials believe that OMB has a bias against regulations.[1171] For example the 10 percent discount rate that OMB mandates for reducing future benefits to present value ensures that fewer regulations that have large future benefits and large present costs will appear beneficial in regulatory analysis documents.[1172] OMB officials generally agree that they have a preference against the command and control regulation that typifies EPA's Effluent Guidelines and New Source Performance Standards programs.[1173] Many agency scientists and engineers believe that OMB simply brings its different policy perspective to bear on the same data and analysis to reach different substantive conclusions.[1174] Hence, in the minds of some EPA technical people, policy preferences, rather than analysis, determine whether a proposed regulation and its regulatory analysis documents are "inconsistent with the Executive Order."[1175]

1170 Ajax Interview, supra note 849; Stasikowski Interview, supra note 859; Vogt Interview, supra note 871.

1171 Ajax Interview, supra note 849; Basala Interview, supra note 807; Stasikowski Interview, supra note 859; Vogt Interview, supra note 871.

1172 Basala Interview, supra note 807.

1173 Fraas Interview, supra note 1160.

1174 Ajax Interview, supra note 849.

1175 Ajax Interview, supra note 849; Stasikowski Interview, supra note 859.

According to agency personnel, most OMB comments address substantive and analytical issues that the agency had previously considered, but resolved in a way that was unacceptable to OMB.[1176] Agency personnel could cite very few instances in which OMB analysts suggested an innovative option that the agency either adopted or seriously considered.[1177] In its review of Effluent Limitations and Guidelines, for example, the alternatives that OMB suggested often went to the possibility of exempting a source or a subcategory from one or more of the rule's requirements, rather than to innovative ways to craft the overall regulation.[1178]

Perhaps the most frequent complaint that EPA personnel have about OMB review is that it unduly delays EPA decisionmaking.[1179] When EPA does not face a court ordered deadline for proposing a rule, OMB can "sit" on the rule for months or even years.[1180] Although the average delay caused by

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1176 Sessions Interview, supra note 801; Thomas Interview I, supra note 780; Vogt Interview, supra note 871. See Hall Hearings, supra note 1082, at 606 (testimony of Joseph Cannon); OMB Pressured GPA, Ex-Aide Says, Washington Post, September 28, 1983, A1, Col. 2.

1177 Sessions Interview, supra note 801; Thomas Interview I, supra note 780; DuPuis Interview, supra note 793.

1178 DuPuis Interview, supra note 793.

1179 Wolcott Interview, supra note 928; Cristofaro Interview, supra note 803, Stasikowski Interview, supra note 859; Vogt Interview, supra note 871; Tonetti interview, supra note 865; Kuzmack Interview, supra note 790; Luken Interview I, supra note 903. Beneficiary groups have also complained that OMB delays were stifling the rulemaking process in EPA. See, e.g., NRDC Blasts Use of Lost-Effectiveness Data in Industrial Boiler NSPS Plan, Inside EPA, October 12, 1984, at 11.

1180 See, OMB, after 7-Month Review, Again Stalls Plans to OK Rodwaste Guidelines, Inside OMB, July 16, 1982 at 8; OMB has sitting on EPA's Superfund Feasibility Study Guidance, Inside EPA, March 22, 1985, at

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OMB is only about four weeks, the fact that EPA cannot know in advance whether OMB will delay any given regulation for four weeks or four months means that the agency loses credibility with its constituent groups.[1181]

OMB has, however, occasionally provided effective input into the agency's decisionmaking process. OMB has had its greatest impact on the content of the agency's analysis of regulatory problems when it has convinced the agency to place greater emphasis on considerations that it has previously slighted.[1182] OMB has also had an impact on agency analytical thinking when it has demanded that the agency establish priorities. For example, during the internal EPA debate on the allowable levels of contaminants in drinking water, the internal debate focused heavily upon the question of how protective the standard should be. OMB broadened the agency's perspective by asking the agency to explain why it picked the contaminants that it had included in the regulation and what priorities the agency gave to particular contaminants. The agency had thought about this question, and agency staff disagreed with the OMB position. But the agency staff decided that since the issue was likely to arise every time that it reviewed a similar rule, the agency should be prepared to discuss it at greater length in the future. While the agency did not halt the particular

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1180 12; OMB, Concerned with Costs, Delays EPA Acton on Benzene Toxic Air Rules, Inside EPA, April 20, 1984 at 4.

1181 Cristofaro Interview, supra note 803 (average delay of four weeks; Vogt Interview, supra note 871 (loss of credibility).

1182 Sessions Interview, supra note 801.

rulemaking effort, it decided to give greater emphasis to priorities in future rulemaking efforts.[1183]

Even when OMB is unable to persuade the agency to change the decision before it, it often extracts a promise from the agency during the negotiating process to consider a new way of doing things in the future.[1184] For example, OMB cleared two or three New Source Performance Standards that imposed costs of nearly $2000 per ton of volatile organic hydrocarbons on the condition that in the future EPA impose costs closer to $1000 per ton.[1185] Indeed, OMB review is probably responsible for the enhanced emphasis that EPA gives to cost effectiveness considerations in setting technology-based standards in all of its programs.[1186]

The tension between OMB's role of "superanalyst" and its roles of enforcer of political accountability and advocate of regulatory relief is central to its relationship with EPA. Most EPA officials who had an opinion on this subject regarded OMB input as political rather than analytical. An example of OMB's policy bias is its consistent objection to the use of "worst case" benefits analysis and its equally consistent failure to object to "worst case" cost analysis.[1187] This biased approach does little to

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1183 Sessions Interview, supra note 801.

1184 Wolcott Interview, supra note 928; Ajax Interview, supra note 849.

1185 Jennings Interview, supra note 820. See, EPA, OMB Negotiate Cost-Effectiveness Cutoff Points for NSPS Pollutants, Inside EPA, Apr. 20, 1984, at 1.

1186 See e.g., Task Force Case Study on the Organic Chemicals Industry Effluent Guidelines (Phase I), supra note 765, at V-9.

1187 Sessions Interview, supra note 801.

persuade EPA analysts that OMB analysts are impartial reviewers of EPA's analytical work. When OMB "remands" a rule as "inconsistent with the executive order," it is usually not because of some easily correctable defect in the agency's analysis. It is because OMB has determined that the agency should not issue the rule as written. In the not infrequent case in which the agency fails to respond to the remand,[1188] the regulation has effectively been killed by OMB on substantive grounds.

The real test of how OMB views its role is when an adequate analysis suggests that a regulation should be more stringent. This has happened on two occasions in OMB reviews of EPA rules. In the lead phasedown rulemaking, OMB initially urged EPA to relax the standard regulating the quantity of lead in gasoline. EPA and many large refineries who had already expended money on facilities capable of producing unleaded gasoline opposed this approach. EPA's re-analysis of the health and economic impacts of various levels of control strongly suggested that lead should be phased out more rapidly than the existing regulations required. It appears that OMB was ultimately persuaded by this analysis, although it is possible that it was also swayed by strong pressures from large refiners.[1189]

A similar conflict between analysis and policy preference occurred when OMB reviewed EPA's proposed National Ambient Air Quality Standard for Particulate Matter. In this case the agency's analysis suggested that the

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1188 Cristofaro Interview, supra note 803.

1189 See Lead Phasedown Case Study [Case Study submitted as Appendix B to this Report].

standard should be made more stringent.[1190] Mid-level OMB analysts believed that the analysis should prevail over OMB's general predilection for less stringent regulations. OMB has not, however, subsequently insisted that EPA look at more stringent alternatives. It has instead focused on the legitimacy of the models that EPA used.

4. Agency Responses to Public Comments.

The agency procedures for responding to public comments on a proposed rule are virtually identical to the procedures governing the preparation of the initial rulemaking and regulatory analysis documents. The Project Officer in the lead office is responsible for assembling the public comments and breaking them down as far as possible by issue.[1191] The agency often hires contractors to read and segregate the comments.[1192] The comments are then distributed to the personnel who drafted the portions of the documents that the comments addressed. The regulatory analysts in the lead office occasionally consult the regulatory analysts in the Economic Analysis Division of the Office of Policy Analysis if the comments raise difficult analytical issues.[1193]

1190 See GAO Cost-Benefit Report, supra note 842, at iv.

1191 Fiorino Interview I, supra note 813; Ajax Interview, supra note 849.

1192 See, Lead Phasedown Case Study, supra note 1192..

1193 Luken Interview II, supra note 802. Similarly, the lead analyst in the Regulatory Policy Division of the Office of Policy Analysis might solicit the aid of an analyst in the Economic Analysis Division in reviewing the program office's response to particular comments. Luken Interview I, supra note 903.

After the various offices have had a sufficient opportunity to respond to the comments, the Project Officer calls a Work Group meeting to discuss how the agency should respond to the comments. The Work Group attempts to reach consensus on the changes that should be made in light of the public comments.[1194] The Work Group recommendations and dissenting opinions are then forwarded to the Steering Committee and from there to Red Border Review. Level I rules may be subjected to another Options Review Meeting if several alternatives are still available and if upper level input seems desirable.

In most EPA programs the regulatory analysis documents attract some comment.[1195] Yet most comments on any given rule still go to the technical basis for the rule, rather than to the regulatory analysis documents.[1196] Comments rarely focus on the threshold question of whether or not an RIA or RFA should be prepared.[1197] A summary of four case

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1194 Cristofaro Interview, supra note 803.

1195 Sessions Interview, supra note 801; Cristofaro Interview, supra note 803; Basala Interview, supra note 807; Thomas Interview I, supra note 780; Shapiro Interview, supra note 785; Stasikowski Interview, supra note 859; Kuzmack Interview, supra note 790; Ruhter Interview, supra note 788; DuPuis Interview, supra note 793.

1196 Tonetti Interview, supra note 865. In the Office of Water Regulations and Standards, many of the comments on the technology-based standards go to the cost analysis, but few go to the cost-effectiveness analysis. DuPuis Interview, supra note 793. This may be because costs are explicitly mentioned in the agency's statute, while it is not clear that the agency can rely heavily upon cost-effectiveness analysis in promulgating its technology-based standards. The
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1197 Fiorino Interview I, supra note 813; Cristofaro Interview, supra note 803. Interestingly in one of the very few instances in which the
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studies that EPA policy analysts undertook in 1983, concluded that "few or no issues arose during the public comment period that resulted in additional economic analysis of new areas."[1198]

Opinions vary as to whether the regulatory analysis documents enhance the quality of public comments. Most of the regulatory analysts who work on the documents believe that they do have a positive impact on the quality of the comments.[1199] Calculating the costs of a regulation, even when costs are by statute largely irrelevant to the final outcome of the proceeding, can enhance the public understanding of the regulation.[1200] It can send a very clear signal to affected parties by telling them the extent to which they will be affected.[1201] Agency regulatory analysts believe that because the regulatory analysis document lays out the agency's rationale and

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1196 regulatees may feel that it is not cost-effective to expend resources critiquing an analysis that can be only marginally relevant to the agency's decision.

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1197 agency received public comment on the threshold issue, the agency had already prepared a Preliminary RIA, and an industry group commented that an RIA was unnecessary. Cristofaro Interview, supra note 803. The RIA indicated that it would be more efficient to make an existing standard more stringent.

1198 Task Force Case Study Executive Summary, supra note 765, at I-6.

1199 Sessions Interview, supra note 801; Stasikowski Interview, supra note 859; Ruhter Interview, supra note 788; Kuzmack Interview, supra note 790.

1200 Ruhter Interview, supra note 788.

1201 A corollary benefit to the agency is the fact that the analysis will identify in advance those groups that the agency can expect to oppose the regulation. Ruhter Interview, supra note 788.

technical support, the commenters are obliged to explain why they are wrong, to suggest better rationales, and to come up with better technical data.[1202]

In the minds of some, the RIA often sharpens the debate between the agency and the outside parties.[1203] In important rulemakings, the regulated industry may even hire outside consultants to critique the agency's regulatory analysis documents.[1204] At the very least, the comments on the regulatory analysis documents can reveal places where the technical support for a rule is weak and suggest further studies that could be done to shore up the agency's technical support.[1205]

Agency regulatory analysts feel that they are quite receptive to well-conceived critiques of the regulatory analysis documents, and they frequently amend the documents to reflect outside criticism.[1206] Indeed,

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1202 Sessions Interview, supra note 801; Shapiro Interview, supra note 785.

1203 Shapiro Interview, supra note 785.

1204 DuPuis Interview, supra note 793; Shapiro Interview, supra note 785. In the rulemaking concerning the National Ambient Air Quality Standard for particulate matter, the regulatees hired a contractor to dissect and critique the agency's regulatory analysis document. Basala Interview, supra note 807; Thomas Interview I, supra note 780. The comments that resulted were cogent and precise. However, they raised few issues about the quality of the analysis that the regulatory analysts in the agency had not already identified. Thomas Interview I, supra note 780. The thrust of the comments was not in the direction of providing better data, but rather toward criticizing the agency's use of the data that was available.

1205 Shapiro Interview, supra note 785; Kuzmack Interview, supra note 790.

1206 Basala Interview, supra note 807; Shapiro Interview, supra note 785; Ruhter Interview, supra note 788; Vogt Interview, supra note 871; Kuzmack Interview, supra note 790; DuPuis Interview, supra note 793.
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the agency often uses the proposed rule as a vehicle for soliciting outside comment on particular issues of relevance to the regulatory analysis documents. The agency is especially receptive to public comments on these issues. Although the agency seldom amends its entire approach to a regulation as a result of public comment,[1207] it has on at least one occasion withdrawn a rule because changes in the agency's cost analysis precipitated by public comments indicated that the rule was no longer economically feasible.[1208] Even when the agency rejects the public criticisms of its analyses, it attempts to demonstrate why the critics were wrong.[1209] This requires the agency analysts to think more about their original analyses, and this ultimately increases the agency's confidence in the correctness of its decisions.

Like the preliminary regulatory analysis document, the final document is usually not completed until about the same time that the lead office has completed the rulemaking documents.[1210] Draft versions of the final document are, however, generally available to the Work Group during the

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1206 In one extreme case, the agency prepared a revised regulatory analysis document and solicited public comment on the revision prior to promulgating the final rule. Kuzmack Interview, supra note 790.

1207 Shapiro Interview, supra note 785.

1208 Vogt Interview, supra note 871.

1209 Kuzmack Interview, supra note 790.

1210 Fiorino Interview I, supra note 813.

latter stages of its deliberations.[1211] The regulatory analysts who are responsible for addressing and responding to the comments keep the Work Group informed of any new information that the comments produce and any resulting changes in their analysis.

5. Retrospective Analysis.

EPA does very little in the way of retrospective analysis of the predictions that it made in earlier rulemaking documents and regulatory analysis documents.[1212] As one analyst in the Office of Policy Analysis candidly put it: "How is my career going to be advanced by doing a study that shows that three years ago the agency made a wrong prediction. It is not in my best interest."[1213]

The agency does attempt a degree of retrospective analysis in programs in which the agency is required by statute to reevaluate existing standards periodically.[1214] For example, the Clean Air Act requires the agency to review New Source Performance Standards every four years, and the agency reviews the National Emission Standards for Hazardous Pollutants on a

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1211 There are exceptions to this general rule. In cases in which the agency does not face external pressure to produce a rule within a given time frame, the Work Group can wait until the final regulatory analysis document is complete before finishing its deliberations on what rule to promulgate. Cristofaro Interview, supra note 803.

1212 Cristofaro Interview, supra note 803; Sessions Interview, supra note 801; Thomas Interview I, supra note 780; Ruhter Interview, supra note 788; Vogt Interview, supra note 871.

1213 Cristofaro Interview, supra note 803.

1214 Basala Interview, supra note 807.

four-five year basis as a matter of agency policy.[1215] The analyses that exist show that EPA tends to overestimate costs.[1216] But these analyses have not focused narrowly on the accuracy of the predictions in regulatory analysis documents. The reevaluation process is aimed at promulgating revised standards. The economic impact of the old standard is not as relevant to that issue as the projected economic impact of possible new standards.

The agency has a Program Evaluation Division in the Office of Management Systems and Evaluation in the Office of Policy, Planning and Evaluation. This office would seem to be the logical place for a general effort aimed at evaluating the accuracy of the predictions of the regulatory analysts in the program offices and the efficacy of the review function of the agency-wide Office of Policy Analysis.[1217] If the agency regulatory analysts are not making reasonably accurate predictions in the agency's regulatory analysis documents, the agency might seriously question whether its large staff of regulatory analysts is worth the resources that the agency puts into regulatory analysis. Nevertheless, the agency's primary program evaluation office does not attempt to probe this crucial aspect of the performance of the agency's regulatory analysts.[1218]

1215 Comments of Mr. Robert L. Ajax, Chief, Standards Development Branch, Emission Standards and Engineering Division, Office of Air Quality
(Continued on page 369)

1216 Cristofaro Interview, supra note 803; Fiorino Interview I, supra note 813.

1217 Sessions Interview, supra note 801.

1218 Sessions Interview, supra note 801.

The failure to assess retrospectively the validity of past calculations is even more perplexing in light of the agency's admitted biases in its predictions. In its cost analyses (but not its benefits analyses), the agency leans toward "worst case" analysis to minimize the possibility of promulgating a standard that has a catastrophic impact on an industry.[1219] This virtually guarantees that the agency will base its decisions on poor predictions. Retrospective studies could over time lead the way toward acceptable "best case" analyses.

In the rare instances in which agency analysts have attempted retrospective studies they have found themselves hamstrung by the fact that the regulated entities do not arrange their financial records in a way that facilitates a retrospective examination of private implementing costs.[1220] In addition, it is very difficult to separate costs imposed by EPA regulations from other factors, such as a recession or a large increase in energy prices, that can have a disproportionate impact on a single industry or that can overwhelm the impact of the compliance costs.[1221]

(Continued from page 368)

1215 Planning and Standards, Office of Air and Radiation, EPA, on an earlier version of this Report, August 22, 1984 [hereinafter cited as Ajax Comments].

1219 The agency has not performed as many "worst case" benefits analyses because OMB routinely objects to worst case benefits analysis. OMB does not object to worst case cost analysis. Sessions Interview, supra note 801.

1220 Luken Interview I, supra note 903.; Ruhter Interview, supra note 788.

1221 DuPuis Interview, supra note 793.

Similarly, nature does not often facilitate a retrospective inquiry into the benefits of a pollution control standard. For example, the installation of water pollution technologies in a steel mill may show little evidence of improvement in a receiving stream that is also the recipient of the untreated effluent of a booming upstream residential community.

Given the fact that the agency is nearly always behind in its statutory schedules for promulgating new standards, it feels that it cannot devote significant resources toward studying the accuracy of its predictions for past standards.[1222]

C. Level of Analysis in Regulatory Analysis Documents.

1. Agency Guidelines.

After much internal debate,[1223] EPA promulgated its "Guidelines for Performing Regulatory Impact Analysis" in late 1983.[1224] The Guidelines state that the goal of regulatory analysis is "to develop and organize information on benefits, costs, and economic impacts so as to clarify trade-offs among alternative regulatory objectives."[1225] The Guidelines

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1222 Cristofaro Interview, supra note 803.

1223 Luken Interview I, supra note 903; note 1242, infra.

1224 EPA RIA Guidelines, supra note 824.

1225 EPA RIA Guidelines, supra note 824, at 2. For a detailed description of the history of these guidelines, see Fisher, An Overview and Evaluation of EPA's Guidelines for Conducting Regulatory Impact Analysis, in Environmental Policy Under Reagon's Executive Order: The Role of Benefit Cost Analysis (V.K. Smith, ed. 1984).

promise that "by developing and organizing information, quantifying and monetizing benefits and costs to the extent possible, and determining distributional effects and economic impacts, the RIA should provide decision makers with a comprehensive assessment of the implications of alternative regulatory actions."[1226]

The Guidelines require that a preliminary regulatory analysis document first state the need for the proposed rule. In this regard the document must collect information on the following points:

-- The market imperfections that necessitate regulatory action;

-- the pollutant creating the problem, its annual discharge mass, and its principal sources, both now and, where feasible, over the time horizon of the analyses;

-- the degree of the pollutant's current or projected impact on the environment, health and safety, and the economy;

-- current control techniques and their effectiveness; and

-- the amount or proportion (or both) of the pollutant that the proposed regulatory action would control and the resulting beneficial effects.[1227]

In addition, the document must discuss how the proposal would

-- improve the way the market functions (primarily through internalizing the damages from pollution) or otherwise meet the regulatory objectives, and

-- produce better results than no regulatory change, taking into account the possibility that regulation fails to achieve its stated goals (this may result from poorly designed rules, as well as from weakness in enforcement and lack of compliance).[1228]

1226 EPA RIA Guidelines, supra note 824, at 2.

1227 EPA RIA Guidelines, supra note 824, at 4.

1228 EPA RIA Guidelines, supra note 824, at 4.

A preliminary regulatory analysis document must also identify and discuss alternatives to the proposal. First, the document must describe a "baseline" state of the environment that would exist in the absence of any regulation. Thus, "no action" is always an alternative to be explained in regulatory analysis documents. The document must then describe: (1) alternatives to federal regulation such as negotiated voluntary actions and market, judicial or state and local solutions to the problem; (2) alternatives within the scope of the agency's statute such as varying degrees of control, delayed compliance dates, emissions trading, less burdensome compliance monitoring, and variances; (3) market-oriented regulatory options (whether or not they are explicitly authorized in the agency's statute) such as labeling, fees or changes, marketable permits or offsets, and changes in insurance provisions; and (4) major alternatives beyond the scope of the agency's statute, such as controlling other routes of exposure.[1229]

The Guidelines recognize that "there may be a trade-off between considering more alternatives and developing more detailed, quantified, and reliable benefit and cost estimates for fewer alternatives."[1230] But they give no guidance for resolving the trade-offs, stating only that the choice must be "subjective, taking into account the nature of the environmental problem, current government regulations and the status of compliance, the amount of flexibility permitted by the law governing the regulation under

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1229 EPA RIA Guidelines, supra note 824, at 5.

1230 EPA RIA Guidelines, supra note 824, at 6.

consideration, the schedule of required action, and resource constraints."[1231]

After exploring the alternatives, the regulatory analysis document must assess the benefits of each proposed option. The Guidelines state that the benefits analysis should "cover the entire spectrum of benefits, from those that can be assigned a dollar value to those that can only be described qualitatively, and from those that are direct and immediate to those that are remote in distance or time."[1232] The Guidelines recognize that benefits assessment involves complex modeling of little-understood phenomena and point out that these undertakings are inevitably characterized by a high degree of uncertainty. They therefore provide that "the analysis should report not only most likely estimates but also upper- and lower-confidence limits."[1233]

The Guidelines distinguish between health and environmental effects in benefits assessment. They suggest the following format for a comprehensive analysis of health effects:

-- evaluation of substances on a case-by-case basis;

-- a discussion of the likelihood that the substance may be harmful to humans and a description of the nature and duration of the harmful effects (this should be based on a weight-of evidence evaluation of scientific information, including the results of both positive and negative studies);

-- estimation of dose-response relationships to extrapolate risk at low doses or, if the information available for noncarcinogens do not

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1231 EPA RIA Guidelines, supra note 824, at 6.

1232 EPA RIA Guidelines, supra note 824, at 6.

1233 EPA RIA Guidelines, supra note 824, at 6.

permit developing dose-response relationships, determination of a no-observed-effect-level or a related parameter (these should include a discussion of the mechanism of action and the procedures used to convert evidence from other organisms to predictions of potential human effects);

-- information on the exposure of people to the substance (this should include the number of people in and the composition of the exposed populations; the level, frequency, and duration of their exposures; and the routes of exposure);

-- an estimate of the distribution of risk to individuals or, if information available for noncarcinogens do not permit risks to be quantified, a margin of safety or recommended limit of exposure (the population and age groups with greater sensitivities should be identified where possible);

-- an estimate of the expected number of adverse health effects; and

-- a discussion of the science policy judgments and uncertainties present in all the analyses.[1234]

In general, the analysis should combine the information on the substance's toxicity with exposure estimates to predict the effect of each regulatory alternative has on improving human health."[1235]

The Guidelines suggest that the value of reduced morbidity (illness) should be measured by medical costs, loss of earnings and impacts on future productivity, unless it is feasible to use "willingness to pay" measures.[1236] They recognize that this is a lower bound on the value of reduced morbidity, because it does not include pain and suffering and subtle health effects that make life less comfortable but do not result in trips to

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1234 EPA RIA Guidelines, supra note 824 at 7.

1235 EPA RIA Guidelines, supra note 824 at 8. The Guidelines further distinguish between carcinogens and noncarcinogens and offers other broad guidelines for risk assessments for these substances..

1236 EPA RIA Guidelines, supra note 824 at 10.

the doctor or lost workdays.[1237] Yet the Guidelines do not suggest any mechanism for producing a more realistic benefits estimate.

For regulations that reduce risks to life, the Guidelines insist that regulatory analysis documents use the term "statistical lives saved," rather than suggesting that the agency is placing a value upon any particular person's life.[1238] This term "refers not to particular lives, but to the sum of small reductions in risk to large numbers of people."[1239] The Guidelines do not demand that the drafter of the regulatory analysis document place a monetary value on a statistical life, but suggest that if it is to be valued, a range of values be used to determine the sensitivity of the results to alternative values.[1240] The Guidelines note that wage rate studies suggest values running from $400,000 to $7,000,000.[1241] Alternatively, the Guidelines suggest that the analyst calculate the "implicit cost per statistical life saved" by subtracting net monetized benefits from net costs and dividing by the number of lives saved.[1242]

1237 EPA RIA Guidelines, supra note 24 at 10.

1238 EPA RIA Guidelines supra note 824 at 10.

1239 EPA RIA Guidelines supra note 824 at 11.

1240 EPA RIA Guidelines supra note 824 at 11.

1241 EPA RIA Guidelines supra note 824 at 11.

1242 Id. at 11. The equivocal way with which the Guidelines treat the question of valuing lives is not surprising. The Guidelines were delayed for a substantial period of time in the Deputy Administrator's Office while the agency debated how they should address quantifying risks to life. See Inside EPA, Sept. 17, 1982, at 10.

The Guidelines offer much less guidance on quantifying environmental benefits, stating only that "[t]he objective of a benefits assessment is to quantify these impacts in physical terms, provide measures of the uncertainty inherent in the estimates, and trace the links to human activities and values."[1243] In addition, they suggest that the analyst should attempt to take into account mitigating measures that individuals might take, such as planting different crops (or perhaps moving to a less polluted city).[1244] Finally, the Guidelines suggest four mechanisms for valuing benefits:

> The direct cost method is best suited for estimating the value of the commercial effects of reduced pollution, such as reduced damage to fisheries, forests, and agriculture and increased lifetimes of buildings or machinery. The monetary value of these effects is estimated as the savings in costs to industry and to consumers.
>
> The travel cost method may be used to estimate the value of the recreational effects of reduced pollution. Monetary values are estimated by developing a demand curve for recreational activities and determining how it would change because of improvements to the environment.
>
> The property value method may be used to estimate the value of the health, aesthetic, and recreational effects of reduced pollution. This method relates differences in property values to housing characteristics, location, and environmental characteristics to infer the values placed on environmental improvements.
>
> The contingent valuation method primarily has been used to estimate the value of nonmarket goods and services, such as improvements in aesthetics (gains in visibility or water clarity and reductions in odor) and the preservation of wildlife and wilderness areas. In this method people are asked what they would be willing to pay to enjoy alternative levels of environmental quality.[1245]

1243 EPA RIA Guidelines supra note 824 at 9.

1244 EPA RIA Guidelines supra note 824 at 9.

1245 EPA RIA Guidelines supra note 824 at 11-12.

The Guidelines define the costs of a regulation broadly to include "the value of goods and services lost by society resulting from the use of resources to comply with and implement a regulation, and from reductions in output."[1246] These fall into five general categories -- private-sector real-resource costs, government regulatory costs, dead-weight welfare losses, adjustment costs, and adverse effects on product quality, productivity, innovation and market structure.[1247] As with benefits, the Guidelines suggest that regulatory analysis documents use "most-likely estimate" of costs, "along with cost ranges and statements about their likelihood."[1248]

Finally, the Guidelines address the balance between benefits and costs and suggest that the final section of a regulatory analysis document contain the following three elements:

> Estimates of the net benefits of each major alternative, based on the benefits and costs for which a dollar value can be assigned, and a discussion of nonmonetizable or unquantifiable benefits and costs;
>
> A schedule of all benefits and costs for each major alternative, including economic impacts and intergenerational effects; and
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> The results of cost-effectiveness analysis of major alternatives, when many benefits are not easily monetized or when the law sets forth specific regulatory objectives.[1249]

Pointing out that OMB's Guidance calls for a 10 percent discount rate in

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1246 EPA RIA Guidelines supra note 824 at 12.

1247 EPA RIA Guidelines supra note 824 at 12.

1248 EPA RIA Guidelines supra note 824 at 12.

1249 EPA RIA Guidelines, supra note 824, at 15.

reducing costs and benefits to present value, the Guidelines suggest several alternative mechanisms for arriving at a more appropriate determination of a discount rate in individual rulemaking proceedings.[1250] The Guidelines stress that the net quantified benefit estimate (which may be negative) "should be carefully evaluated in light of all of the effects that have been excluded because they would not be assigned a dollar value."[1251]

In addition, the Guidelines suggest that regulatory analysis documents examine the distributional effects of regulations, a concern that is not directly relevant to efficiency.[1252] The Guidelines put particular stress on intergenerational equity considerations, but admit that [n]o entirely satisfactory method exists for evaluating intergenerational effects."[1253]

When the benefits of an environmental regulation cannot easily be monetized or when the agency's statute articulates a specific regulatory objective, the Guidelines provide that the regulatory analysis document

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1250 EPA RIA Guidelines, supra note 824, at 15-16.

1251 EPA RIA Guidelines, supra note 824, at 16.

1252 EPA RIA Guidelines, supra note 824, at 16-17.

1253 EPA RIA Guidelines, supra note 824, at 17. The Guidelines suggest three techniques to evaluate intergenerational impacts:

> Discounting benefits and costs at a lower social rate of discount, rather than at the rate of return on capital;
>
> Indicating the number of years until net undiscounted benefits become positive and the number of years and amounts by which they remain positive; and
>
> Directly comparing benefits to future generations with costs to the current generation.

Id.

should provide a "cost-effectiveness" analysis.[1254] The analyst should calculate the cost effectiveness of each regulatory alternative "by dividing the annualized cost of the regulatory alternative by a measure of its effectiveness."[1255] The Guidelines suggest three increasingly sophisticated measures of effectiveness -- pounds of pollution removed, units of exposure avoided, and statistical lives saved. They recommend that "the measure of effectiveness used should be as close as possible to the final effect thought to result from the regulation."[1256] According to the Guidelines, programs may use cost-effectiveness analysis to measure the relative effectiveness of alternative regulatory mechanisms in meeting stated goals, to compare the effects of environmental regulations across industries, and to compare the costs of different environmental programs that regulate the same environmental medium.[1257]

2. Agency Practice.

Agency practice only remotely approximates the ambitious goals of the agency's Guidelines. The level of analysis that goes into regulatory analysis documents varies from office to office and among programs within a single office.[1258] Regulatory analysts in the Office of Policy, Planning

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1254 EPA RIA Guidelines, supra note 824, at 18-19.

1255 EPA RIA Guidelines, supra note 824, at 18-19.

1256 EPA RIA Guidelines, supra note 824, at 18.

1257 EPA RIA Guidelines, supra note 824, at 19.

1258 Task Force Memo, supra note 765, at 2.

and Evaluation report that some offices within the agency do a much better job of assessing the benefits of regulations than other offices. The analysts in the Office of Policy, Planning and Evaluation generally view the Office of Air Quality Planning and Standards as the best office at preparing benefits analyses (even though benefits analyses cannot in theory be used in setting National Ambient Air Quality Standards), while they believe that the Office of Solid Waste does the poorest job of benefits analysis. Analysts in the Office of Policy, Planning and Evaluation cannot remember a single instance in which the Office of Solid Waste has attempted to assess on paper the benefits of its regulations.[1259]

The level of analysis also depends upon whether the rule is characterized as "major" or "nonmajor." For major rules the agency attempts to comply with the command of Executive Order 12291 that the agency conduct a full scale analysis of the proposal's costs and economic impacts.[1260] Not all RIAs that the agency produces, however, contain a quantitative benefits analysis. For most of the agency's history, benefits analyses have been extremely rare.[1261] More recently, the Office of Policy, Planning and Evaluation has assigned a high priority to inducing regulatory analysts in the program offices to undertake quantitative benefits analyses.[1262]

1259 The Branch Chief of the Economic Analysis Branch of the Waste Management and Economics Division of the Office of Solid Waste, however, responds that his office has prepared benefits analyses in
(Continued on page 381)

1260 Cristofaro Interview, supra note 803.

1261 Task Force Memo, supra note 765.

1262 Luken Interview I, supra note 903.

When the regulatory analysts in the program offices do prepare quantitative analyses they do not always attempt to provide a range of estimates, as apparently required by the Guidelines.[1263] Nor do the RIAs for major rules always undertake a full cost-benefit analysis for all relevant alternatives.[1264]

The regulatory analysis documents that the agency prepares for "significant" nonmajor rules often contain a cost-benefit analysis of the preferred alternative, but many include only a cost-effectiveness analysis.[1265] Although not required by Executive Order 12291, many programs prepare some kind of regulatory analysis document for virtually every substantive nonmajor regulation that the program promulgates.[1266] These normally include only an analysis of the direct costs and economic impacts of the proposed option.[1267] According to the Acting Director of the Regulatory Policy Division of the Office of Policy Analysis, the

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(Continued from page 380)

1259 internal briefing packages detailing the implicit cost-per-unit-case (of cancer) avoided by its regulations. Ruhter Interview II, supra note 1079.

1263 GAO Cost-Benefit Report, supra note 843, at iv.

1264 Fiorino Interview I, supra note 813; GAO Cost-Benefit Report, supra note 843, at 25-27.

1265 Fiorino Interview I, supra note 813; Cristofaro Interview, supra note 803.

1266 See Luken Interview II, supra note 802.

1267 Sessions Interview, supra note 801.

analyses that accompany the vast bulk of regulations that are neither significant nor major are not especially sophisticated.[1268]

The agency's RIA Guidelines suggest that the standard-setting office consider alternatives beyond the agency's statutory authority. High level personnel in the Office of Policy, Planning and Evaluation firmly believe that regulatory analysis documents should consider options beyond the agency's authority so as to "rub everyone's nose in the senselessness of the statute."[1269] One mid-level regulatory analyst in the Office of Policy, Planning and Evaluation believes that public dissemination of regulatory analysis documents that consider alternatives beyond the agency's authority "has increased public awareness of the measured consequences of environmental regulations and has increased pressure on government officials to justify the efficiency of their decisions."[1270] As a consequence, he believes that "EPA decisionmakers now scrutinize each situation carefully to determine whether or not the law truly prohibits considerations of economic

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1268 Sessions Interview, supra note 801.

1269 Campbell Interview, supra note 766. Mr. Campbell suggests the hypothetical example of a power plant with a copper smelter next door. Because the copper smelters have political clout, the statute requires them to clean up their sulfur dioxide emissions very little. Power plants, having less political clout, must spend million of dollars more to achieve extremely clean emissions streams. Mr. Campbell believes that an RIA on regulations for either power plants or smelters should document this disparity and explore the costs and benefits of eliminating the disparity through legislative action, even though the agency has no power to do so. In this way Congress and the public can see the true costs of the inequitable statute. Campbell Interview, supra note 766.

1270 Luken, The Emerging Role of Benefit-Cost Analysis in the Regulatory Process at EPA 2 (unpublished manuscript dated July, 1984) [hereinafter cited as Luken manuscript].

benefits and costs."[1271] The program office regulatory analysts, however, very rarely include a discussion of such options in regulatory analysis documents.[1272] Yet extra-statutory options do come up routinely in Work Group Meetings and other internal agency discussions.[1273] Given the constant press of other business on the agency's analytical resources, it is not surprising that the regulatory analysts in the program offices are not enthusiastic about discussing options that cannot be implemented in the absence of an Act of Congress.

Similarly, while the agency's Guidelines at many places suggest that the regulatory analysts should attempt to characterize the confidence with which they make their cost and benefit projections, the agency's regulatory analysis documents to date have not considered uncertainties in a sophisticated way.[1274] The documents still rely heavily upon single number estimates that mask very large uncertainties.[1275]

a. The Office of Air Quality Planning and Standards.

i. National Ambient Air Quality Standards.

Since all National Ambient Air Quality Standards are assumed to be

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1271 Luken manuscript, supra note 1270, at 3.

1272 Sessions Interview, supra note 801.

1273 Sessions Interview, supra note 801.

1274 Sessions Interview, supra note 801; Stasikowski Interview, supra note 859; GAO Cost-Benefit Report, supra note 842, at 27-28.

1275 Sessions Interview, supra note 801.

major rules, the agency prepares a full-blown RIA for each standard or revision. These documents adhere closely to the agency's RIA Guidelines, quantifying costs and benefits and monetizing them to the extent possible for several alternatives.[1276] The agency expends large resources on cost-benefit analyses, even though its statute does not allow the Administrator to consider this analysis in deciding where to set the standard.[1277] Regulatory analysts in the Regulatory Impact Section, however, believe that it is important to measure the benefits of regulatory analyses against the costs. If the regulatory analysis documents and the thinking that goes into them persuade upper level decisionmakers to adopt a less expensive regulatory option, the value of the analysis in terms of reduced compliance costs can be hundreds of millions of dollars in the context of a single National Ambient Air Quality Standard.[1278] The agency has still not decided how heavily it will rely upon benefits analysis in promulgating National Ambient Air Quality Standards.[1279]

ii. New Source Performance Standards.

The regulatory analyses for New Source Performance Standards have historically consisted only of the analysis of direct costs and economic impact on profits and capital requirements of regulated companies and the

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1276 Basala Interview, supra note 807; Thomas Interview I, supra note 780.

1277 See text accompanying notes 1327-1330, infra.

1278 Basala Comments, supra note 781.

1279 See GAO Cost-Benefit Report, supra note 842, at 18.

market response to those costs. This analysis comprises one of the nine chapters of the agency's lengthy background document for a standard.[1280] More recently, the regulatory analysts in the Office of Air Quality Planning and Standards have combined the economic impact assessment with the predicted effectiveness of alternative control technologies to arrive at a rudimentary cost-effectiveness analysis for New Source Performance Standards.[1281] Still more recently, the regulatory analysts in the Office of Air Quality Planning and Standards and the Office of Policy Analysis have been working together to produce a "generic" assessment of the dollar benefit of removing a single ton of a given pollutant from the air.[1282] The agency may gravitate in this direction in the future.

iii. National Emissions Standards for Hazardous Air Pollutants.

The Office of Air Quality Planning and Standards generally prepares a "cost-risk" analysis for National Emissions Standards for Hazardous Air Pollutants.[1283] The agency first analyzes most primary and some secondary costs of compliance for sources of the hazardous pollutant at issue. It then calculates the risk posed by that pollutant using existing risk

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1280 See text accompanying notes 1098-1115, supra .

1281 Sessions Interview, supra note 801; Fiorino Interview I, supra note 813.

1282 Luken Interview I, supra note 903; Ajax Interview, supra note 849; Nichols Interview, supra note 804.

1283 Cristofaro Interview, supra note 803.

assessment models.[1284] Finally, the quantified, but unmonetized risks are compared to the monetized costs.

b. The Office of Toxic Substances.

The level of sophistication of regulatory analysis in the Office of Toxic Substances depends upon the section of Toxic Substances Control Act under which the agency is proposing to act. For all chemical control rules under Section 6 of the Act[1285] the regulatory analysts undertake a full cost-benefit analysis of the proposal and all important alternatives.[1286] While the analysts do not attempt to "monetize" all of the benefits of a Section 6 rule, they generally attempt to calculate an implicit "cost-per-statistical-life-saved" for rules that address health effects.[1287] The analysts further prepare an extensive analysis of chemicals that are likely to be used as substitutes for the regulated chemical.[1288] This is consistent with the risk-benefit approach that section 6 adopts toward rulemaking. For all other rules the Office analyzes

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1284 Ajax Interview, supra note 849.

1285 15 U.S.C. § 2605 (1982).

1286 Shapiro Interview, supra note 785.

1287 Comments of Mr. Michael Shapiro, Acting Director, Economics and Technology Division, Office of Toxic Substances, Office of Pesticides and Toxic Substances, EPA, on an earlier draft of this Report, August 13, 1984.

1288 Toxic Substances Appendix to Task Force Report, supra note 765, at 28.

the direct costs of the regulation, the impact of those costs on the industry, and the extent of any resulting price increases.[1289]

c. The Office of Solid Waste.

The Office of Solid Waste has not consistently implemented any analytical approach. Since many rules that the office has promulgated have been exempt from the Executive Order's requirements by virtue of the fact that they were required by court order, the regulatory analyses that the Office prepares have not been as influenced by the Executive Order as those of some of the other programs.

For some large rules the agency conducts a full-scale cost-benefit analysis.[1290] Analysts in the Office of Hazardous Wastes, however, are uncomfortable with attempting to place a dollar value on pain and suffering or statistical lives.[1291] In some cases the analysts prepare a cost-effectiveness analysis of several alternatives,[1292] but in most cases it analyzes only the single alternative that the Office recommends.[1293]

1289 Shapiro Interview, supra note 785.

1290 Ruhter Interview, supra note 788.

1291 Ruhter Interview, supra note 788.

1292 The regulatory analysts in the Office of Solid Waste believe that while costs cannot be a dominant consideration in setting standards for hazardous waste facilities, cost effectiveness analysis is appropriate for locating alternative ways of protecting health and the environment. Letter from Mr. Dale Ruhter, Chief, Economic Analysis Branch, Waste Management and Economics Division, Office of Solid Waste, Office of Solid Waste and Emergency Response, EPA to Thomas O. McGarity, July 25, 1984.

1293 Ruhter Interview, supra note 788; Sessions Interview, supra note 801.

d. The Office of Drinking Water.

Consistent with its obligation to consider the feasibility of any standard that it promulgates, the Office of Drinking Water prepares a primary cost analysis for all of its rules.[1294] The regulatory analysts in the program office believe that the nature of the program renders cost-effectiveness analysis by and large inapplicable to its standards.[1295] While cost-benefit analysis seems appropriate to the program's regulatory analysts,[1296] there has been debate within the program over whether its regulatory analysis documents should employ that analysis. Upper level decisionmakers in the Office are hesitant to place explicit values on statistical lives, and they do not read the agency's RIA Guidelines to suggest that the program office should attempt to do so.[1297]

The Office uses a cost-effectiveness analysis of sorts that might more appropriately be labeled "affordability analysis." The analysts in the Office examine the "cost per family" of requiring drinking water suppliers to improve drinking water quality, and then they determine whether the increase is "affordable."

1294 Kuzmack Interview, supra note 790.

1295 Kuzmack Interview, supra note 790.

1296 The program's regulatory analysts feel fairly confident in their ability to prepare a cost-benefit analysis for standards addressing carcinogens, where several risk assessment models are available. They are less confident in their ability to measure the benefits of standards addressing noncarcinogens, because no generally accepted models exist for predicting the health effects of human exposure to these substances. Kuzmack Interview, supra note 790.

1297 Kuzmack Comments, supra note 976.

e. The Office of Water Regulations and Standards.

The Office of Water Regulations and Standards prepares a cost-benefit analysis only for Effluent Guidelines and Limitations that cross the "majorness" threshold of Executive Order 12291.[1298] Even for these regulations the RIA only analyzes the costs and benefits of the single option that the Office plans to propose.[1299]

The engineers in the office decide upon a preferred technology and the analysts perform a cost-benefit analysis to determine whether the benefits of the preferred technology outweigh the costs. If so, then the Office will recommend that the agency base the standard on that technology. If not, the engineers will generally reconsider their approach.[1300] Agency analysts feel that this narrow approach is warranted, because for most categories and subcategories of polluting industries only a very limited number of alternative control technologies are available.[1301]

EPA has had a difficult time in attempting to quantify the benefits of technology-based effluent guidelines and limitations. Since the limitations apply across categories of industries without explicit regard for geographic

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1298 DuPuis Interview, supra note 793; Task Force Case Study on the Organic Chemicals Industry Effluent Guideline (Phase I), supra note 765, at V-4.

1299 DuPuis Interview, supra note 793.

1300 DuPuis Interview, supra note 793.

1301 DuPuis Interview, supra note 793. For example, one technology may be capable of taking 100 pounds per hour of pollutant down to 3 pounds while another technology can reduce the 100 pounds to 2.5 pounds. Given the huge uncertainties involved in benefits analysis, it is simply impossible to distinguish between the two technologies on benefits grounds. DuPuis Interview, supra note 793.

location, it is difficult to predict the impact that they will have on water quality in any particular stream segment. In addition, it is difficult to translate a particular improvement in water quality attributable to a single plant into quantifiable health or environmental benefits. Moreover, there is very little information available on the recreational benefits of cleaner water.[1302]

The regulatory analysts in the program office do, however, conduct an economic impact and cost-effectiveness analysis for all alternatives for technology-based standards.[1303] The analysts attempt to compare the cost-per-ton of removing a particular pollutant across several alternative technologies. In addition, the cost-per-ton for alternative technologies for the industry to which the standard is to apply is compared with the cost per ton of removing the same pollutant in other industries. This heavy focus on cost-effectiveness analysis has come largely at the behest of OMB, which greatly prefers cost-effectiveness analysis to the "economic achievability analysis" that the Office of Water Regulations and Standards has undertaken in the past.[1304] There is, however, a question in the minds of attorneys in the Office of General Counsel whether the agency may

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1302 GAO Cost-Benefit Report, supra note 842, at 8.

1303 Task Force Case Study on the Inorganic Chemicals Industry Effluent Guidelines (Phase I), supra note 765, at V-4.

1304 Task Force Case Study on the Inorganic Chemicals Industry Effluent Guideline (Phase I), supra note 765.

legally rely on cost-effectiveness analysis for setting "best available technology" standards under the Clean Water Act.[1305]

D. The Impact of Regulatory Analysis on the Decisionmaking Process.

1. The Impact of the Regulatory Analysis Documents.

The Agency's RIA Guidelines prescribe a fairly modest role for regulatory analysis documents in the agency's decisionmaking process. They acknowledge that cost-benefit analysis is of limited usefulness to real-world decisionmaking, because "determining which regulatory options are best in terms of economic efficiency often is made difficult by uncertainties in data, by inadequacies in analytical techniques, and by the presence of benefits and costs that can be quantified but not monetized or that can only be qualitatively assessed."[1306] In addition, the Guidelines recognize that cost-benefit analysis is not very useful in determining whether the distributional impacts of regulations are equitable.[1307] The Guidelines conclude:

> In view of the limitations of current analytical techniques and the range of factors that may enter into decisionmaking, the RIA is best viewed as a document that organizes information and comprehensively assesses the effects of alterative actions and the trade-offs among them. The results should identify which regulatory alternatives are reasonable, while leaving considerable latitude to decisionmakers in

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1305 Task Force Case Study on the Inorganic Chemicals Industry Effluent Guideline (Phase I), supra note 765 at V-10.

1306 EPA RIA Guidelines, supra note 824, at 20.

1307 EPA RIA Guidelines, supra note 824, at 20.

selecting the preferred regulatory approach.[1308]

In actual practice the regulatory analysis documents are even less useful to the lead offices and the Work Groups than the Guidelines suggest. The completed documents are rarely available to the scientists and engineers in the lead office and other members of the Work Group until the Work Group has completed its work on the rule and has agreed upon a recommendation. Under the agency's typically tight schedules, the members of the Work Group must make decisions without awaiting the completed document.[1309]

Although a Work Group does not read the completed regulatory analysis document before making options-limiting decisions, its members have access to the preliminary and final contractor and staff reports that form the basis for those documents as soon as they are available to the analysts in the program offices.[1310] The preliminary analyses of the regulatory analysts in the program office is also available to the Work Group as they are completed. Much of the information that makes up the completed document is therefore available to influence Work Group's deliberations at an early stage in a rule's development.[1311] Indeed, because it often has an

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1308 EPA RIA Guidelines, supra note 824, at 20.

1309 Fiorino Interview I, supra note 813; Thomas Interview I, supra note 780; Kuzmack Interview, supra note 790. See also, Task Force Memo, supra note 765, at 2. (Only two programs that the Task Force examined
(Continued on page 393)

1310 Stasikowski Interview, supra note 859; Shapiro Interview, supra note 785; Ruhter Interview, supra note 788; Thomas Interview I, supra note 780.

1311 Stasikowski Interview, supra note 859; Ruhter Interview, supra note 788; Kuzmack Interview, supra note 790.

opportunity to help shape the contractors' reports, the Work Group can play a role in determining the contents of the resulting regulatory analysis documents.[1312] As work on a document progresses, members of the Work Group can identify analytical gaps and ask the regulatory analysts in the program office and their contractors to examine particular questions more carefully.[1313] When the document evolves in this closely supervised fashion, its contours can strongly affect how the Work Group asks and answers important substantive questions.[1314]

Most agency officials who found that the information in the regulatory analysis documents had a large impact on the Work Groups' deliberations

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(Continued from page 392)

1309 "conducted economic impact analysis prior to selecting the regulatory option(s).")

1312 Stasikowski Interview, supra note 859; Sessions Interview, supra note 801.

1313 Sessions Interview, supra note 801.

1314 Stasikowski Interview, supra note 859; Shapiro Interview, supra note 785. In at least one program, however, the regulatory analysis documents do not have much impact on substantive decisions, because the information in the documents rarely has any substantive impact. The regulatory analysis documents for New Source Performance Standards under the Clean Air Act generally reveal that impact of installing available technologies is seldom more than 0.1% of the expected profits of the average company in the industry. The Office of Air Quality Planning and Standards is not likely to allow such a minuscule economic impact to affect its choice among available technologies. Ajax Interview, supra note 849. For a few standards that have an important impact on small businesses, however, the economic impact data may have an important role to play in choosing from among the available technologies. For example the economic impact data can suggest a further subcategorization of the industry into small and large entities. These are by and large exceptions to the general rule that EPA's New Source Performance Standards have minimal impact on expected profits. Ajax Interview, supra note 849.

believed that the information was helpful in weeding out options that were clearly too expensive.[1315] Usually economic impact analysis alone could show what options were clearly unacceptable. When cost-effectiveness analysis was available to the Work Groups, the regulatory analysis document could help narrow options even farther. The regulatory analysis document has apparently not been especially useful in selecting the particular option that the Work Group recommends for the proposed rule.[1316]

As the decision package works its way through the Division Director to the Steering Committee and to Red Border Review, the completed RIA can have an impact on mid-level and upper-level management. These personnel are, however, usually too busy to read the actual document.[1317] They therefore rely upon summaries of the contents of the documents that staff

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1315 Ajax Interview, supra note 849; Shapiro Interview, supra note 785.

1316 In [the Task Force Case studies] the programs initially developed a range of reasonable and technically feasible alternatives, and then used information on costs and economic impacts to determine which option(s) was affordable. In instances where decisionmakers judged costs or economic consequences to be significant, this situation typically triggered: (1) a closer look by the decision maker at the methods, assumptions and data underlying the economic analysis, and/or (2) reevaluation of the program's technical choices and development of other options to reduce significant economic impacts. In this way, cost and/or economic impact analyses functioned as a check on technical choices. For example, in the Superfund Reportable Quantities case, the cost savings analysis resulted in development of a different set of regulatory options after triggering review of the technical criteria the program used to develop the original set of options.
Task Force Memo, supra note 765, at 3.

1317 Fiorino Interview I, supra note 813; DuPuis Interview, supra note 793; Cannon Interview, supra note 768; Shapiro Interview, supra note 785; Vogt Interview, supra note 871; Kuzmack Interview, supra note 790; Wolcott Interview, supra note 928.

prepares.[1318] If the staff accurately summarizes the contents of the documents, they can affect the decisionmaking process at these higher levels.[1319] Ultimately, however, the regulatory analysis documents can affect these upper level decisionmakers only to the extent that they believe that these considerations are important, and this varies from program to program.[1320] Mid-level managers also rely upon the advice that they receive from their staffs. To the extent that low level personnel have read the regulatory analysis documents, their contents can influence actual decisions of mid-level managers.[1321]

For many statutory programs that the agency administers, it is unclear whether the agency may base its decisions on the kind of cost-benefit analysis that Regulatory Impact Analyses are supposed to provide under Executive Order 12291.[1322] For example, the statutory command to set Primary National Ambient Air Quality Standards at a level that protects the public health with an adequate margin of safety leaves little room for balancing considerations.[1323] Similarly, while costs are obviously

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1318 Sessions Interview, supra note 801; DuPuis Interview, supra note 793; Cannon Interview, supra note 768; Kuzmack Interview, supra note 790; Cristofaro Interview, supra note 803.

1319 Sessions Interview, supra note 801; Nichols Interview, supra note 804; Vogt Interview, supra note 871; Kuzmack Interview, supra note 790.

1320 See Task Force Memo, supra note 765, at 3.

1321 Fiorino Interview I, supra note 813; Cristofaro Interview, supra note 803; DuPuis Interview, supra note 793.

1322 See Task Force Memo, supra note 765, at 2.

1323 Cristofaro Interview, supra note 803; Thomas Interview I, supra note 780.

relevant to setting technology-based standards, such as New Source Performance Standards and Effluent Guidelines and Limitations, it is less clear that Congress intended for the standard-setter to consider the health and environmental benefits of a pollution control technology when determining whether it is the "best available."[1324] Nor is it clear that EPA may legally rely heavily upon cost-effectiveness analysis in setting technology-based standards.[1325] The agency thus faces a dilemma. While Congress has made some considerations irrelevant to the standard setting process, OMB has insisted that those considerations be made part of the decisionmaking process in the regulatory analysis documents.[1326] In addition, the current EPA management consists of personnel who are committed to regulatory analysis and would therefore probably insist that regulatory analysis be undertaken in the rulemaking process irrespective of OMB's desires. Yet if the Administrator considers the contents of regulatory analysis documents in making substantive decisions, he or she risks reversal in the appellate courts.

The current EPA administration has resolved this dilemma in an unsatisfying manner. Although the regulatory analysts in the program office are required to prepare a regulatory analysis document that contains cost

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1324 DuPuis Interview, supra note 793. Other programs in which the relevance of benefits analysis is questionable include the prevention of significant deterioration program under the Clean Air Act and the water quality standards program under the Clean Water Act. Luken Interview I, supra note 903.

1325 Task Force Case Study of the Inorganic Chemicals Industry Effluent Guideline (Phase I), supra note 765, at V-9.

1326 See GAO Cost-Benefit Report, supra note 842, at 18-20.

and benefit comparisons and although that document is made available to the Work Group, the Steering Committee and Red Border Reviewers, it is detached from the decision package when that package goes to the Administrator for his or her signature.[1327] In addition, the cost and benefits analyses do not undergo the same level of peer review by outside scientists during the pre-proposal stage as do the other supporting documents.[1328] Yet the total cost of a deleted analysis can exceed two million dollars.[1329]

This seems disingenuous at best. The evolving contents of the regulatory analysis document are available to the Work Group as it writes the Development Plan and drafts the rulemaking documents, and they are often summarized in the trade press. The Work Group considers the contents of the document as it narrows options, commissions technical analyses, and reviews public comments. The Work Group members undoubtedly rely on the information on costs and benefits available to them as they brief the First Level Options Review Committee, the Steering Committee and the Red Border Review Committee. If the considerations explored in a regulatory analysis document are in fact irrelevant to the agency's decision, it borders on dishonesty to suggest that isolating the ultimate decisionmaker from that document at the moment that he or she chooses from among two or three narrowly contoured options effectively purges the agency decisionmaking process of those

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1327 Environmental Protection Agency, Proposed Revisions to the National Ambient Air Quality Standards for Particulate Matter, 49 Fed. Reg. 10408, 10421 (1984). Campbell Interview, supra note 766; Thomas Interview I, supra note 780.

1328 GAO Cost-Benefit Report, supra note 842, at 19.

1329 GAO Cost-Benefit Report, supra note 842, at 19-20.

considerations. The institution has considered costs and benefits and the advice that the Administrator receives orally from subordinates reflects those considerations.[1330]

One could argue, however, that considerations that are irrelevant to the agency's final choice from among two or three regulatory options may appropriately be used to set priorities, design alternatives and narrow the range of options.[1331] For example, even though benefits analysis is not directly relevant to setting a technology-based standard, a benefits analysis might reveal that a technology that reduces discharges of one pollutant to much lower levels than any other technology is not as successful as other available technologies in reducing discharges of a much more toxic pollutant in the same industrial effluent stream. Even a very rough benefits analysis might reveal that that technology should not be included in the list of seriously considered alternatives, because it allows discharges that are on balance much more harmful than those of other available technologies.

Moreover, the information in the regulatory analysis document is entirely relevant to the public's evaluation of the overall regulatory program.[1332] Congress may have made costs, benefits and cost/benefit

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1330 Luken Interview I, supra note 903; Nichols Interview, supra note 804.

1331 Luken Interview I, supra note 903.

1332 Nichols Interview, supra note 804. In the case of the Clean Air Act National Ambient Air Quality Standards, the regulatory analysis can also be useful to the states, who may consider costs and benefits in setting the individual emission limitations necessary to meet the standards. GAO Cost-Benefit Report, supra note 842, at 14.

comparisons irrelevant to the agency's decision, but they are not necessarily irrelevant to the public's evaluation of the program that Congress has prescribed.[1333] If they are made aware of the full costs and benefits of a regulatory program, members of the public can decide for themselves whether it was wise for Congress to preclude agency decisionmakers from considering those factors.[1334]

Regulatory analysis documents also make the public aware of the extent of the agency's knowledge about the regulatory problem. The public can ascertain what the agency does and does not know about the issues that define the regulatory problem.[1335] To the extent that the agency substitutes assumptions for uncertainties, those assumptions should be explicitly stated in the regulatory analysis documents, and those documents can thereby focus public debate on the legitimacy of the assumptions.[1336]

According to one agency analyst, a regulatory analysis document can have an educational impact that is broader than its effect on a single rulemaking proceeding.[1337] Over time, such documents increase the awareness of technical staff in the program office and mid- and upper-level management of the fact that environmental regulations have societal costs

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1333 See GAO Cost-Benefit Report, supra note 842, at 20-21.

1334 The General Accounting Office recommends that RIAs be transmitted directly to Congress when they cannot be used by agency decisionmakers in promulgating rules. GAO Cost-Benefit Report, supra note 842, at 21.

1335 Nichols Interview, supra note 804.

1336 Nichols Interview, supra note 804.

1337 Luken Interview II, supra note 802; Luken manuscript, supra note 1270.

beyond the immediate impact on the regulated entities. Regulatory analysis documents also suggest different decision criteria, such as cost per unit of risk reduction rather than cost per ton of pollutant removed for cost-effectiveness analysis. Over time, the documents can suggest changes in overall regulatory strategy.[1338]

There is, however, a correlative danger that in the process of adopting new criteria and changing regulatory strategies, the agency will depart from its statutory design. When Congress has explicitly mandated the criteria that agencies should use in the decisionmaking process, it is inappropriate for the agency to substitute different criteria, however wise that might appear from the comprehensive analytical rationality perspective of the regulatory analyst. In addition, it is an open question whether the benefits of preparing a full-fledged RIA for major rules in which they can play no substantive role is worth the substantial preparation costs.

2. The Impact of the Regulatory Analysis Office.

a. The Impact of the Regulatory Analysts in the Program Office.

With a few exceptions, the regulatory analysts in the program offices are thoroughly incorporated into their programs' decisionmaking processes on most regulatory issues. In many program offices the branch or division containing the regulatory analysts is considered the equal of the branches

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1338 Luken Interview II, supra note 802; Luken I, supra note 903.

containing the scientists, engineers, and project managers, and the regulatory analysts participate fully in the substantive decisionmaking process. In other programs, the role of the economists and regulatory analysts appears to be limited to that of information-provider. In at least one program, some of the regulatory analysts have historically felt excluded from the decisionmaking process. Since the role of the program office's regulatory analysts varies from program to program, each program will be examined separately.

i. The Office of Air Quality and Standards.

(I). National Ambient Air Quality Standards.

The National Ambient Air Quality Standards Program in the Office of Air Quality Planning and Standards is probably the most conspicuous exception to the general rule that the program office's regulatory analysts are thoroughly incorporated into the decisionmaking process. An evaluation of the status of the policy analysts in that program, however, is hindered by the fact that the program has two independent groups of analysts.

The Ambient Standards Branch of the Strategies and Air Standards Division has a small staff of two full-time and a few other part-time analysts that works intimately with the scientists and other technical staffs in the Division. This group of regulatory analysts is also responsible for the RIAs that come out of the Division. The group, however, does not draft the benefits analysis, the economic impact analysis and the benefit-cost analysis sections of the RIAs. A second staff of analysts in

the Regulatory Impact Section of the Economic Analysis Branch of the Division is responsible for preparing these analyses for National Ambient Air Quality Standards, subject to review by the analysts in the Ambient Standards Branch.

The regulatory analysts in the Ambient Standard Branch are content with the role they play in the standard setting process.[1339] It seems likely that to the extent that cost considerations play a role in the process the document that the regulatory analysts in the Ambient Standards Branch are responsible for that role.[1340] They do not, however, contribute innovative options or new regulatory approaches to the decisionmaking process, and it is not clear that they are regarded as equals in the process of making substantive choices among existing technical options.

It is quite clear that the role of the regulatory analysts in the Regulatory Impact Section of the Economic Analysis Branch is limited to providing benefits, cost/benefit, and economic impact information. That office does not formally review the parts of the regulatory analysis documents that it does not draft, although it may be asked informally for its opinions about those documents. It has historically played no role at all in the preparation and review of the "staff paper" that is probably the most important decisionmaking document in the standard setting

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1339 Thomas Interview I, supra note 780.

1340 Recall, however, the internal agency debate over whether costs can play any role whatsoever in setting National Ambient Air Quality Standards. See text accompanying notes 1327-1330, supra.

process.[1341] This situation, however, may change with the advent of new leadership in the Strategies and Air Standards Division.

The influence of the Regulatory Impact Section has historically been reduced even farther by the fact that the regulatory analysts in the Ambient Standards Branch have the power to revise its work product.[1342] The regulatory analysts in the Regulatory Impact Section feel that the regulatory analysts and engineers and health scientists in the Ambient Standards Branch are generally unreceptive to innovative options.[1343] The regulatory analysts in the Regulatory Impact Section would prefer to participate more actively in setting the agency's research agenda. In the decisionmaking process their contributions are criticized for lack of data; yet, traditionally, their views about what data the agency will attempt to acquire have not been solicited.[1344]

The regulatory analysts in the Regulatory Impact Section are convinced that the very limited role that they play in the decisionmaking process, which contrasts sharply with the larger role that the section plays in the standard setting process for New Source Performance Standards, is attributable largely to the strong desire of the upper level decisionmakers

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1341 Basala Interview, supra note 807.

1342 Basala Interview, supra note 807.

1343 Basala Interview, supra note 807. In the rulemaking process for the National Ambient Air Quality Standard for ozone, for example, the Regulatory Impact Branch suggested that the agency use cost-effectiveness analysis to identify and limit alternatives. This suggestion was rejected in the Ambient Standards Branch. Basals Interview, supra note 807.

1344 Basala Interview, supra note 807.

in the Office of Air Quality Standards and Planning to achieve consensus within that office.[1345] Historically, the informal intra-office teams have felt such pressure to reach consensus that they would rather remove potential dissenters from the decisionmaking process rather than risk discord.[1346] By bringing some regulatory analysts into a program office that is dominated by technical staffs and by excluding the regulatory analysts in the Regulatory Impact Branch, the Ambient Standards Branch has, in this view, effectively co-opted the regulatory analysis function. Recent changes in leadership within the Office of Air Quality Planning and Standards portend changes in the past practices within the Strategies and Air Standards Division. The extent to which independent regulatory analysts will play a strong role in the future decisionmaking process, possibly interjecting statutorily forbidden considerations, remains to be seen.

(II). New Source Performance Standards and National Standards for Hazardous Pollutants.

The Emissions Standards and Engineering Division of the Office of Air Quality Planning and Standards depends entirely upon the Economic Analysis Branch of the Strategies and Air Standards Division for virtually all of its economic analysis. In the past the regulatory analysts have limited their contribution to economic impact analysis, taking the engineers' cost data

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1345 Basala Interview, supra note 807.

1346 Basala Interview, supra note 807.

and projecting impacts on profits, jobs, and so on.[1347] More recently the analysts have attempted to provide benefits analysis for one or two important rules, and it may attempt to provide some "generic" benefits assessments.[1348] Because it is the only source of economic analysis for New Source Performance Standards and National Emission Standards for Hazardous Air Pollutants, the Economic Analysis Branch does not feel excluded from the decisionmaking process.[1349] The engineers routinely go to the regulatory analysts for advice on how to structure regulations.[1350] The economists in the Economic Analysis Branch are represented on the team that develops the rule from its inception to the point at which the Director of the Emissions Standards and Engineering Division approves the proposed rule.[1351]

According to the Chief of the Standards Development Branch, the standards development process -- not any single individual -- is responsible for all except the most fundamental and important decisions. The data, analysis, policy precedents, internal views and comments, legal advice, and outside reviews and comments that are systematically gathered during the process of developing a rule all contribute to the final standard. Since

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1347 Wehe Interview, supra note 781; Task Force Case Study on the NSPS for the Coil Coating Industry, supra note 765, at II-15..

1348 See Task Force Case Study on the NSPS for the Coil Coating Industry, supra note 765, at II-16.

1349 Basala Interview, supra note 807; Wehe Interview, supra note 781.

1350 Wehe Interview, supra note 781.

1351 Ajax Interview, supra note 849; Wehe Interview, supra note 781.

the economists from the Economic Analysis Branch are part of the process, they can have an impact on the substantive decisions that result.[1352] Yet while the engineers in the Emission Standards and Engineering Division generally defer to the economists in their areas of expertise, it seems clear that they regard the Economic Analysis Branch as a provider information, much like an external contractor, rather than as a decisionmaking entity.[1353] The regulatory analysts rarely play an advocacy role on substantive issues. The information and analysis of costs, affordability, and general economic impacts of individual standards, however, can often determine in the choice from among various technological options.[1354]

The regulatory analysts in the Economic Analysis Branch believe that an important aspect of their role is to educate the engineers in the Emissions Standards and Engineering Division about the nature and importance of economic considerations.[1355] Many of the regulatory analysts have

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1352 One regulatory analyst in the Economic Analysis Branch cites as a "success story" a National Emissions Standard for Hazardous Pollutants to control emissions of maleic anhydride. The regulatory analysts opined that the engineers in the Emissions Standards and Engineering Division were concentrating too narrowly upon engineering control technologies without considering innovative alternatives such as changing the feedstock for the plants. When this was proposed as an option in the Notice of Proposed Rulemaking the industry, like the agency's engineers, reacted negatively. However, in less than two years, all but two of the plants in the industry adopted the change in feed stocks that the agency suggested, because the change actually
(Continued on page 407)

1353 Ajax Interview, supra note 849.

1354 Ajax Comments, supra note 1215.

1355 Wehe Interview, supra note 781.

training in both engineering and economics, and they attempt to blend the two disciplines as they participate on rulemaking teams. Although they get along well with the engineers, the regulatory analysts feel that they have to educate the engineers continually to get them to understand the economic aspects of their rules.[1356] Because they are procedurally integrated into the decisionmaking process, and because they can constantly play this educational role, the regulatory analysts believe that they have a substantial impact on the substantive output of that process.[1357]

ii. The Office of Toxic Substances.

The technical staffs and the regulatory analysts in the Office of Toxic Substances appear to have a cordial and mutually supportive relationship. Depending on the section of the Toxic Substances Control Act that a rulemaking proceeding is addressing, the regulatory analysts provide analyses of both the costs and the benefits of several regulatory options. According to the Deputy Director of the Chemical Control Division, the regulatory analysts play a very large role in the decisionmaking process.[1358] The regulatory analysts are full-fledged members of the internal rulemaking teams to whom the technical personnel on the teams turn

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(Continued from page 406)

1352 proved more profitable than the existing process. Basala Interview, supra note 807.

1356 Wehe Interview, supra note 781.

1357 Wehe Interview, supra note 781.

1358 Stasikowski Interview, supra note 859.

for aid and support.[1359] The technical personnel in the office regard the regulatory analysts as "very thoughtful," and the Director of the Economics and Technology Division is "a well-respected participant in the process."[1360]

This favorable assessment of the contribution of the regulatory analysts may stem in part from the technical staff's impression that the regulatory analysts in the Economics and Technology Division "have a good feel for the limitations of regulatory analysis."[1361] Since the management of the Office attempts to make the internal team meetings "participatory," the regulatory analysts can have as much input at those meetings as they desire. Yet although rapport appears to be good, the regulatory analysts are not hesitant to criticize the work of the scientists and engineers, and they have occasionally suggested innovative options that, in the minds of the technical personnel, provided "more bang for the buck."[1362]

Although the regulatory analysts in the Economics and Technology Division are not formally represented on the intra-agency Work Groups, they often participate in an advisory capacity. Because of their extensive involvement in the generation of the rule within the program office,

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1359 Stasikowski Interview, supra note 859.

1360 Stasikowski Interview, supra note 859.

1361 Stasikowski Interview, supra note 859.

1362 Stasikowski Interview, supra note 859; Shapiro Interview, supra note 785.

however, the Economics and Technology Division staff rarely makes a separate contribution at Work Group meetings.[1363]

iii. The Office of Solid Waste.

The regulatory analysts in the Economic Analysis Branch of the Economics and Waste Management Division of the Office of Solid Waste attempt to play at least three roles in the internal decisionmaking process. First, they attempt to quantify the cost and affordability considerations that the technical staffs in the office use in arriving at their "best engineering judgment."[1364] Second, they play the role of institutional critic. They attempt to sharpen the thinking of the technical personnel about regulatory requirements, and they try to make the regulation drafters aware of a broader range of options than they might otherwise consider.[1365] Third, the regulatory analysts are advocates for efficiency and free markets. When the scientists and engineers attempt to justify a national regulation on isolated reports of harm, the regulatory analysts press for more evidence that there is really a national problem.[1366] However, the regulatory

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1363 Shapiro Interview, supra note 785.

1364 Ruhter Interview, supra note 788.

1365 Ruhter Interview, supra note 788.

1366 Ruhter Interview, supra note 788.

analysts acknowledge that the solution that the engineers arrive at is not always inefficient.[1367]

In the view of the engineers and scientists in the Land Disposal Branch of the Office of Solid Waste, the most important role of the regulatory analysts is in "costing out" options that the technical staffs identify.[1368] In the minds of the technical staffs, the regulatory analysts do not play a large role in identifying options in the first place,[1369] and they believe that benefits analysis is still so rudimentary in the context of hazardous waste regulation that it cannot have much impact on substantive decisions. Even the role of the regulatory analysts' economic impact assessment is limited somewhat by the technical staffs' view that cost considerations cannot play a large role in the decisionmaking process when health concerns are at issue.[1370] Accordingly to the technical staff, "the cost work does not substantially affect our decisions."[1371]

From the above description of the regulatory analysts' and technical staffs' view of the decisionmaking process in the Office of Solid Waste, it is difficult to draw any conclusions about the role that the regulatory analysts play. They provide economic impact analysis and, to a more limited

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1367 Ruhter Interview, supra note 788.

1368 Tonetti Interview, supra note 865.

1369 Tonetti Interview, supra note 865.

1370 Tonetti Interview, supra note 865 ("We cannot compromise public health based on cost".)

1371 Tonetti Interview, supra note 865.

extent, benefits analysis. They sit on the rulemaking teams, but they apparently do not come forward with many innovative options. They consider themselves advocates of efficiency. Yet the view of the technical staffs that public health considerations always trump cost considerations suggests that they have not been persuaded.

iv. The Office of Drinking Water.

In the Office of Drinking Water, the regulatory analysts in the Economic and Policy Analysis Branch of the Office of Program Development and Evaluation are regarded as the "office intellectuals."[1372] They are present on all important Work Groups, and they are frequent contributors of options and analysis on both costs and benefits of alternatives. Their counsel is highly valued by the Director, who was himself an agency regulatory analyst prior to assuming his current management position. The relationship between the regulatory analysts in Economic and Policy Analysis Branch and the scientists and engineers in the Criteria and Standards Division appears to be cordial and mutually supportive. According to the Deputy Director of the Criteria and Standards Division, the regulatory analysts play a "very important role" in the Office's internal decisionmaking process.[1373] The current Office Director considers the input of the regulatory analysts so important that he will not allow a proposal to go forward without the advice of regulatory analysis

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1372 Vogt Interview, supra note 871.

1373 Vogt Interview, supra note 871.

division..[1374] Thus, the two staffs appear to be equals in the substantive decisionmaking process.[1375]

v. The Office of Water Regulations and Standards.

In the view of the Chief of the Economic Analysis Staff of the Office of Analysis and Evaluation in the Office of Water Regulations and Standards, the economists and regulatory analysts on that staff play two important roles in the decisionmaking process. First, they play a "quality control" role in analyzing and critiquing the cost projections of the engineers for technology-based standards.[1376] Second, they probe the cost data that the engineers provide with an eye toward reducing the economic impact of the agency's standards on particularly hard-hit industry segments.[1377] The regulatory analysts analyze the cost data to identify such industry segments and then attempt to develop a regulatory mechanism for reducing the regulation's impact on the identified segments. This might involve nothing more than exempting particular segments from the regulation or prescribing a lesser degree of control for those segments. But the regulatory analysts can suggest innovative approaches for reducing the impact of the standards on these segments.[1378]

1374 Vogt Interview, supra note 871.

1375 Vogt Interview, supra note 871; Kuzmack Interview, supra note 790.

1376 DuPuis Interview, supra note 793.

1377 DuPuis Interview, supra note 793.

1378 DuPuis Interview, supra note 793.

The regulatory analysts do not, however, appear to be major participants in the internal decisionmaking process. They are primarily a provider of information on economic impacts. They have not put much effort into benefits analysis, although they may evolve into this role in the future. They play a relatively minor role in suggesting options to reduce impacts on small industry segments. They have not played a large role in developing larger innovative options such as the water bubble. At most, they appear to be marginal participants in the substantive decisionmaking process.

vi. Conclusion.

In 1983, the Deputy Administrator of EPA convened a special Task Force on Analytical Resources. This Task Force undertook four case studies of EPA rules to determine the extent to which "economic analysis" affected the decisionmaking process. An Executive Summary of the four case studies concluded that:

> (1) Economic analyses focus mainly on costs. Cost effectiveness was very limited in application and its role in decisionmaking was ambiguous. . . .
>
> (2) Economic analysis served mainly as a check on technical choices. The programs developed a range of reasonable and technically feasible regulatory alternatives and then used the information on the costs and economic impacts to determine if the options were affordable.
>
> (3) Programs conducted most economic analysis of regulatory options before proposal of the regulation. Programs did most of the economic impact analysis prior to proposal between the state of defining regulatory options and the stage of presenting such options to the decisionmaker for selection . . . .

(4) The use of economic analysis varied by individual decisionmaker and individual case. Different decisionmakers paid attention to different criteria. The importance of the analysis in the decisionmaking process depended on what results the analysis showed. If the analysis showed an economic consequence judged to be important or significant by the decisionmaker, the situation typically triggered a closer look by the decisionmaker at the methods, assumptions and data underlying the conclusions. Otherwise, the decisionmaker did not usually question the underlying analysis. . . .

These conclusions are borne out in the interviews and case study prepared for this Report, with the exception that benefits analysis appears to be playing a larger role in EPA decisionmaking now than it did in mid-1983. It is still true that economic analysis per se rarely impels agency decisionmakers to a particular choice, although it does aid the agency in narrowing options. Moreover, the regulatory analysis offices in the programs are not often the source of innovative options and alternatives.

The analysis set out in a regulatory analysis document can help "raise the decisionmakers' comfort level with a proposed action, rather than being an essential reason for that action."[1379] This apparently happened in EPA's "lead phasedown" rulemaking effort in which the regulatory analysis document that accompanied the briefing package demonstrated that the negative economic impact of a speedier phasedown would not be nearly as large as the industry had suggested. Although public health considerations dominated the upper level decisionmaking process, the fact that the economic impact would not be devastating made the upper level decisions feel better about the final decision to reverse field and speed up the phasedown process.[1380]

1379 Task Force Case Study on the Role of Economic Analysis in the 1982 Decision to Ban Toxaphene, supra note 765, at III-12.

1380 See Lead Phasedown Case Study, supra note 1189.

One aspect of the role of regulatory analysis in EPA program offices not highlighted in the Task Force report is the occasional role of the regulatory analysis office as an advocate for particular substantive results. It is not at all atypical for a regulatory analyst in a program office to advocate a result that is supported, but not dictated by the regulatory analysis document. The source of the analyst's policy preference is unclear, but it probably stems from his or her training in economics and substantive preference for economically efficient tools and results.

b. The Impact of the Central Regulatory Analysis Office.

In all of the agencies studied in connection with this report, the central regulatory analysis office can be characterized as a "mini-OMB." In no other agency, however, did this description apply with greater force than EPA. The Office of Policy, Planning and Evaluation has evolved through several agency reorganizations as an extremely powerful institutional actor. That Office has been "consciously integrated" into the internal rulemaking process.[1381] It participates in every important regulatory decision; it relishes its role of institutional critic and gadfly; it is not hesitant to provide its own information and analysis through its own staff and contractor efforts when it believes that the program offices are not likely to undertake adequate analysis on their own; it is the chief institutional proponent of market-oriented innovations; and in recent years it very obviously has had the ear of the two most influential persons in the agency -- the Administrator and the Deputy Administrator. The Office is quite

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1381 Sessions Interview, supra note 801.

clearly an influential determinant of choices among regulatory options for virtually all programs in the agency.

In the mid-1970s, when EPA first implemented the regulatory analysis requirement, the predecessor of the Office of Policy Analysis bore the primary responsibility for drafting regulatory analysis documents and responding to inter-agency and public comment on those documents.[1382] In the late 1970s, however, the agency began expanding the analytical capacities of most of the program offices, and those offices began to take responsibility for supervising the contractors, drafting the documents and responding to comments and criticisms. The predecessor of the Office of Policy Analysis did not correspondingly shrink; indeed, it expanded somewhat in staff and resources to fill the multiple roles that it currently plays in the regulatory process.

The Office of Policy Analysis still drafts a few regulatory analysis documents and manages economic impact consulting contracts for programs, such as the Office of Mobile Sources, the Office of Radiation Programs and the Office of Emergency and Remedial Response, that lack their own regulatory analysis staffs.[1383] Although it is not clear that this results from any explicit institutional design, the theory appears to be that the agency should not waste resources building an analytical staff in a program that promulgates few rules requiring analysis.

In addition, regulatory analysts in the Office of Policy Analysis draft the benefits sections of the RIAs for some programs.[1384] This function

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1382 Sessions Interview, supra note 801.

1383 See Task Force Case Study on Reparable Quantities-Superfund, supra note 765; Task Force Panel Transcripts, supra note 765, at 2.

1384 Luken Interview I, supra note 903.

also has a historical explanation. Prior to 1981, the agency did not attempt to analyze the benefits of many of its regulations.[1385] When Executive Order 12291 required the agency to analyze the benefits of major rules, the regulatory analysis staffs in the program office lacked the training and resources to undertake this task. Therefore a special Branch in the Economic Analysis Division of the Office of Policy Analysis was established to draft benefits analyses for programs that requested them and to offer guidance to programs that undertook their own benefits analyses.[1386] At this point, that Office still drafts the benefits analyses for most of the programs.[1387] Only the Office of Air Quality Planning and Standards the Office of Drinking Water and the Office of Toxic Substances attempt independent benefits analyses.[1388]

The Office of Policy Analysis has also prepared Guidelines for the analysts in the program offices to follow in drafting RIAs.[1389] The Appendices to these guidelines offer guidance on some of the more difficult issues of cost and benefit analysis of health and environmental problems. Nevertheless, regulatory analysts in the program offices encounter substantial difficulties in the practical applications of the guidelines to real-world analytical efforts.[1390] In addition the Economic Analysis

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1385 The agency did undertake benefits analysis for programs such as toxic substances control and pesticides regulation, where the statutes call for risk-benefit decisionmaking.

1386 Luken Interview I, supra note 903; DuPuis Interview, supra note 793.

1387 Luken Interview I, supra note 903.

1388 Luken Interview I, supra note 903; Cristofaro Interview, supra note 803; Ajax Interview, supra note 849; Basala Interview, supra note 807.

1389 EPA RIA Guidelines, supra note 824.

1390 Kuzmack Comments, supra note 976.

Division has an ongoing research program on techniques for assessing costs and benefits of environmental regulations that the Office will draw upon in updating and expanding the Guidelines.[1391] Finally, personnel in the Economic Analysis Division are generally available to regulatory analysts in the program offices for consultation on regulatory analysis questions.

The Office of Policy Analysis plays a second important role in reviewing and critiquing the regulatory analysis documents that the program offices prepare.[1392] In this role it serves a quality control function,[1393] and it attempts to ensure some measure of objectivity and consistency.[1394] Personnel from the Office of Policy Analysis interact routinely with regulatory analysts in the program office and with their contractors. Since the Office of Policy Analysis personnel play the role of critic in this interaction, there is some danger that program office personnel may become defensive. Yet while there is evidence that this happens on occasion, the relationship on the whole seems supportive and fruitful. This may be explained by the fact that the regulatory analysts share a common discipline. The similarities in approaches that they take to regulatory problems in general may form a common bond that prevents criticism from erupting into acrimony. Indeed, it is not unusual for the regulatory analysts in the program office to form alliances with their

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1391 For example the Office of Policy Analysis is doing experimental work on benefits assessment for health and ecological effects. Luken Interview I, supra note 903.

1392 Luken Interview I, supra note 903; Jennings Interview, supra note 820.

1393 Basala Interview, supra note 807.

1394 Wolcott Interview, supra note 928; Task Force Case Studies Executive Summary, supra note 765, at I-10.

counterparts in the Office of Policy Analysis against the technical staff in their own program.

The Office of Policy Analysis also plays a more substantive role in agency decisionmaking by suggesting novel options and innovative regulatory approaches. The office performs this function in both its role as reviewer of regulatory analysis documents and in its role as a member of Work Groups, the Steering Committee, the Options Review Committee and the Red Border Review Committees.[1395] The input from the Office of Policy Analysis is intended to counteract the tendency of the technical staff in the program offices attach early on to a single solution to a regulatory problem and adhere to it throughout the rulemaking process.[1396]

Program office technical staffs, however, do not often find the regulatory analysts in the Office of Policy Analysis helpful in identifying realistic regulatory options.[1397] Usually the regulatory analysts simply elaborate upon options that the program office has already identified. Occasionally, however, the Office of Policy Analysis representatives have proved useful in suggesting new permutations of previously identified options[1398] and in providing an overview of how other programs in the agency handle similar problems.[1399]

1395 Fiorino Interview I, supra note 813; Wolcott Interview, supra note 928; Jennings Interview, supra note 820.

1396 Jennings Interview, supra note 820.

1397 Tonetti Interview, supra note 865; Ajax Interview, supra note 849; Stasikowski Interview, supra note 859; Vogt Interview, supra note 871.

1398 Tonetti Interview, supra note 865.

1399 Stasikowski Interview, supra note 859. The recent decision in the Regulatory Policy Division of the Office of Policy Analysis to assign analysts to particular programs may diminish this advantage, given the

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Another factor that limits the input of the Office of Policy Analysis in options identification in some programs is the fact that its representatives do not participate in the standard-setting activities of some programs until relatively late in the process, after significant new options are precluded.[1400] While officials in the Office of Policy Analysis acknowledge the value of providing input at a very early stage in the rulemaking process,[1401] resource constraints apparently preclude early participation in all programs.[1402] The Options Selection/Rejection Process could alleviate this source of friction by forcing the Office of Policy Analysis to involve itself at an earlier data. However, since that process is limited to very high profile rules, which the Office of Policy Analysis would probably designate as high priority in any event, the potential of that process to encourage early participation by that office may be limited.[1403]

Beyond identifying options in individual rulemaking proceedings, the Office of Standards and Regulations in the Office of Policy, Planning and Evaluation has a small Regulatory Reform Staff that explores the possibility of intergrating innovative (often market-oriented) techniques into the

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1399 limited attempts in the office of Policy Analysis to provide mechanisms for "cross-fertilization" within that office.

1400 Ajax Interview, supra note 849; Kuzmack Interview, supra note 790; Tonetti Interview, supra note 865.

1401 Nichols Interview, supra note 804.

1402 Cristofaro Interview, supra note 803.

1403 In addition, the Options Selection/Rejection Process will not encourage early participation by the Office of Policy Analysis in rules promulgated by Office of Water Regulations and Standards, because that process is apparently inapplicable to those standards.

existing decisionmaking structures. Although this staff usually works on specially selected regulatory projects, the learning derived from those projects can help Work Groups identify options in rulemaking proceedings involving similar or related regulatory issues. Finally, the Office of Policy, Planning and Evaluation makes some effort to "cross-fertilize" ideas within that Office by conducting office seminars on topics relating to regulatory analysis.[1404] These efforts have combined to place a list of regulatory reform issues, such as benefits analysis and cost-effectiveness analysis, on the agency's rulemaking agenda.[1405]

In both its review and participant roles, the Office of Policy Analysis attempts to force the program offices to think about what they are doing and why they are doing it.[1406] Of all the functions mentioned in interviews with personnel in the Office of Policy, Planning and Evaluation, this was the most intensely and consistently stressed. The Special assistant for Policy to the Deputy Administrator referred to the Office as the "institutional skeptic."[1407] Others have referred to it as a "devil's advocate"[1408] and the "chief critic and reviewer" of the agency's regulatory activities.[1409]

1404 Although the Office of Policy, Planning and Evaluation has made some "cross-fertilization" efforts across media, there is still not a great deal of communication between lead analysts who work with one program and those who work with another. Sessions Interview, supra note 801.

1405 Sessions Interview, supra note 801; Nichols Interview, supra note 804.

1406 Fiorino Interview I, supra note 813; Cannon Interview, supra note 768; Campbell Interview, supra note 766; Wolcott Interview, supra note 928.

1407 Wolcott Interview, supra note 928.

1408 Stasikowski Interview, supra note 859.

1409 Fiorino Interview I, supra note 813.

The Deputy Assistant Administrator for Policy, Planning and Evaluation opined that the personnel serving under him should be "pushing decisionmakers' noses in the facts and the principles that are or are not being followed" so that they "know what they are buying into."[1410] In this view, "winning" for the regulatory analyst is not prevailing upon a specific view of the facts or public policy; it is ensuring that the decisionmaker knows what he or she is doing and why.[1411] If this educational effort is reduced to writing and made public in a regulatory analysis document, it has the added value of informing the public of the reasons for and consequences of the agency's decisions, and it thereby enhances public accountability.[1412]

There is, of course, a presumption built into this view of the regulatory analyst's role that the agency decisionmakers do not ordinarily know what they are doing and why they are doing it. This presumption is not lost upon the technical staff in the program offices, and they do not generally agree. Clearly, this attitude can contribute to an adversarial relationship between the regulatory analysis office and the program offices.[1413] Indeed, this presumption is at the nub of the differences between the two rulemaking cultures. Without it, the regulatory analyst is little more than an information provider. With it, the regulatory analyst becomes essential to the decisionmaking itself. Without a regulatory

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1410 Campbell Interview, supra note 766.

1411 Campbell Interview, supra note 766.

1412 Campbell Interview, supra note 766.

1413 Campbell Interview, supra note 766.

analyst to force the decisionmaker to come to grips with reasons for and consequences of his or her decisions, rational decisions are impossible.

Yet upon closer inspection, it is clear the agency regulatory analysts view "rational decisionmaking" through their own special lens. For them, "rationality" is defined as comprehensive analytical rationality. Policy analysts cannot, for example, understand why an engineer would view the installation of a particularly effective pollution reduction technology as an end in-and-of-itself, apart from any measure of the benefits of the pollution removal that will result from the installation of that technology. They cite such conduct as proof that the engineer-decisionmaker does not know what he or she is doing and why.[1414] Yet it is unfair to characterize this as a mindless bureaucratic act. The engineer may have devoted considerable attention to the matter and have very comprehensible reasons for viewing the installation of a technology as an end in itself; they are just not reasons that regulatory analysts generally consider valid.[1415] Still, the regulatory analysts in EPA feel that forcing agency decisionmakers to think "rationally" about regulatory problems is one of their most important functions.

In the view of many program office technical staffs, on the other hand, the Office of Policy Analysis is not so much concerned with analysis as it is interested in the substance of the rules that the agency promulgates. Rather than engaging in a single broad agency-wide debate on a single policy issue, such as the dollars per ton that should apply in cost-effective analysis of the removal of a given pollutant, they interject substantive

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1414 Campbell Interview, supra note 766.

1415 McGarity, supra note 852.

policy considerations into the process on an ad hoc basis in individual rulemaking efforts. Technical staffs in the program office take this as an attempt to second-guess their technical judgments, which often have a large policy component.[1416]

The ad hoc input of the regulatory analysis office can have the effect of holding up individual rulemaking efforts and making the project officers appear ineffective as managers. Similarly, program office technical staffs often view the Office of Policy Analysis' frequent insistence upon additional analysis as an excuse to delay the issuance of a rule. The technical staffs insist that virtually the same rule will be issued in any event, and they question the marginal value of an additional analysis that is not likely to change the outcome of the proceeding. One engineer suggested that in cases in which the agency is working under court ordered deadlines that preclude extensive analytical efforts, the agency promulgates about the same rules that it would have promulgated after a thoroughgoing regulatory analysis.[1417]

The view of the program office technical staffs that the Office of Policy Analysis is more concerned with substance than analysis has a sound basis. Many regulatory analysts in the Office of Policy, Planning and Evaluation believe that that office has the substantive role of "explicit advocate for efficiency."[1418] The representative from that Office on Work Groups, the Steering Committee, the Option Selection/Rejection Committee, and the Red Border Review Committee have an obligation not only to identify

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1416 Stasikowski Interview, supra note 859.

1417 Ajax Interview, supra note 849.

1418 Wolcott Interview, supra note 928. See, Hall Hearings, supra note 1082, at 606 (testimony of Joseph Cannon).

options for which benefits outweigh costs, but also to advocate the adoption of those options.[1419] While they recognize that efficiency is not the only appropriate goal of the regulatory process,[1420] those officials believe that efficiency considerations at least deserve the careful consideration of the decisionmaker. This position as efficiency advocate often makes the regulatory analyst an advocate of less regulation as well,[1421] because the regulatory analysts tend to place more emphasis on efficiency than on public health and environmental protection.[1422]

Agency regulatory analysts in the Office of Policy Analysis, for example, have on occasion cooperated with OMB to insist that the program office use lower values for the benefits of removing pollutants from emission streams.[1423] In adopting this position, the Office of Policy Analysis is not simply advocating more or better analysis. It is making a substantive recommendation on which controls are warranted and which controls are too expensive. The cost-effectiveness cut-off suggested by OMB and EPA regulatory analysts for National Emission Standards for Hazardous Air Pollutants, for example, derives directly from the subjective value that those entities place on human life.[1424] This determination does not go to

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1419 Campbell Interview, supra note 766; Sessions Interview, supra note 801.

1420 Campbell Interview, supra note 766; Sessions Interview, supra note 801.

1421 Sessions Interview, supra note 801.

1422 Wolcott Interview, supra note 928.

1423 See, Policy Office Sides with OMB in Seeking Relaxed Benzene NESHAPS Package, Inside EPA, Apr. 27, 1984, at 1.

1424 In the case of the Benzene National Emission Standard for Hazardous Pollutants, OMB and the Office of Policy Analysis used $1,000,000 for

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how the agency thinks about problems; it is the essence of the public policy choice that the agency makes when it sets National Emission Standards for Hazardous Air Pollutants.[1425]

The regulatory analysts who stress the advocacy role of the Office of Policy, Planning and Evaluation recognize that there is a tension between this role and the Office's roles of information provider, neutral reviewer and identifier of innovative options.[1426] Because of this role conflict, upper level decisionmakers generally recognize that "neutral" advice from that Office must be viewed with a grain of salt.[1427] There may also be a conflict between this role and the position adopted Congress in the agency's statute, thus creating a tension between the Office of Policy, Planning and Evaluation and the Office of General Counsel. Nevertheless, the Office of Policy, Planning and Evaluation is a very influential participant in upper-level deliberations over the substantive content of regulations, and in many cases it prevails over the program office.[1428]

c. Comparison of the Roles Regulatory Analysts in the Program Office and the Central Regulatory Analysis Office.

To a large extent, the regulatory analysts in the program offices share

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1424 the value of a human life in reaching a cost-effectiveness cut-off of approximately $1,000 for volatile organic carbon compounds. Inside EPA, supra note 1423, at 1.

1425 Indeed, the legality of factoring cost-benefit considerations so explicitly into a decision regarding a standard that is required to protect the public health with an "ample margin of safety" is questionable.

1426 Campbell Interview, supra note 766.

1427 Wolcott Interview, supra note 928.

1428 Fiorino Interview I, supra note 813.

the perspectives of the regulatory analysts in the Office of Policy, Planning and Evaluation. They believe that they have an obligation to force program officials to think about the reasons for and consequences of their actions;[1429] they attempt ot identify innovative market-oriented options for solving regulatory problems;[1430] many are partial toward cost-benefit and cost-effectiveness analysts; and some consider themselves advocates for efficiency regulatory results.

The recent Report of the President's Private Sector survey on Cost Control was critical of the bifurcated nature of the regulatory analysis function at EPA.[1431] The Report argued that one result of placing regulatory analysts in a centralized office and in the program office was "a lack of leadership, coordination and consistency in inter-program policy development".[1432] The Report recommended that the regulatory analysis function in the program office be eliminated and transferred to the centralized office at an estimated cost savings of $1.5 million per year.

The regulatory analysts in the program office are obviously closer to the technical issues than the regulatory analysts in the Office of Policy Analysis, and they often have a better understanding of the technical issues and uncertainties with which the technical staff in the program office must grapple. As a practical matter, this means that the regulatory analysts in the program are likely to be more sympathetic to the technical staff's concerns. They can also on occasion be asked to bend their judgment to put

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1429 Basala Interview, supra note 807; Ruhter Interview, supra note 788.

1430 Kuzmack Interview, supra note 790.

1431 Inside EPA, Nov. 12, 1982, at 12.

1432 Inside EPA, supra note 1431, at 12.

a favorable slant on the option favored by the technical staff. No regulatory analyst interviewed in connection with this report however, felt obliged to manipulate analyses in an unprofessional way. Generally, the information that regulatory analysis builds upon is sufficiently ambiguous to support widely varying interpretations, and there is sufficient flexibility in the quantitative analysis to support many different predictions.

The program office regulatory analysts occasionally act as advocates of the technical staff's point of view in interaction with personnel from the Office of Policy Analysis.[1433] On the other hand, the regulatory analysts can represent the perspective of the Office of Policy Analysis in internal program office deliberations. Since they often share the "comprehensive analytical rationality" perspective of the personnel in the Office of Policy Analysis, the regulatory analysts in the program office can suggest considerations to the technical staff that may help avoid conflicts with the Office of Policy Analysis later in the rulemaking process when that office reviews the rule. Finally, it is possible for the regulatory analysts in the program to arm the Office of Policy Analysis regulatory analysts for battles that they lost internally.[1434] Obviously, this is not especially conducive toward program office espirit de corps.

1433 Fiorino Interview I, supra note 813.

1434 Sessions Interview, supra note 801.