UNITED STATES GOVERNMENT RULEMAKING

TRANSPARENCY, PARTICIPATION, ANALYSIS, AND ACCOUNTABILITY

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CONTENTS

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I. Background

This United States Government document is a revised and updated version of a document originally issued by the U.S. in 1999 pursuant to the Transatlantic Economic Partnership (TEP) initiative announced at the May 1998 United States-European Union (U.S.-EU) Summit in London. [i]

II. Introduction

The globalization of commercial activity is increasing the potential scope of the effects of, and therefore interest in, the social regulation of products, i.e., the regulation of their safety, health and environmental effects. The desire to improve the quality of life as well as the health and growth of national economies is likewise creating increasing interest in the quality of regulatory decisions and the process by which they are made. [ii] In response to these ongoing phenomena, this document seeks to promote common understanding, regulatory cooperation and more effective and beneficial regulation by describing and explaining the provisions for transparency, public [iii] participation, regulatory analysis, access to information and accountability in rulemaking proceedings conducted at the Federal level in the U.S. to develop, propose, establish, amend and repeal regulations for products. [iv]

Since the product regulations are, for the most part, established by Federal agencies using the informal (as opposed to formal) rulemaking procedures of the Administrative Procedure Act, 5 U.S.C. §§ 551 *et seq.* (APA), [v] this paper focuses on the informal procedures. (These and other statutory provisions cited in this paper can be found at http://uscode.house.gov/ and http://www4.law.cornell.edu/uscode/.) [vi]

The discussion in this document is organized around and highlights the following elements of the U.S. rulemaking process:

- Transparency in the making of technical assessments, factual findings, and normative policy choices, and transparent and open opportunities for public participation regarding those matters to ensure effective monitoring, critiquing and reviewing of rulemaking;

- Regulatory analyses, based on sound data, of the need for, approaches to and stringency of regulation;

- Strong support, centralized in a single executive branch body, for the use of regulatory best practices; and

- The review mechanisms within the executive, legislative and judicial branches of the Federal government for holding Federal agencies accountable for conducting sound economic and scientific analyses, complying with the requirements for procedural fairness, providing rational explanations for agency decisionmaking in

conducting rulemaking, and observing the limits on agency authority and discretion regarding the substance of those regulations.

(A flowchart graphically depicting the rulemaking process, as well as the associated public participation opportunities and the review mechanisms, appears at the end of this paper. An additional, more detailed flowchart can be found at http://reginfo.gov/public/reginfo/Regmap/index.jsp.)

These elements of the U.S. rulemaking process increase the quality and legitimacy of the rulemaking process and the resulting regulations. More specifically, their benefits include:

- Better regulations, i.e., ones that provide higher levels of consumer protection and economic efficiency and, at the same time, are more targeted and less intrusive;

- Greater public understanding of the purposes and effects of, and justifications for regulations;

- Greater public confidence and trust that participants in rulemaking proceedings will have their concerns not only heard, but also fairly resolved, and that the agencies will make their rulemaking decisions in accordance with law and on an openly stated, well reasoned, and well-supported basis;

- Greater predictability in the final decisions made in rulemaking proceedings; and

- Greater public acceptance of the regulations adopted.

All three branches of the Federal government play important, distinctive roles in securing those benefits. The legislative branch, Congress, enacts laws delegating rulemaking authority to Federal agencies to establish product regulations and specifying requirements concerning the use of that authority. The executive branch implements those laws, gathering and analyzing information, selecting rulemaking priorities, and developing and establishing the regulations. In response to lawsuits brought before it, the judicial branch can vacate regulations or return them to the issuing agency for further consideration if a court determines that the agency violated the procedural requirements governing rulemaking proceedings or the substantive requirements in the law cited by the agency as authorizing the regulation.

The public also plays important roles. These include asking Congress to enact laws relating to rulemaking, providing Federal agencies with data, views, arguments and analyses regarding their rulemaking plans and proposals, and bringing lawsuits in Federal courts to enforce compliance with those laws.

III. Federal Rulemaking

A. Congressional Authorization and Decisionmaking Factors/Criteria

To engage in rulemaking, agencies must be statutorily authorized by Congress to do so. "Rulemaking" is agency action that regulates the future conduct of governmental agencies, persons, [vii] or both, through development and issuance of an agency statement designed to implement, interpret or prescribe law or policy. There are several types of rules. This document focuses on legislative or substantive ones, which create new duties and have the force and effect of law. The other types of rules are non-legislative ones, i.e., guidance (interpretive) documents, general statements of policy, and management and procedural rules.

While Congress could establish the details of individual product regulations legislatively, in most instances it enacts legislation delegating authority to Federal agencies in the executive branch to establish such regulations administratively. In that legislation, it delegates rulemaking authority and sets forth factors/criteria to guide and limit how the agencies exercise their discretion regarding their use of that authority in making decisions about what rules to propose and adopt. The degree of specificity in Congress' delegation of authority and guidance varies from statute to statute. At the more detailed end of the spectrum, Congress may specify the subject, and even some of the key substantive details, of particular individual regulations. At the other end, Congress may make a more general delegation of authority and provide more general direction, e.g., authorizing the issuance of regulations that meet the need for safety and specifying the factors, e.g., practicability, to be considered in deciding what regulations to adopt and the general policy goals to be achieved by those regulations. The latter is, by far, the more common practice, and is described in greater detail below.

When Congress enacts legislation creating a regulatory agency, or giving new authority to an existing regulatory agency, it typically includes provisions that implicitly or explicitly delegate its rulemaking authority to the agency with respect to a specified policy goal. [viii] The legislation containing the rulemaking authority granted by Congress to an agency is known as the agency's authorizing or “enabling” statute. An agency may have more than one enabling statute, one for each of its regulatory programs. Alternatively, some enabling statutes may have subparts, each authorizing a different regulatory program.

An agency’s enabling statute specifies the general purposes for which rulemaking may be conducted, and may identify at least some of the individual regulations to be adopted to achieve those purposes. The statute often enumerates factors that an agency must consider in its rulemaking and may specify criteria that the resulting regulations must meet. [ix] Some factors and criteria are fairly generic, while others are unique to a particular program. The generic factors and criteria typically include the likelihood that regulations will contribute to achieving their stated purposes, and the practicability (often both economic and technological) of the regulations. They also address the role, if any, that the costs of compliance are to play in the agency's decisionmaking about the regulations. In some environmental rulemaking, for example, those costs may not be considered. Other generic factors and criteria may include objectivity of the method for determining compliance with a standard, performance orientedness (as opposed to design specific) of a standard, and impacts on ability to comply with standards of other U.S. regulatory programs.

Congress may supplement an agency's enabling statute by later enacting new legislation directing the agency to use its existing general rulemaking authority in a specific way. In these

instances, Congress directs the agency to issue at least a Notice of Proposed Rulemaking, and sometimes a Final Rule as well, on a particular subject, e.g., a particular pollutant or type of vehicle safety equipment or performance. Among the more common circumstances in which Congress has enacted such legislation are those in which it has concluded that an agency should initiate or increase its efforts regarding a specific aspect of the problems that the agency is already authorized to address through rulemaking. Even in these cases, however, Congress normally leaves the key substantive provisions of the rule to be issued to the discretion of the issuing agency. Congress usually does not dictate any of the specific performance requirements to be adopted for products. Further, it typically does not precisely specify the particular regulatory approach, level of stringency of requirements, or test procedures to be adopted. It may, however, impose certain restrictions or define certain parameters for the rulemaking and establish a mandatory schedule for completing whatever actions are required.

In addition to enabling statutes, there are various general sources of requirements that govern the development and issuance by Federal agencies of rules regulating products. These sources include other statutes and Presidential Executive Orders that impose procedural requirements that are intended to ensure reasoned and fair decisionmaking. These other statutes and, except to the extent inconsistent with an agency's enabling statute or other law, the Executive Orders require that the agencies adopt these rules only after thoroughly analyzing their potential impacts. This typically, but not always, includes an assessment and comparison of either the benefits and costs, or the cost-effectiveness, or both, of alternative regulatory approaches or alternative levels of stringency. They also require an open and transparent U.S. rulemaking process that gives all members of the public the opportunity to participate -- from the Notice of Proposed Rulemaking to the Final Rule. The process also seeks to give the public the information and explanations it needs to understand what the regulatory agencies are proposing and adopting and the rationales for those actions. (For more information about these informational and analytical requirements, see below the section on Regulatory Analyses and Other Rulemaking Requirements (III.C).)

B. Public Participation in Pre-Rulemaking and Rulemaking Actions

1. Initiation of Rulemaking

Most rulemaking proceedings conducted by Federal agencies are initiated in one of the following three circumstances.

First, an agency may begin a rulemaking proceeding on its own initiative, or at the request of another Federal agency. The rulemaking must be within the limits of its existing enabling statute or other legislation granting it authority to engage in rulemaking.

Second, an agency may also initiate rulemaking within the limits of its existing authority in response to a request by a member of the public. The APA provides that each Federal agency shall afford interested persons the right to Petition for Rulemaking, i.e., for the issuance, amendment, or repeal of a rule. Agencies must respond to such a petition. [x] If the petition appears to be meritorious and consistent with the agency's priorities and if the agency's available resources are sufficient, the agency may grant the petition and begin a

rulemaking proceeding. The granting of such a petition and the commencing of a rulemaking proceeding do not necessarily mean that the agency will ultimately issue the requested rule. Further, the agency's initial response might not be the issuance of any notice, but the conducting of research to determine if appropriate requirements or test procedures can be developed. The decision ultimately whether to issue a rule is made later in accordance with statutory criteria and on the basis of all available information developed or received in the course of the rulemaking proceeding. For example, the public comments on a rulemaking proposal may contain data, views and arguments that persuade the agency that the requested rule lacks sufficient merit and therefore should not be issued.

Third, an agency may be statutorily directed by Congress to begin a rulemaking proceeding on a specific issue. If the agency does not initiate or complete such a rulemaking within the time specified by Congress, a member of the public may seek judicial enforcement of the directive. In some instances, Congress encourages an agency to initiate rulemaking proceedings on a particular subject by lesser means, such as holding a public hearing on that subject and asking the agency to testify regarding its activities concerning that subject.

2. Types of Rulemaking

The primary mechanism for ensuring transparent and open rulemaking in the U.S. is a standardized system of opportunities for public participation as rules are developed, issued and revised. The APA, which applies across-the-board to all Federal agencies, specifies requirements governing how those agencies provide those opportunities. Substantive rules issued by an agency under the APA have the force and effect of law.

If an agency's enabling statute authorizes the agency to conduct rulemaking proceedings, the statute typically specifies that either informal or formal procedures be followed. If the statute does not specify which procedures an agency is to use, it may choose either. Agencies that have this choice usually choose informal procedures.

Informal rulemaking procedures specified by the APA include, with certain limited exceptions, the publication by the agency of a Notice of Proposed Rulemaking notifying the public that it may adopt that rule in the future and providing an opportunity for the public to comment by submitting written data, views, and arguments in response to the publication of a proposed rule. [xi] The agency has discretion whether to supplement the opportunity to submit written comments with an opportunity to make oral presentations at a public meeting. Usually, participation is limited to the submission of written presentations.

The opportunity to comment is universal; there are no restrictions on who may participate. Persons wishing to comment are not subject to any governmentally controlled or sponsored accreditation or other type of selection process. Businesses and consumers decide for themselves whether to participate and may participate directly (i.e., individually), indirectly through associations, or both. Any member of the public,

regardless of geographical location, may submit comments. This includes, for example, individuals, businesses, and government agencies of other countries and regions.

Under the APA, the agency must consider the data, views, and arguments submitted by the public and, in issuing any Final Rules, must provide a statement of the rule's basis and purpose. That statement must include the agency's discussion of and response to the public comments. (For a fuller discussion of informal rulemaking procedures, see below the section on Informal (Notice and Comment) Rulemaking (III.B.3).)

Formal rulemaking procedures are trial-type procedures that require an agency to conduct a complete oral evidentiary hearing. These hearings are open to all persons. The agency must offer persons wishing to participate an opportunity to appear and present oral and documentary evidence and arguments and to cross-examine other participants in the hearing. The hearings are generally presided over by an Administrative Law Judge. The record of the proceeding consists of the transcripts of the testimony and exhibits presented at the hearing, together with all documents filed in the proceeding.

Informal rulemaking procedures are statutorily required for most rulemaking proceedings, including, as noted above, most rulemakings conducted by most agencies involved in establishing product regulations. This nearly universal application of the APA's informal rulemaking procedures means that the public enjoys the same minimum rights to participate, and that the agencies must meet the same minimum procedural obligations, regardless of the product, enabling statute or agency involved. This makes the basic elements of the rulemaking process very predictable for the public.

The use of formal rulemaking procedures has been, and continues to be, the exception. An agency must use formal rulemaking procedures if it is engaged in rulemaking under a statute requiring that rulemaking be conducted "on the record." Most of the relatively few agencies required to use these procedures are independent regulatory commissions, such as the Federal Communications Commission. These commissions use formal procedures for such actions as granting licenses and promulgating regulations or making rates that are not generally applicable to all persons regulated by these commissions.

Some statutes require the use various kinds of "hybrid" rulemaking procedures. For example, one kind of hybrid procedure combines an informal opportunity to provide written comments with an opportunity to make oral presentations of some kind. In addition, agencies that are not required to use these expanded procedures may nevertheless decide, in their discretion, to use them. For example, they may decide to hold public meetings when they believe that it would be beneficial to have a face-to-face exchange of views and data between the agency and the public. [xii] Rulemaking proceedings involving hybrid procedures other than a public meeting represent a fairly small portion of rulemaking proceedings government-wide.

Agencies may add to, but never subtract from, procedures required by the APA or other statutes. (For a discussion of the APA's limited exceptions to the use of those procedures, see below the section on Rulemaking without Notice and Comment, III.B.3.f.) The additional procedures used by an agency must not violate the procedural requirements in the APA or other statutes, and in

the case law interpreting those requirements, such as the requirement concerning consideration of and response to written comments submitted during a rulemaking proceeding.

Informal rulemaking proceedings generally follow the steps set forth below. Not all steps, e.g., preliminary notices, are used in every rulemaking proceeding. Although practice varies among agencies and regulatory programs, a majority of rulemaking proceedings involve only three steps: issuance of a Notice of Proposed Rulemaking soliciting public comment, agency consideration of all relevant available information, including public comments, and the issuance of a Final Rule after consideration of that information. Both the Notice of Proposed Rulemaking and Final Rule are published in the Federal Register. [xiii] Since additional steps are particularly likely to be used for some of the more costly and complex proposed rules, the full potential range of steps is outlined below. It should be noted that the duration of an informal rulemaking proceeding might vary from a few months to several years, depending on the complexity, novelty, the degree of controversy, and nature of the action.

3. Informal (Notice and Comment) Rulemaking

The APA's requirements for informal rulemaking proceedings seek to ensure that the public has a "meaningful opportunity to comment," i.e., an informed two-way dialogue between the public and the agencies. To provide such an opportunity, Federal agencies:

- Publish proposals and invite public comments at an early stage, when their minds are still open and amendments can be made;

- In conjunction with the issuance of proposals, give notice and make publicly available the key data, analyses and other information relied upon by them in developing the proposals; and

- In issuing Final Rules, provide written, reasoned explanations of why the agencies agreed or disagreed with the key public comments.

An agency's providing the public with a thoughtful discussion of the public comments and reasoned explanations of its acceptance or rejection of the key arguments and requests for changes made in those comments is the best evidence that the public is being heard and fairly treated. In other words, it is the best evidence that the public is being given a meaningful opportunity to comment.

a. Preliminary Notices

When an agency is contemplating the initiation of rulemaking on a problem that may warrant a regulatory response, it uses a variety of means to gather more information about the nature and extent of that problem or to obtain public views on which regulatory approach would be most effective and desirable. One means is the issuance of a preliminary notice seeking public comments. Although the APA does not require or even address the subject of preliminary notices, they are issued by some regulatory agencies with sufficient frequency to warrant their discussion here. Other means for gathering more information include conducting research and

surveys, holding interactive public workshops, and forming and obtaining input from advisory committees. (For a brief discussion of advisory committees, see below the section on Other Opportunities for Public Participation (III.B.4).)

The most common type of preliminary notice is the Advance Notice of Proposed Rulemaking (ANPRM). It is a means of public outreach and opportunity for public comment used very early in the rulemaking process. ANPRMs vary in the degree of their detail. The more detailed ones describe the particular problem, e.g., a safety or health problem, that the agency may later decide to address through issuing a proposal; discuss the agency's current knowledge about the nature, extent, and apparent cause of the problem; ask whether the problem warrants a regulatory response; explore, in general fashion, possible regulatory approaches for addressing the problem; discuss information gathered to date and plans for gathering more; and ask for public comment on all of those matters. They also invite the public to identify any additional relevant issues and regulatory approaches. Documents and data mentioned in the ANPRM are typically placed in a public rulemaking docket.

The ANPRM specifies the period of time within which the public may submit comments. The comment period is usually 60 days, but it can be longer or shorter, depending on the complexity and importance of the subject matter and the circumstances in which the notice is issued, e.g., whether the problem is a particularly urgent one or Congress has established a tight rulemaking schedule. Any person or entity may submit comments. Some agencies immediately place all comments on the ANPRM in a docket where they are available to the public, while others later docket only those comments that support a subsequent Notice of Proposed Rulemaking. In both cases, trade secrets and confidential business information are removed from the comments before they are placed in the public docket. [xiv] To the extent that the comments are made public, their availability enables the members of the public to sharpen their comments and respond to opposing viewpoints, thus narrowing the issues and aiding the agency in analyzing and resolving them.

Given the relatively general nature of most ANPRMs, the public comments may likewise be general. Since the commenters do not yet know whether the agency will decide to issue a proposal and, if it does, the nature and extent of the proposal, much less the details about the requirements and their levels of stringency or about the test procedures, they will likely comment only generally on the possible courses of action that the agency might take.

b. Notice of Proposed Rulemaking

In most rulemaking proceedings on product regulations, the initial step is to develop and then publish a proposed rule. The proposal is called a Notice of Proposed Rulemaking (NPRM). The purpose of the NPRM is to inform the public about the proposal, explain it, and request public comment on it. The NPRM must provide sufficient information and description to enable the public to envision and anticipate the major aspects of the Final Rule. In an attempt to ensure that their NPRMs do this, some agencies include in their NPRMs a discussion of alternative possible outcomes of the rulemaking.

The NPRM typically consists of two parts: a preamble, which is a narrative discussion, and the proposed amendments (commonly referred to as the regulatory text of an NPRM) to the Code of Federal Regulations (CFR). For more information about the CFR, see the section below on Access to Information, III.D.) Some, however, do not include any regulatory text.

The preamble must inform the public of the relevant issues and considerations. The amount of detail in NPRM preambles varies with the complexity and extent of controversy involved in the rulemaking. The more detailed preambles:

- Identify the problem addressed by the proposal,

- Identify, discuss and analyze available information regarding the existence, nature, extent, and causes of the problem,

- Explain why the agency has tentatively concluded that a regulatory response is warranted,

- Lay out the details of the contemplated response--the nature of the proposed regulatory approach as well as the details about the requirements, their levels of stringency, and the test procedures,

- Describe the available research studies and empirical data and explain how and why they led to the agency's tentative selection of that particular approach and of the particular details of that approach, including the agency's tentative choice about the level of stringency,

- Explain how the proposal would reduce the problem, and

- Analyze the potential benefits and costs or cost-effectiveness of the proposal.

The NPRM also discusses the agency's analysis of the proposal under various statutes and Executive Orders which seek to ensure that rules are proposed and adopted only after careful consideration of various types of potential impacts, e.g., Regulatory Flexibility Act; Paperwork Reduction Act; and Executive Order 12866, Regulatory Planning and Review (E.O. 12866). Typically, the agency officials who prepare these analyses are independent from the officials who prepare the NPRM. (For a discussion of these analytical requirements, see below the sections on Regulatory Analyses and Other Rulemaking Requirements (III.C) and on Executive Oversight and Review (III.E.2.a).)

If the NPRM was preceded by the issuance of a preliminary notice, the NPRM may summarize and respond to the public comments on the preliminary notice. The NPRM provides instructions for submitting written or electronic comments and identifies an agency contact person who can respond to questions. To the extent that the NPRM does not set forth and explain the factual assumptions, analyses, and methodologies underlying the proposal, the agency places documents containing those matters in a public docket so that the public has an opportunity to read and comment on them. These documents become part of the administrative record in the event that a

Final Rule is issued and a lawsuit seeking review of the rule is filed. (For a discussion of administrative records, see below the section on Judicial Review (III.E.2.c).)

The NPRM specifies a certain period of time within which any person who wishes to do so may submit comments. The APA does not specify a minimum period. E.O. 12866 recommends a comment period of at least 60 days for all NPRMs. The period can be longer or shorter, depending on the complexity of and degree of controversy associated with the proposal, and the circumstances in which it is issued. [xv] (See below the sections on Regulatory Analyses (III.C.1) and Executive Oversight and Review (III.E.2.a) for further discussion of the Executive Order.) In an informal rulemaking proceeding, the agency typically considers late comments to the extent consistent with its rulemaking schedule. If that schedule is constrained by statutorily or judicially mandated deadlines, consideration of late comments may not be possible. The agency places all comments in a public docket, except that trade secrets and confidential business information are not revealed. As noted above, the public availability of the comments enables the public to sharpen their comments and respond to opposing viewpoints, thus narrowing the issues and aiding the agency in analyzing and resolving them.

The public comments on an NPRM tend to be much more detailed and focused than those submitted on preliminary notices. This difference reflects the fact that, by the time an agency issues an NPRM, the agency has typically reached tentative conclusions about the particular regulatory approach, the type and stringency of the requirements, and the test procedures, and sets them forth in the NPRM.

The opportunity to submit comments on NPRMs serves a number of purposes, including enabling the public to:

- Provide the agency with information that will enhance the agency's knowledge about matters discussed in the NPRM;

- Challenge the agency's interpretation and application of data and research, factual assumptions, analytical methodologies, tentative factual, technical and policy conclusions, practicability assessments, and assessments of the benefits and other impacts of the proposal; and

- Suggest alternatives to the proposed requirements and test procedures.

While the Federal agencies possess considerable expertise regarding these matters, private individuals, consumer groups, individual companies, and industry associations also possess considerable expertise. They provide data, views, and arguments on these matters based on their particular experience and perspective. Sometimes the views of these disparate individuals and groups reflect a broad consensus; more often, they express differences in opinion and interpretation. Together, those views, and the facts and analyses supporting them, provide the agencies with a fuller, more accurate understanding of the strengths and weaknesses of their proposals. As a result, the agencies are able to determine where and how best to modify their proposals in order to fashion and adopt better Final Rules.

If, after the comment period, the agency obtains new data or analysis that is not simply cumulative, i.e., similar to the data and analysis already in the agency's possession, and has a potentially significant bearing on the substance of the Final Rule, the agency must make it available so that the public may comment on it before the issuance of the Final Rule. If the agency has an established practice of considering late, i.e., post-comment period, comments and will consider any late comments on the new information or analysis, it may not need to re-open the comment period on the NPRM when it places that material in the docket. If, in addition to being non-cumulative, the new information or analysis will likely lead to significant and unexpected changes in the Final Rule, it is particularly necessary that the agency publish a notice in the Federal Register to ensure that the public is aware of the material and has an opportunity to comment on it.

In response to the comments on the NPRM or to developments (e.g., new research results) after the NPRM is issued, the agency generally changes certain aspects of its proposal. In most cases, the changes are within the range of potential regulatory approaches discussed in the NPRM. No further opportunity for public comment is required because the public should be able to anticipate the possibility of those changes. However, if any of the changes desired by the agency involve matters that were not discussed in the NPRM and that are not a logical outgrowth of the matters that were discussed and the comments that were submitted, then the agency must give the public a chance to comment on a revised proposal before issuing a Final Rule. To provide that chance, the agency issues a Supplemental Notice of Proposed Rulemaking.

c. Supplemental Notice of Proposed Rulemaking

The Supplemental Notice of Proposed Rulemaking (SNPRM) identifies changes to the original proposal in the NPRM and highlights those that were not within the "scope of notice" provided by the NPRM, i.e., those that could not reasonably be anticipated by the public from reading the NPRM. It also may identify significant new factual information, e.g., a significant new study, that was not included in the administrative record during the comment period on the NPRM, and upon which the agency wishes to rely in explaining and justifying the Final Rule. SNPRMs seek public comment on the changed regulatory text and explain the basis for the new text. They are subject to the same analytical and review requirements as NPRMs. SNPRMs are issued significantly less frequently than ANPRMs.

d. Final Rule

After considering all information available to it, including the public comments, the agency decides whether to terminate rulemaking or issue a Final Rule. If the agency issues a Final Rule, it includes in the preamble a detailed statement of the basis and purpose of the rule, including the objectives of the rule and the reasons for:

- the agency's belief that the rule will achieve those objectives;

- the agency's belief that the rule is consistent with the information in the administrative record of the rulemaking;

- the agency's agreement or disagreement with the substantive comments it received;

- the changes it made to the rule in response to the comments with which it agreed; and

- the rejection of any plausible alternatives, suggested by the public, to the rule it adopted.

The necessity for drafting such a preamble serves as an internal self-check on agency action by ensuring that, prior to taking final action, an agency expressly confronts the relevant issues and is able to articulate clearly the reasons for its decisions. At the end of the preamble, the agency sets forth the finally adopted version of the regulatory text. Public comment is not solicited in a Final Rule. However, if the agency allows the submission of Petitions for Reconsideration, it must state that Petitions for Reconsideration may be submitted and may specify a deadline for doing so. The Final Rule also specifies a date on which compliance with the rule will become mandatory. An interval of 1 to 3 years or even longer between the publication of a Final Rule and the date for mandatory compliance is not unusual, particularly for costly rules or rules governing new technologies or products. If the agency decides not to issue a Final Rule, it may issue and publish a Notice of Withdrawal of the proposal, explaining the reasons for that action.

Normally, the APA requires that a Final Rule not become effective in less than 30 days after it is published. However, compliance with the 30-day requirement is not necessary if the rule provides an exception to or otherwise relaxes an existing regulation, or if the agency makes and publishes a finding that an earlier effective date is required "for good cause."

e. Response to Petitions for Reconsideration

Even after a Final Rule is issued, the public may have a further chance to request the agency to make changes to the rule. [xvi] If permitted by an agency's procedural regulations, members of the public may submit Petitions for Reconsideration. The submission of such a petition generally does not delay the effective date of the rule.

Some agencies respond to Petitions for Reconsideration by issuing a new Final Rule making changes to the original Final Rule without soliciting additional public comments, if those changes were either discussed in the NPRM or are a reasonable outgrowth of the NPRM. Other agencies may issue a new NPRM before making any changes in response to Petitions for Reconsideration, regardless of whether the changes are within the scope of the discussion in the NPRM.

f. Rulemaking without Notice and Comment

In certain limited circumstances, an agency may publish a Final Rule without first issuing an NPRM and receiving and considering public comments. The APA provides an exception to the notice and comment requirements for all rules relating to public property, loans, grants, benefits, or contracts, as well as rules relating to national defense, foreign relations, and internal agency management. However, these rules are still subject to the publication requirements of the APA. Moreover, many agencies voluntarily waive this exception and issue such rules after notice and

comment. Congress has also passed some program-specific laws that establish public participation requirements for otherwise excepted rules.

In addition, the requirement for prior notice and an opportunity for public comment on other types of rules may be waived if the agency finds for "good cause" that following such procedures in a particular instance would be "impracticable, unnecessary, or contrary to the public interest." (5 U.S.C. § 553(b)(3)(B)). Courts have interpreted this language to allow an agency to waive the notice and comment procedures and issue rules when the agency can show it is confronting one or more of the following "emergency" situations: (1) where the agency was subject to a short, statutorily-imposed deadline; (2) where the immediate issuance of a rule is necessary to address a serious risk to public health and safety; (3) where giving notice before issuing a Final Rule would thwart the purpose of the rule; or (4) where immediate clarification of existing rules and regulations is needed to alleviate confusion. It is important to note that the "good cause" exception is construed narrowly. Further, agencies may not automatically waive informal rulemaking procedures whenever one of the aforementioned situations arises or in the agency's judgment an emergency situation exists. Instead, an agency must clearly demonstrate that the waiver of the APA's notice and comment procedures is proper in that particular circumstance.

The strongest case for a waiver is when the agency shows that the emergency arose due to circumstances beyond its control, provides for notice and comment soon after issuing the Final Rule, and reasonably promptly changes the rule, as appropriate, based on the comments. These Final Rules are commonly referred to as "Interim Final Rules."

4. Other Opportunities for Public Participation

Private citizens, industry, and organizations can participate in an agency's rulemaking activities in variety of ways. In addition to submitting comments and petitions, as discussed above in the section on the Public Participation in Pre-Rulemaking and Rulemaking Actions (III.B), persons can directly contact the agencies in accordance with the agencies' own particular procedural requirements, participate in advisory committees formed by the agencies, or participate in negotiated rulemakings.

While the APA limits ex parte oral communications in formal rulemakings, it does not do so in informal rulemakings. [xvii] However, the various Federal agencies have adopted their own policies about such communications during informal rulemakings. These policies vary. Some agencies discourage, but do not prohibit, ex parte oral communication during all stages of a rulemaking proceeding, even before an NPRM is issued. Other agencies discourage ex parte oral communications only after an NPRM has been issued. Still others permit them at any time during a rulemaking proceeding. In all cases, however, to the extent that an agency wishes to rely in its Final Rule on information or data received in ex parte oral communications, it must describe the substance of the communications in a memorandum that is made publicly available. Such documentation is necessary to ensure that the public and the courts (in the event of a lawsuit) are aware of the communications.

Federal agencies may meet with committees or groups of persons to increase the opportunity for dialogue and public input in their rulemakings. Some of these committees or groups may be

advisory committees within the meaning of the Federal Advisory Committee Act, 5 U.S.C. App. 2 (FACA). Under the Act, an "advisory committee" is any committee or group that contains at least one member who is not a full-time Federal employee, and that is established or utilized by a Federal agency, in the interest of obtaining consensus advice or recommendations. An agency may establish an advisory committee under the FACA after giving public notice and making a determination that establishment of the committee is in the public interest. Each committee must be chartered and have a clearly defined purpose. Membership must be fairly balanced in terms of the points of view represented and functions performed. Meetings of an advisory committee must generally be announced in advance in the Federal Register and open to the public. Subject to the Freedom of Information Act (see section below on Access to Information (III.D)), minutes of the meetings and all documents related to the committee's work must be made public.

The Negotiated Rulemaking Act of 1990 establishes a framework for conducting a negotiated rulemaking and encourages agencies to use negotiated rulemaking procedures to enhance the informal rulemaking process. 5 U.S.C. §§ 561 *et seq.* The premise underlying negotiated rulemaking is that bringing together representatives of an agency and the various affected interest groups to negotiate, and reach consensus on, a proposed rule will lessen the likelihood of litigation if and when a Final Rule is issued. If an agency wishes to conduct a negotiated rulemaking, the agency forms an advisory committee consisting of representatives of the affected interests and representatives of the agency for the purpose of reaching consensus on a proposed rule to be issued in an NPRM. The committee is subject to the FACA, and thus generally must hold its meetings in public. A neutral facilitator is generally used to facilitate the negotiations within the committee by applying consensus-building techniques. The goal of the committee is to reach consensus within the limits of the agency's legal authority and policy objectives for the rulemaking. If consensus is reached, the agency uses the product of the consensus as the basis of its NPRM. As in the case of rulemaking proceedings that do not involve negotiated rulemaking, the agency must consider the public comments on that notice and respond to them in issuing a Final Rule. Negotiated rulemaking procedures are used only rarely.

C. Regulatory Analyses and Other Rulemaking Requirements

1. Regulatory Analyses

In addition to the requirements in their enabling statute, Federal agencies are subject to other requirements for analyzing the likely impacts or consequences of their proposed and Final Rules. The purpose of these requirements is to improve the quality of rulemaking and resulting regulations by requiring the agencies to define and show the need for Federal regulatory action, consider and inform the public about alternative approaches for achieving their regulatory goals, and to select the one that tends to maximize the positive consequences and minimize the negative ones. Alternative approaches include such matters as different degrees of stringency, different requirements for different sized firms, different compliance dates, and different enforcement methods. Pursuant to these requirements, the agencies conduct regulatory analyses to identify and, to the extent possible, quantify the likely consequences of the alternative approaches. The result is better informed policy decisions on rulemaking and more protective and more economically efficient rules.

Foremost among the sources of these additional analytical requirements is E.O. 12866. The Executive Order guides agencies in developing more beneficial, less intrusive, and more cost-effective rules. [xviii] The Office of Information and Regulatory Affairs (ORIA) of the Office of Management and Budget (OMB) is charged in the Executive Order with reviewing "significant" notices prior to their issuance and publication in the Federal Register. [xix] A list of the significant notices currently under review at OIRA, as well as those notices whose review was recently completed, can be found at http://www.reginfo.gov/public/do/eoPackageMain. The principal purpose of that review is to ensure the consistency of those rules with the President's policies and the principles in the Executive Order. Those principles apply to all rules, even those whose impacts are not economically significant. The Executive Order provides that agencies should, to the extent permitted by law, follow those principles. Those principles provide for, among other things, assessing both costs and benefits (quantitative and qualitative) of each intended rule and proposing or adopting a rule only upon making a reasoned determination that the benefits of the intended rule justify its costs. [xx] The Executive Order states also that, in choosing among alternative regulatory approaches, agencies should select those approaches that maximize net benefits.

E.O. 12866 requires the preparation of a regulatory impact analysis whose detail and complexity are proportional to the magnitude of the impacts of the NPRM or Final Rule being analyzed. NPRMs and Final Rules that are significant, but not economically significant, must be accompanied by an extensive regulatory impact analysis. [xxi] The analysis of ones that are economically significant, i.e., those whose benefits or costs exceed $100 million per year, must be even more extensive. [xxii] These latter analyses must provide a particularly detailed and extensive assessment of the benefits and costs of the planned regulatory action and of potentially effective and reasonably feasible alternatives to that action. When an agency submits an economically significant draft NPRM or Final Rule for OIRA review, it submits the accompanying regulatory impact analysis as well. If the NPRM or Final Rule is later approved by OIRA and issued by the agency, the agency places the analysis in its public docket.

After seeking and considering public comment on draft guidance and subjecting that draft to external peer review, OIRA issued detailed guidance to help the agencies prepare the analyses required by E.O. 12866. See "Regulatory Analysis" ("Circular A-4") (September 17, 2003) at http://www.whitehouse.gov/omb/circulars/a004/a-4.pdf. Circular A-4 explains the need for regulatory analyses [xxiii] and provides guidance on how to conduct them. [xxiv] For major health and safety rulemakings, it provides that a benefit-cost analysis should be conducted if the expected health and safety outcomes can be monetized. In addition, a cost effectiveness analysis should be conducted if a valid effectiveness measure can be developed for the expected outcomes. For other major rulemakings, a benefit-cost analysis should be conducted.

Uncertainties about benefits and costs must be analyzed. Benefit and cost estimates should reflect the full probability distribution of potential consequences. If fundamental scientific disagreement or lack of knowledge prevents construction of a scientifically defensible probability distribution, agency should conduct sensitivity analyses, describing benefits or costs under plausible scenarios and characterizing the evidence and assumptions underlying each alternative scenario. For rulemakings involving annual effects equal to or greater than $1 billion, agencies must conduct a formal quantitative analysis of the key uncertainties about the benefits

and costs. (See below the section on Executive Oversight and Review (III.E.2.a) for further discussion of the Executive Order.) In addition, various other Executive Orders require additional analyses. While they too are important, the most important are those required by E.O. 12866.

If a rule would require subfederal governments or the private sector to spend more than $100 million in any one year, the Unfunded Mandates Reform Act requires the issuing agency to "identify and consider a reasonable number of regulatory alternatives, and from those alternatives select the least costly, most cost-effective or least burdensome alternative that achieves the objective of the rule" or explain why it could not select such an alternative. 2 U.S.C. §§ 1532 *et seq.* These requirements are similar to the requirements in E.O. 12866 for economically significant rules.

The Paperwork Reduction Act requires that the impact of the information collection requirements in any rule be analyzed and that approval for the requirements be obtained from OIRA before those requirements can be enforced. 44 U.S.C. §§ 3501 *et seq.* Information collection requirements include not only requirements to submit information directly to the Federal government, but also requirements to disclose information, such as information on the safe use of a product and on product performance, to third parties such as consumers.

The Regulatory Flexibility Act requires agencies to analyze and consider the impacts of any NPRM or Final Rule on small businesses. 5 U.S.C. §§ 601 *et seq*. Under that Act, an agency must either certify that the rulemaking will not "have a significant economic impact on a substantial number of small entities," and provide the factual basis for that certification or prepare an analysis explaining, among other things, what the agency has done to minimize burdens for small entities, and the reasons for its choice among the identified regulatory alternatives. If the non-selected alternatives would have minimized burdens for small entities more than the selected alternative would, the agency must explain why it rejected those other alternatives.

The National Environmental Policy Act (NEPA) requires that an agency prepare an Environmental Impact Statement (EIS) for any major federal action, including a rule, "significantly affecting the quality of the human environment." 42 U.S.C. §§ 4321 *et seq.* If it is unclear whether a rule will have a significant impact, the agency must prepare an Environmental Assessment (EA). If the EA leads the agency to make a Finding of No Significant Impact (FONSI), the agency is not required to take any further action under the NEPA. However, if the EA indicates that the rule will have a significant effect, the agency uses the EA in preparing an EIS. The agency is required to obtain public comment on a draft EIS before issuing a final one.

All of these analyses, like the other required analyses, must be made public.

2. Harmonization

In their rulemaking, the Federal agencies draw upon the work of a variety of fora and organizations involved in the harmonization of regulations. Examples include the Codex Alimentarius Commission (food safety), International Conference on Harmonization of

Technical Requirements for Registration of Pharmaceuticals for Human Use, World Organization for Animal Health, Food and Agriculture Organization, World Forum for Harmonization of Vehicle Regulations, and International Civil Aviation Organization.

The agencies are subject to several statutory requirements relating to harmonization. The National Technology Transfer and Advancement Act (NTTAA) of 1995 directs Federal agencies to use non-governmental voluntary consensus standards, both domestic and international, in lieu of developing and using unique government standards in their rulemaking, except when doing so would be inconsistent with law or otherwise impractical. (Public Law 104-113) (15 U.S.C. § 272 note). See also OMB Circular A-119, Federal Participation in the Development and Use of Voluntary Standards, http://www.whitehouse.gov/omb/circulars/a119/a119.html. If relevant voluntary consensus standards exist and an agency decides not to use them in a rulemaking, the agency is required to explain that decision in its Final Rule. (A-119, section 11.)

Federal agencies are prohibited by Title IV of the Trade Agreements Act of 1979 (19 U.S.C. § 2531) from setting standards that create "unnecessary obstacles to the foreign commerce" of the U.S. Originally enacted in 1979, this Act was subsequently amended to implement the World Trade Organization (WTO) Agreement on Technical Barriers to Trade. However, standards addressing legitimate domestic objectives, such as the protection of legitimate health or safety, essential security, environmental, or consumer interests, are not considered unnecessary obstacles if those standards do not operate to exclude imported products which fully meet the objectives of those standards. Federal agencies are also required, in developing their regulations, to take into consideration relevant international standards established by international standards organizations and, if appropriate, base their regulations on those international standards. (19 U.S.C. § 2532(2)). The Act expressly provides that the reasons for which it may not be appropriate to base a regulation on an international standard include, but are not limited to, the protection of human health or safety, animal or plant life or health, or the environment.

The Act also requires nondiscriminatory treatment by Federal agencies in applying standards-related activities with respect to any imported product. (19 U.S.C. § 2532(2)). More specifically, the Act requires the agencies to ensure that such products are treated no less favorably than are like domestic or imported products, including, but not limited to, when applying tests or test methods, no less favorable treatment with respect to the acceptance of the product for testing in comparable situations; the administration of the tests in comparable situations; the fees charged for tests; the release of test results to the exporter, importer, or agents; the siting of testing facilities and the selection of samples for testing; and the treatment of confidential information pertaining to the product.

3. Information Quality

Federal agencies are required to develop procedures for reviewing and substantiating (by documentation or other means selected by the agency) the quality, objectivity, utility, and integrity of information before disseminating it. The purpose of the requirement is to ensure that the agencies rely on sound science. "Information" includes, but is not limited to, scientific, financial, and statistical information. In addition, agencies are required to establish administrative mechanisms allowing affected persons to request correction of information

disseminated by an agency on the basis that it does not comply with guidelines issued by OIRA or the agency. OIRA's guidelines can be found at http://www.whitehouse.gov/omb/fedreg/reproducible2.pdf. Links to the agency guidelines can be found at http://www.whitehouse.gov/omb/inforeg/agency_info_quality_links.html. An agency may generally handle requests received during a rulemaking proceeding in the same manner as comments on the NPRM in that proceeding and respond to the requests in the preamble to the Final Rule.

Federal agencies planning to release important scientific information to the public in connection with a rulemaking must ensure that that information has been peer reviewed in accordance with OIRA's "Final Information Quality Bulletin for Peer Review." The purpose of that bulletin, which can be found at http://www.whitehouse.gov/omb/fedreg/2005/011405_peer.pdf, is to enhance the quality and credibility of the government's scientific information. "Scientific information" is defined as including factual inputs, data, models, analyses, technical information, or scientific assessments based on the behavioral and social sciences, public health and medical sciences, life and earth sciences, engineering, or physical sciences. Assessing and improving the quality of scientific information used in rulemaking is vital because that information is the basis for estimates of the costs and benefits of regulation, and thus for decisions on whether to regulate, what regulatory approach to use, and what level of stringency to select.

Before an agency "disseminates" any influential scientific information, i.e., initiates or sponsors the distribution of the information to the public, it must peer review the information. Agencies need not peer review regulatory impact analyses or regulatory flexibility analyses, but they must peer review any "underlying data and analytical models" that constitute influential scientific information. Each agency must maintain a Web-accessible agenda listing its forthcoming influential scientific disseminations and its plans for peer reviewing them.

Agencies have substantial discretion regarding the type of peer review used for "influential scientific information," i.e., information that the agency reasonably can determine will have or does have a clear and substantial impact on important public policies or private sector decisions. The more complex and novel the information is or the greater impact it has on an agency rulemaking, the more rigor must be applied in the peer review. Agencies must conduct an independent and more formal peer review for "highly influential scientific assessments," i.e., influential scientific information that potentially has an impact exceeding $500 million in any year or is "novel, controversial, or precedent setting or has significant interagency interest." The term "scientific assessment" means an evaluation of a body of scientific or technical knowledge that typically synthesizes multiple factual inputs, data, models, assumptions, and/or applies best professional judgment to bridge uncertainties in the available information. These assessments include, but are not limited to, state-of-science reports; technology assessments; weight-of-evidence analyses; meta-analyses; health, safety, or ecological risk assessments; toxicological characterizations of substances; integrated assessment models; hazard determinations; or exposure assessments. A scientific assessment is considered "highly influential" if the agency or OIRA determines that the dissemination of it could have a potential impact of more than $500 million in any one year on either the public or private sector or that the dissemination is novel, controversial, or precedent-setting, or has significant interagency interest.

While agencies have discretion regarding the timing of a peer review during a rulemaking, the guidelines state, "(I)t is most useful to consult with peers early in the process of producing information." When information "is a critical component of rule-making, it is important to obtain peer review before the agency announces its regulatory options so that any technical correction can be made before the agency becomes invested in a specific approach or the positions of interest groups have hardened."

D. Access to Information

The official U.S. Government document for publishing rulemaking notices, and thus making them available to the public, is the Federal Register. The Federal Register, which is published each business day, is available in hard copy on a paid subscription basis. It is also available online at http://www.gpoaccess.gov/fr/index.html or http://www.archives.gov/federal_register/publications/about_the_federal_register.html) without charge. In addition, U.S. Federal agencies make extensive use of their Internet websites to provide information on their rulemaking activities. However, it should be noted that the agencies' posting of such information on the Internet does not constitute an official publication.

Pursuant to E.O. 12866, OIRA publishes an updated Unified Agenda of Federal Regulatory and Deregulatory Actions (Agenda) in the Federal Register every six months, usually in April and October. The Agenda can be viewed on-line by going to http://reginfo.gov/ or http://ciir.cs.umass.edu/ua/. Each agency must include in the agenda a brief description of and schedule for each new rule that the agency is likely to issue in proposed or final form within the next 12 months. [xxv] Each agency must also list each existing regulation that the agency is likely to review during that same period to determine whether the regulation is still needed and if so, whether it should be modified. In addition, agencies must provide OIRA with a program for periodically reviewing existing significant regulations to determine whether to modify or eliminate them. By reading the Agenda, the public can learn whether any of the new rules being developed by the agencies are classified as significant under E.O. 12866 and thus subject to review by OIRA. (The definition of "significant regulatory actions" appears in an endnote to the section above on Regulatory Analyses (III.C.1).) Persons wishing to find out more about a particular rulemaking action may contact the individual listed in the Agenda for that action.

After the publication of a Final Rule in the Federal Register, the regulatory text in the rule is codified, along with all existing regulations, in the CFR. The CFR is divided into 50 titles that represent broad areas subject to Federal regulation. Each title is further divided into chapters, which usually bear the name of the issuing agency. Each chapter is subdivided into parts covering the specific regulatory areas under the authority of that agency. The index refers users to the appropriate titles and chapters affecting specific areas. The paperback version of the CFR is updated annually and is available for a charge. It is also available free of charge on the Internet at http://www.gpoaccess.gov/nara/index.html. A continuously updated version of the CFR (e-CFR) is available free of charge on a beta test site at http://www.gpoaccess.gov/ecfr/.

Federal agencies establish a public docket for the documents that they rely upon or seriously consider in each of their rulemaking proceedings. The public may inspect and comment on the documents in those dockets. A docket number identifies each docket. The documents include

materials such as studies generated by the agency to support its position, regulatory analyses (See section III.C.1 above) prepared by the agency, and comments and supporting documents submitted by the public in response to the agency's documents (except information that has been submitted confidentially). [xxvi] While some agencies accept and rely upon confidential information in their rulemaking proceedings, others do not.

Many agencies either have established or are in the process of establishing an electronic rulemaking docket system on the Internet. For example, the Department of Transportation and the Food and Drug Administration have established systems that enable any person anywhere in the world to view and download documents that have been submitted to any of their rulemaking dockets. (http://dms.dot.gov/) (http://www.fda.gov/ohrms/dockets/default.htm). The Department of Transportation's system also permits people to file comments electronically. Other agencies have conducted public meetings via the Internet, eliminating the need for persons to travel to a particular geographical location in order to participate. Some agencies, like the Environmental Protection Agency, provide links to electronic versions of all of their recently issued rulemaking documents. (See http://www.epa.gov/epahome/rules.html#proposed). In addition, agencies are posting a wide variety of information relating to their rulemakings, such as research reports and analyses, so that they can be examined online and downloaded without charge. (See, e.g., http://www.nhtsa.dot.gov/.) Links to all Federal departments and agencies in the President's Cabinet and to all independent agencies and commissions can be found at http://www.whitehouse.gov/government.

The eRulemaking Initiative is a cross-agency E-Government effort to coordinate and build on the activities of the individual departments and agencies. The initiative seeks to build an integrated and cost effective rulemaking docket and management system to ensure efficiency, economies of scale, and increased accountability of the Federal rulemaking process to the public. The eRulemaking Initiative is managed by the Environmental Protection Agency in conjunction with 12 Federal department and agency partners. The first accomplishment was the launching of Regulations.gov in January 2003. (See http://www.regulations.gov/eRuleMaking.cfm.) This Web site provides an easy and consistent way for the public to search, view, and comment on proposed Federal regulations open for comment. The eRulemaking partners are currently developing the second component of the Initiative, a Federal government-wide centralized docket management system. This system will allow the public to access and search all publicly available regulatory material, such as Federal Register notices and rules, supporting analyses, and comments submitted by the public.

Federal agencies are required by the Freedom of Information Act (FOIA) (5 U.S.C. § 552) to make records, e.g., documents, in their possession available upon receipt of a request that reasonably specifically describes the records desired by the requestor. The purpose of this Act is to expand the areas of public access to information beyond those originally set forth in the APA. The public typically uses the FOIA to learn more about what agencies have done or are doing and about what information agencies possess. The FOIA gives any person the right to request records from agencies. The FOIA does not require agencies to create new records or to answer specific questions. Upon receipt of a request, an agency must search for existing records responsive to the request. The FOIA requires an agency to respond to a request within 20 working days of its receipt. The agency must make available copies of all responsive records

located in the search, unless the records are protected from disclosure under one of nine statutory exemptions in the FOIA. [xxvii] Public access to government information was facilitated in 1996 by the enactment of the Electronic Freedom of Information Act Amendments (E-FOIA). The E-FOIA requires agencies to make more material available electronically. In addition, the FOIA was supplemented by Executive Order 12600, Predisclosure Notification Procedures for Confidential Commercial Information (1987), which gives private parties, especially business firms (including foreign firms), a right to prior notice from an agency before it releases information about or received from the firm that the agency believes does not fall within the exception for trade secrets and confidential business information.

For detailed guidance on the FOIA, see the Department of Justice's Freedom of Information Act Guide, May 2004, at http://www.usdoj.gov/oip/foi-act.htm.

E. Strong Centralized Support for and Accountability in Agency Rulemaking

1. Inter-agency Coordination

Federal agencies monitor each other's rulemaking activities and directly coordinate with each other as appropriate. Much of the coordination is done at the agencies' own initiative out of mutual self-interest. In some cases, Congress ensures that coordination occurs by statutorily requiring it. Further, E.O. 12866 provides that the Federal agencies should avoid issuing rules that are inconsistent, incompatible, or duplicative with those of other Federal agencies. Typically, the consultation occurs initially on a working level among technical staff and later, as the agency's development of alternative approaches to addressing the regulatory problem progresses, on a policy level among top management as well. There are also inter-agency working groups, such as the Interagency Council on Standards Policy, that meet on an ongoing basis to discuss issues of mutual interest and to share information on their agency's activities.

OIRA is charged under the Executive Order with coordinating inter-agency review of significant proposed or Final Rules prior to their issuance and publication in the Federal Register. If the proposed or Final Rule of one agency would create a serious inconsistency, or otherwise interfere with an action taken or planned by another agency, that rule is treated as a significant rule under the Executive Order, and thus is subject to OIRA review. OIRA provides a copy of the rule to the top management in other interested agencies for comment during the review process.

2. Review

While each Federal agency is responsible in the first instance for its compliance with the various substantive and procedural requirements applicable to the rulemaking process, there are separate mechanisms within the executive, legislative and judicial branches of the U.S. Federal government for promoting accountability in U.S. rulemaking.

a. Executive Oversight and Review

Regulatory oversight and review within the executive branch are centralized in OIRA and are accomplished primarily through that office's implementation of E.O. 12866. In implementing E.O. 12866, and as part of the Executive Office of the President, OIRA provides the centralized support for and management of agency rulemaking to help promote regulatory best practices. Specifically, the Executive Order sets forth a common regulatory philosophy and a common set of principles and requirements regarding how the agencies should exercise their discretion in making decisions about what rules to propose and adopt. These provisions apply to all agencies other than independent regulatory commissions (e.g., the Securities and Exchange Commission and the Federal Trade Commission). Centralizing this responsibility in OIRA and applying the Executive Order across-the-board to all those agencies promotes consistency in regulatory policy and guidance, interpretation of the Executive Order, level of rigor in analysis of the benefits and costs of proposed and final regulations, and consideration of alternative courses of action.

During its review of rules, OIRA typically recommends improvements in the notices and accompanying regulatory analyses. It may, for example, recommend that an agency consider additional regulatory alternatives or take other steps that could lead to the adoption of a more cost effective rule. When OIRA determines that the substance of a draft NPRM or Final Rule is inconsistent with the Executive Order or that a regulatory analysis is deficient, it works with the agencies to correct the problem.

In some cases, OIRA returns the draft proposal or rule and the accompanying analysis to the agency that submitted them. Such a return may occur if the quality of the agency's analysis is inadequate, if the proposal or rule is not justified by the analysis, if the rule is not consistent with the regulatory principles stated in the Executive Order or with the President's policies and priorities, or if the rule is not compatible with statutes or other Executive Orders. Such a return does not necessarily imply that OIRA is opposed to the draft proposal or rule. Instead, the return letter explains why OIRA believes that the proposal or rule would benefit from further consideration and development by the agency.

In other instances, OIRA may send prompt letters to a Federal agency suggesting how the agency could better achieve its regulatory goals. For example, OIRA may suggest that an agency explore a promising approach to rulemaking on a particular regulatory problem, accelerate an ongoing rulemaking proceeding, or consider modifying an existing rule.

Another objective of the Executive Order is to make regulatory processes more accessible and open to the public by ensuring the transparency of meetings between private parties and OIRA concerning rules under OIRA's review. For example, the public can consult OIRA's website and learn each day which rules are under formal review at OIRA and which have been approved. OIRA's website identifies the outside groups that have recently lobbied OIRA on rules under review, providing their names, organizations, date of the meeting, and the topic of the discussion. All written information and comments submitted to OIRA while a rule is under review is sent to the agency seeking to issue the rule, placed in OIRA's public docket reading room, and posted on OIRA's website. In addition, return letters sent to the agencies outlining OIRA's concerns with rules sent back to them are posted on the OIRA website. OIRA views this transparency as good government, because it has helped shift the public debate on regulation from process toward substance.

The Executive Order can be found at http://www.whitehouse.gov/omb/inforeg/eo12866.pdf. For other information relating to OIRA guidance on rulemaking matters, go to http://www.whitehouse.gov/omb/inforeg/regpol.html.

b. Congressional Review

Most Final Rules are subject to Congressional review under the Congressional Review Act, 5 U.S.C. §§ 801 *et seq*. (CRA), as added by the Small Business Regulatory Enforcement Fairness Act of 1996. [xxviii] The CRA established a special, expedited legislative process through which Congress may reject any Final Rule. The effect of a disapproving vote is to nullify the rule and to prohibit the issuing agency from subsequently issuing any rule having "substantially the same form" as the nullified rule. A rule is rejected if both houses of Congress adopt a joint resolution of disapproval by majority vote and if the President then signs the resolution. If the President vetoes the resolution, Congress can override the veto if both houses of Congress vote to do so. If they do, the rule is nullified. While Congress can adopt a resolution rejecting a rule in its entirety under the CRA, Congress cannot adopt a resolution under that Act either amending a rule or directing that a rule be amended. Congress can either take no action or adopt a disapproving resolution. Since enactment of the CRA in 1996, there has been only one instance in which Congress has adopted a joint resolution of disapproval. In March 2001, Congress adopted a joint resolution disapproving a rule issued by the Occupational Safety and Health Administration concerning work-related musculoskeletal disorders and workplace ergonomics hazards. The President signed the resolution, thus nullifying the rule.

In addition, Congress may use the normal legislative process to exercise control over rulemaking. For example, it can, in effect, at least temporarily nullify an agency's rule by enacting new legislation that prohibits the agency from using appropriated funds to enforce the rule. Alternatively, Congress may enact legislation identifying existing regulatory provisions to which it objects and specifying that the agency cannot maintain those provisions, or issue a new rule re-adopting them. In either event, the legislation must be signed by the President to become law.

c. Judicial Review

In general, Final Rules establishing, amending, or revoking regulations may be judicially reviewed pursuant to the APA or particular agency-specific statutes. A court might be asked to review a variety of aspects of an agency's final rule and the rulemaking proceeding leading up to its issuance, including the agency's interpretation of applicable law, compliance with procedural and substantive requirements of law, and findings of fact, and the reasonableness of the agency's rationales and conclusions in light of the administrative record.

An agency's enabling statute typically specifies that persons wishing to obtain judicial review of a Final Rule issued under that statute must file for review within a relatively short specified time period (e.g., 60 days) after the issuance or publication of the rule. The enabling statute also generally specifies that petitions for review must be filed in the U.S. Circuit Courts of Appeal. In addition to Final Rules, other types of final agency actions are judicially reviewable, including

denials of petitions for rulemaking, denials of petitions for reconsideration, and decisions to terminate rulemaking after the issuance of an NPRM.

Although the percentage of rules that are issued through informal rulemaking and then challenged in court is relatively small, those challenges generate a steady and significant volume of judicial decisions affecting informal rulemaking. The influence of these decisions can extend beyond the Federal agencies directly involved in those cases to other agencies as well. The possibility that one of their rules might face a similar challenge in court induces other agencies to take precautions in conducting their own informal rulemaking proceedings. Given that the decision in a case will be given precedential effect, i.e., followed, in later cases involving similar legal and factual circumstances, decisions setting aside a rule can have a significant and long-lasting influence on subsequent rulemaking by the Federal agencies.

Under the APA, any person may seek to have a Final Rule or other final agency action set aside by a Federal court if he has "standing" to do so. To have standing, a person must make several showings. The person must show that the final agency action injured him in fact by demonstrating that the injury is concrete and particular, and is actual or imminent. He must also show that the injury is causally related to the challenged rule, and that it is likely that the injury will be redressed by a favorable decision by the court.

Finally, the person must demonstrate that his injury is within the "zone of interests" which Congress sought to protect in enacting the statute under which the final agency action was taken. Generally, any person who is directly subject to a product regulation and any person who purchases or uses the products subject to the regulation can demonstrate that his or her injury is within the zone of interests protected by the statute under which the regulation was issued. An organization that has not itself suffered such an injury may nevertheless have standing if it can demonstrate that its members would otherwise have standing if they sued as individuals, the interests it seeks to protect are germane to the organization's purpose, and neither the claim asserted nor the relief sought requires the participation of individual members in the suit.

If a court concludes that the person or organization has standing, it reviews the rule based on the administrative record for the rulemaking proceeding in which the rule was established. The record is compiled by the agency and consists of all notices issued in the rulemaking proceeding, all public comments, all material (e.g., data, studies, research results, surveys and analyses) that the agency seriously considered or relied upon in issuing the Final Rule, and any other contemporaneous material required to be made public. The administrative record is critical to the ability of a reviewing court to identify and examine the information and views that the agency possessed when it made its final decision and the reasoning used by the agency in making that decision. [xxix]

The court will not consider any post hoc rationalizations [xxx] by government counsel in defending an agency action. Documents and information received or generated by the agency after the issuance of the Final Rule cannot be made part of the administrative record. Also, non-public documents discussing internal agency deliberations that occurred during the rulemaking proceeding are not made part of the administrative record.

Generally, a person's ability to obtain judicial review of a Final Rule is not conditioned on having submitted comments on the NPRM that preceded that rule. However, a court may decline to consider an issue that was not raised by any person during the rulemaking proceeding.

The most common shortcomings alleged by persons seeking to have Final Rules set aside are:

- failure of the issuing agency to follow required procedures;

- inconsistency of the Final Rule with substantive legal requirements; and

- arbitrariness, capriciousness or abuse of discretion in the agency's decisionmaking. [xxxi]

Lawsuits challenging agency rules typically allege procedural grounds as well as one or both of the other two above grounds for setting aside those rules. Among the commonly alleged procedural grounds is lack of adequate notice. Persons making this allegation often argue that the differences between the NPRM and Final Rule were so great that commenters could not reasonably have anticipated from the NPRM, and thus could not comment on, some important issue addressed and resolved in the Final Rule. Another common argument relating to lack of adequate notice is that, in order to support the Final Rule, the agency relied on data or analyses that were not made known to commenters in time for them to offer comments before the issuance of the Final Rule.

Moreover, many enabling statutes may specify procedures for rulemaking that extend beyond the general requirements of the APA. Likewise, an agency may issue procedural regulations that govern its rulemaking proceedings. In both instances, a failure by the agency to adhere to these additional procedures can result in the agency's rule being vacated by a reviewing court.

The standards of review applied by a court vary depending upon whether it is dealing with questions of law or fact or with exercises of discretion. As to questions of law, if the meaning of a statute is clear and an agency nevertheless adopts a contrary interpretation, a court will reject it. If the meaning of an agency's enabling statute is ambiguous and thus multiple interpretations are possible, a court will defer to the agency's interpretation if it is reasonable or permissible as judged against the purpose and language of the statute. In reviewing an agency's finding of fact, a court will examine whether there is sufficient basis in the administrative record for that finding.

Most challenges to agencies' Final Rules are based on the claim that the rules are arbitrary and capricious. While a court's review of exercises of discretion under the arbitrary and capricious standard is described as narrow, agencies risk having one of their Final Rules set aside by a court on the grounds of arbitrariness and capriciousness to the extent that they fail to do any of the following in the preamble to their rules:

- Clearly state the factual predicates (i.e., key facts used to explain and justify the rule) for the rule;

• Support the factual predicates by linking them to evidence in the administrative record of their existence;

• Explain how it reasoned from the factual predicates to the expected effects of the rule;

• Relate the factual predicates and expected effects to each of the goals, purposes or criteria that are made relevant by the statute authorizing the issuance of that rule;

• Demonstrate consideration of all important aspects of the problem addressed by the rule;

• Demonstrate consideration of all of the factors that Congress intended to be considered under the authorizing statute;

• Avoid basing any aspect of its rule on factors that Congress did not intend to be considered under that statute;

• Give rational explanations for its agreement or disagreement with major criticisms and requests for change in the public comments, and for its choice of the ways in which it changed the regulation in response to those criticisms and requests;

• Give rational explanations for rejecting plausible alternatives to the rule it adopted, especially those that arguably would better promote the goals of the statute under which the rule was issued; and

• Ensure that all explanations are consistent with the information in the administrative record. [xxxii]

A reviewing court generally will not substitute its judgment for that of the agency or set aside the agency's factual conclusions so long as the agency's judgment and conclusions have a substantial basis in the administrative record. A court is particularly likely to defer to an agency when the subject matter is technical, concerns a newly developing technology, or involves exercise of the agency's expertise.

A Final Rule revoking a regulation is subject to the same degree of judicial scrutiny as a Final Rule establishing or amending a regulation. Since revoking a regulation involves reversal of the revoking agency's former views as to the proper course of action, there is a presumption that, by continuing to pursue that course, i.e., retaining the regulation, the agency would best carry out the policies committed to it by Congress. Thus, if the agency departs from its past methodologies, practices, or positions in revoking an old regulation and adopting a new one, the agency must explain in some detail in the Final Rule why it did so. For example, if the rule revokes a regulation, the agency must provide a reasoned analysis for the change. That analysis must be more extensive than the analysis that may be required when an agency proposes, then decides not to adopt a rule.

If the court sets aside a Final Rule, it will remand the rule to the agency for further consideration. The court may vacate the rule, in which case, the rule has no legal effect. Alternatively, the court may simply remand the rule, requiring the agency to reconsider its position, but leaving all or part of the rule in effect during that period of reconsideration. Simple remands often occur when undue harm could be caused in the absence of an applicable rule or when the remand is based on procedural deficiencies that are unlikely to change the agency's final decision. Only in rare circumstances, in which the agency has very limited discretion under its enabling statute, will a court direct the agency to reach a particular conclusion regarding a remanded rule.

IV. Federal Agency Guidance Documents

Federal agencies often issue guidance documents that interpret their regulations and the statutes that they administer, either in response to requests from regulated entities and other members of the public or on their own initiative. These interpretations do not have the same force of law as the regulation or statute to which they apply. The interpretations are, however, binding on agencies in that the public is assured that agencies will act in accord with them.

Interpretations are generally not subject to the notice and comment requirements that apply to rulemakings, unless notice or a hearing is required by an agency's enabling statute or another agency-specific statute, because interpretations do not establish or amend laws or regulations. Instead, they merely clarify laws and regulations that already exist.

Agencies are not required to publish their interpretative rules in the Federal Register. However, the FOIA requires that each agency make available for public inspection and copying all statements of interpretation that have been adopted by the agency and have not been published in the Federal Register. 5 U.S.C. § 552(a)(2). Many agencies now do this by putting their interpretations in searchable databases on the Internet.

However, transparency is not required when formulating interpretations. Unlike rulemakings, interpretations do not involve the making of statutory judgments such as whether a requirement meets the need for vehicle or food safety or is practicable. An interpretation is the agency's position as to what a statute or regulation means. It is based largely on the language of the statute or regulation, but may also reflect the purpose of the statute or regulation and the agency's general policy goals. The only additional information that the agency might need are facts surrounding the particular situation of the person who requested the interpretation, such as details about the design, performance or use of a particular product produced or sold by the requester. When some vital fact is missing, the agency generally asks for clarification from the requester since that person is in the best position to supply the information.

V. Subfederal Rulemaking

The due process requirements of the U.S. Constitution ensure that State regulatory activity is open and transparent. To meet the Constitutional requirements of due process, most States have enacted statutes containing transparency procedures. For example, most States have enacted administrative procedure acts whose procedures are similar to those of the APA. The majority of

States have also enacted statutes that provide for public access to information and judicial review.

Federal laws and regulations may either expressly or impliedly preempt State law. Express statutory preemption exists when Congress adopts language specifically providing that States cannot adopt or maintain any regulation that differs from the Federal regulations. Federal law may also impliedly preempt State law if (1) Congress has fully occupied the particular field of regulation in question; or (2) the State law conflicts with any Federal law or interferes with the objectives of Federal law.

VI. Glossary of Acronyms

ANPRM	Advance Notice of Proposed Rulemaking
APA	Administrative Procedure Act
CFR	Code of Federal Regulations
CRA	Congressional Review Act
FACA	Federal Advisory Committee Act
FOIA	Freedom of Information Act
FR	Federal Register
NEPA	National Environmental Policy Act
NPRM	Notice of Proposed Rulemaking
NTTAA	National Technology Transfer and Advancement Act
OIRA	Office of Information and Regulatory Affairs, an office within OMB
OMB	Office of Management and Budget, a part of the Executive Office of the President
SNPRM	Supplemental Notice of Proposed Rulemaking
USC	United States Code

VII. Further Reading

These publications were consulted during the preparation of this document:

Kenneth Culp Davis and Richard J. Pierce, Jr., Administrative Law Treatise. Published by Little, Brown and Company (3rd ed. 1994).

Jeffrey S. Lubbers, A Guide to Federal Agency Rulemaking. Published by the American Bar Association's Government & Public Sector Lawyers Division and the Section of Administrative Law & Regulatory Practice (3rd ed.1998). The Guide is organized into six parts, including parts on:

- The statutory structure of rulemaking, including relevant sections of the Administrative Procedure Act (APA) and other statutes that impact current rulemaking
- A step-by-step description of the informal rulemaking process, from preliminary considerations to the Final Rule
- A review of the law on judicial review of agency rulemaking, examining cases decided in recent years
- An Appendix including key federal statutes and other rulemaking documents

Section of Administrative Law and Regulatory Practice of the American Bar Association, *A Blackletter Statement of Federal Administrative Law*, 54 Administrative Law Review 17 (Winter 2002) (See also pages 13-61 of the document found at http://www.abanet.org/adminlaw/apa/blackletter1101.doc.)

Endnotes

[i] The TEP initiative is designed to deepen and systematize U.S.-EU cooperation regarding trade. Under TEP, the U.S. and EU identified a number of broad areas in which they committed to work together in order to increase trade, avoid disputes, address disagreements, remove barriers, and achieve mutual interests.

Under the Action Plan for implementing TEP, the U.S. and EU agreed to identify ways and means to improve their regulatory cooperation. To that end, they agreed to "jointly review the access to each others' [sic] regulatory procedures with respect to transparency and participation of the public - including the opportunity for all interested parties to have meaningful input in these procedures and receive reasonable consideration of their views" and "identify ways and means to improve access to each other's regulatory procedures, develop jointly agreed general principles/guidelines on such procedures, and when possible, work to accommodate those improvements, while preserving the independence of domestic regulatory authorities." An important initial part of the effort to improve regulatory cooperation and transparency is to promote a better understanding of the transparency of existing regulatory procedures in each other's territories, particularly at the Federal level in the U.S. and the Community level in the EU.

[ii] 2005 OECD Guiding Principles for Regulatory Quality and Performance, Organisation for Economic Co-Operation and Development, http://www.oecd.org/dataoecd/24/6/34976533.pdf.

[iii] As used in this document, “public” generally has the same broad meaning as “persons.” See endnote 6. The term generally includes domestic and foreign individuals and entities, e.g., individual citizens, regulated parties and their industry associations, and nongovernmental organizations. In most instances, it also includes foreign governments.

[iv] As used in this document, “product” has the same meaning that term has in the WTO Technical Barriers to Trade Agreement. Paragraph 1.3 of Article I of that Agreement provides that the Agreement applies to all products, including industrial and agricultural products.

Given its relative brevity, this paper makes general statements about the requirements applicable to the development, issuance and review of product regulations. It is important to note that the statutes authorizing the issuance of some types of product regulations create exceptions to those generalizations. This paper does not attempt to identify or catalogue those exceptions, although it does note some of them.

[v] The distinction between the formal and informal rulemaking processes can be found in the section of this paper on Types of Rulemaking (III.B.2).

[vi] In the electronic version of this document, this and the other web addresses are hypertexted or "hotlinked," i.e., clicking a mouse on the address should automatically cause that website to appear on screen. (Web addresses are subject to change. If a link does not work, try the home page of the entity identified in the link.)

[vii] "Persons" are defined broadly in the APA as "an individual, partnership, corporation, association, or public or private organization other than [a U.S. Federal] agency." "Persons" include individuals and entities located outside the United States.

[viii] Examples of these policy goals are reducing pollutants harmful to public health, meeting the need for motor vehicle safety, and increasing food or drug safety.

[ix] The distinction between factors to be considered in developing a regulation and criteria to be met by the resulting regulation can be hard to discern and may not always be critical to make. Something may be treated as a factor in one statute and a criterion in another. For example, a statute might require that standards be set at the maximum feasible level (criterion) and that technological feasibility and economic practicability (factors) be considered in determining that level. Another statute might require that standards be practicable (criterion).

[x] The APA does not specify a schedule for the issuance of agency responses to petitions for rulemaking. However, an agency's enabling statute or procedural regulations may specify a schedule.

[xi] APA requirements for informal rulemaking. Section 553(b) of title 5, U.S.C. provides

> (b) General notice of proposed rule making shall be published in the Federal Register, unless persons subject thereto are named and either personally served or otherwise have actual notice thereof in accordance with law. The notice shall include –
>
> (1) a statement of the time, place, and nature of public rule making proceedings;
>
> (2) reference to the legal authority under which the rule is proposed; and
>
> (3) either the terms or substance of the proposed rule or a description of the subjects and issues involved.
>
> . . .
>
> (c) After notice required by this section, the agency shall give interested persons an opportunity to participate in the rule making through submission of written data, views, or arguments with or without opportunity for oral presentation. After consideration of the relevant matter presented, the agency shall incorporate in the rules adopted a concise general statement of their basis and purpose. …
>
> (d) The required publication or service of a substantive rule shall be made not less than 30 days before its effective date, except –
>
> (1) a substantive rule which grants or recognizes an exemption or relieves a restriction;
>
> (2) interpretative rules and statements of policy; or
>
> (3) as otherwise provided by the agency for good cause found and published with the rule.
>
> (e) Each agency shall give an interested person the right to petition for the issuance, amendment, or repeal of a rule.

[xii] Some meetings resemble legislative hearings. In those meetings, public participants typically read prepared statements and then answer questions from a presiding panel of agency officials. In some of those meetings, the panel may invite the audience to supplement those questions by submitting their own questions to the panel. After reviewing the audience questions for relevance and clarity, the panel then poses the appropriate ones to the participants. Other meetings are less hierarchical. The discussions in them involve more give-and-take between the public participants and the agency officials.

[xiii] All proposed rules, final rules, and notices issued by Federal agencies and independent commissions, as well as Executive Orders and other Presidential Documents, are published in the Federal Register. (For more information about the Federal Register, see below the section on Regulatory Analyses and Other Rulemaking Requirements (III.C).

[xiv] Some agencies direct persons submitting comments containing materials that are claimed to be trade secrets and confidential business information to submit two different versions of their comments: one version that includes those secrets and information, and a second version that excludes them. The former version is typically reviewed by agency lawyers to determine the appropriateness of the submitter's claims. The latter version is placed in the public docket.

[xv] Executive Order 12889, Implementation of the North America Free Trade Agreement, requires that an agency subject to the APA to provide a comment period of at least 75 days for "any proposed Federal technical regulation or any Federal sanitary or phytosanitary measure of general application."

[xvi] The APA does not specify a schedule for the issuance of agency responses to petitions for reconsideration. However, an agency's enabling statute or procedural regulations may specify a schedule.

[xvii] "Ex parte communication" is defined in the APA as meaning "an oral or written communication not on the public record with respect to which reasonable prior notice to all parties is not given, but it shall not include requests for status reports on any matter or proceeding..." (5 U.S.C. § 551(14)). These communications include written communications sent to an agency official instead of the rulemaking docket. They also include conversations during a private meeting with or telephone call to an agency official.

[xviii] Statement of Regulatory Philosophy and Principles in E.O. 12866. Section 1 of E.O. 12866 sets forth a Statement of Regulatory Philosophy and Principles and the Principles of Regulation applicable to nonsignificant as well as significant proposals and final rules:

> Statement of Regulatory Philosophy and Principles.
>
> (a) The Regulatory Philosophy. Federal agencies should promulgate only such regulations as are required by law, are necessary to interpret the law, or are made necessary by compelling public need, such as material failures of private markets to protect or improve the health and safety of the public, the environment, or the well-being of the American people. In deciding whether and how to regulate, agencies should assess all costs and benefits of available regulatory alternatives, including the alternative of not regulating. Costs and benefits shall be understood to include both quantifiable measures (to the fullest extent that these can be usefully estimated) and qualitative measures of costs and benefits that are difficult to quantify, but nevertheless essential to consider. Further, in choosing among alternative regulatory approaches, agencies should select those approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity), unless a statute requires another regulatory approach.
>
> (b) The Principles of Regulation. To ensure that the agencies' regulatory programs are consistent with the philosophy set forth above, agencies should adhere to the following principles, to the extent permitted by law and where applicable:
>
> > (1) Each agency shall identify the problem that it intends to address (including, where applicable, the failures of private markets or public institutions that warrant new agency action) as well as assess the significance of that problem.
> >
> > (2) Each agency shall examine whether existing regulations (or other law) have created, or contributed to, the problem that a new regulation is intended to correct and whether those regulations (or other law) should be modified to achieve the intended goal of regulation more effectively.
> >
> > (3) Each agency shall identify and assess available alternatives to direct regulation, including providing economic incentives to encourage the desired behavior, such as user fees or marketable permits, or providing information upon which choices can be made by the public.
> >
> > (4) In setting regulatory priorities, each agency shall consider, to the extent reasonable, the degree and nature of the risks posed by various substances or activities within its jurisdiction.
> >
> > (5) When an agency determines that a regulation is the best available method of achieving the regulatory objective, it shall design its regulations in the most cost-effective manner to achieve the regulatory objective. In doing so, each agency shall consider incentives for innovation,

consistency, predictability, the costs of enforcement and compliance (to the government, regulated entities, and the public), flexibility, distributive impacts, and equity.

(6) Each agency shall assess both the costs and the benefits of the intended regulation and, recognizing that some costs and benefits are difficult to quantify, propose or adopt a regulation only upon a reasoned determination that the benefits of the intended regulation justify its costs.

(7) Each agency shall base its decisions on the best reasonably obtainable scientific, technical, economic, and other information concerning the need for, and consequences of, the intended regulation.

(8) Each agency shall identify and assess alternative forms of regulation and shall, to the extent feasible, specify performance objectives, rather than specifying the behavior or manner of compliance that regulated entities must adopt.

(9) Wherever feasible, agencies shall seek views of appropriate State, local, and tribal officials before imposing regulatory requirements that might significantly or uniquely affect those governmental entities. Each agency shall assess the effects of Federal regulations on State, local, and tribal governments, including specifically the availability of resources to carry out those mandates, and seek to minimize those burdens that uniquely or significantly affect such governmental entities, consistent with achieving regulatory objectives. In addition, as appropriate, agencies shall seek to harmonize Federal regulatory actions with related State, local, and tribal regulatory and other governmental functions.

(10) Each agency shall avoid regulations that are inconsistent, incompatible, or duplicative with its other regulations or those of other Federal agencies.

(11) Each agency shall tailor its regulations to impose the least burden on society, including individuals, businesses of differing sizes, and other entities (including small communities and governmental entities), consistent with obtaining the regulatory objectives, taking into account, among other things, and to the extent practicable, the costs of cumulative regulations.

(12) Each agency shall draft its regulations to be simple and easy to understand, with the goal of minimizing the potential for uncertainty and litigation arising from such uncertainty.

[xix] Definition of significant regulatory action in E.O. 12866. Section 3(f) of E.O. 12866 defines "significant regulatory action" as

Any regulatory action that is likely to result in a rule that may:

(1) Have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities;

(2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;

(3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or

(4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in this Executive order.

[xx] Some statutes authorizing the issuance of product regulations limit the extent to which the issuing agency can consider cost in selecting those regulations. Some even provide that the regulations are to be selected and issued without regard to cost.

[xxi] Analysis of significant rules under E.O. 12866. Section 6(a)(3)(B) of E.O. 12866 requires that when a significant proposed or final rule is submitted to OIRA for review, it must be accompanied by:

> An assessment of the potential costs and benefits of the regulatory action, including an explanation of the manner in which the regulatory action is consistent with a statutory mandate and, to the extent permitted by law, promotes the President's priorities and avoids undue interference with State, local, and tribal governments in the exercise of their governmental functions.

[xxii] Analysis of economically significant rules under E.O. 12866. Section 6(a)(3)(C) of E.O. 12866 requires that when an economically significant (effects > $1,000,000) proposed or final rule is submitted to OIRA for review, it must be accompanied by:

> An assessment of the potential costs and benefits of the regulatory action, including an explanation of the manner in which the regulatory action is consistent with a statutory mandate and, to the extent permitted by law, promotes the President's priorities and avoids undue interference with State, local, and tribal governments in the exercise of their governmental functions.
>
> …
>
> An assessment, including the underlying analysis, of benefits anticipated from the regulatory action (such as, but not limited to, the promotion of the efficient functioning of the economy and private markets, the enhancement of health and safety, the protection of the natural environment, and the elimination or reduction of discrimination or bias) together with, to the extent feasible, a quantification of those benefits;
>
> An assessment, including the underlying analysis, of costs anticipated from the regulatory action (such as, but not limited to, the direct cost both to the government in administering the regulation and to businesses and others in complying with the regulation, and any adverse effects on the efficient functioning of the economy, private markets (including productivity, employment, and competitiveness), health, safety, and the natural environment), together with, to the extent feasible, a quantification of those costs; and
>
> An assessment, including the underlying analysis, of costs and benefits of potentially effective and reasonably feasible alternatives to the planned regulation, identified by the agencies or the public (including improving the current regulation and reasonably viable nonregulatory actions), and an explanation why the planned regulatory action is preferable to the identified potential alternatives.

[xxiii] The Need for Analysis of Proposed Regulatory Actions. Circular A-4 summarizes the need for regulatory analysis as follows:

> Regulatory analysis is a tool regulatory agencies use to anticipate and evaluate the likely consequences of rules. It provides a formal way of organizing the evidence on the key effects - good and bad - of the various alternatives that should be considered in developing regulations. The motivation is to (1) learn if the benefits of an action are likely to justify the costs or (2) discover which of various possible alternatives would be the most cost-effective.
>
> A good regulatory analysis is designed to inform the public and other parts of the Government (as well as the agency conducting the analysis) of the effects of alternative actions. Regulatory analysis sometimes will show that a proposed action is misguided, but it can also demonstrate that well-conceived actions are reasonable and justified.
>
> Benefit-cost analysis is a primary tool used for regulatory analysis. Where all benefits and costs can be quantified and expressed in monetary units, benefit-cost analysis provides decision makers with a

clear indication of the most efficient alternative, that is, the alternative that generates the largest net benefits to society (ignoring distributional effects). This is useful information for decision makers and the public to receive, even when economic efficiency is not the only or the overriding public policy objective.

It will not always be possible to express in monetary units all of the important benefits and costs. When it is not, the most efficient alternative will not necessarily be the one with the largest quantified and monetized net-benefit estimate. In such cases, you should exercise professional judgment in determining how important the non-quantified benefits or costs may be in the context of the overall analysis. If the non-quantified benefits and costs are likely to be important, you should carry out a "threshold" analysis to evaluate their significance. Threshold or "break-even" analysis answers the question, "How small could the value of the non-quantified benefits be (or how large would the value of the non-quantified costs need to be) before the rule would yield zero net benefits?" In addition to threshold analysis you should indicate, where possible, which non-quantified effects are most important and why.

[xxiv] Key Elements of a Regulatory Analysis. Circular A-4 summarizes the key elements of a for regulatory analysis as follows:

A good regulatory analysis should include the following three basic elements: (1) a statement of the need for the proposed action, (2) an examination of alternative approaches, and (3) an evaluation of the benefits and costs—quantitative and qualitative—of the proposed action and the main alternatives identified by the analysis.

To evaluate properly the benefits and costs of regulations and their alternatives, you will need to do the following:

• Explain how the actions required by the rule are linked to the expected benefits. For example, indicate how additional safety equipment will reduce safety risks. A similar analysis should be done for each of the alternatives.

• Identify a baseline. Benefits and costs are defined in comparison with a clearly stated alternative. This normally will be a "no action" baseline: what the world will be like if the proposed rule is not adopted. Comparisons to a "next best" alternative are also especially useful.

• Identify the expected undesirable side-effects and ancillary benefits of the proposed regulatory action and the alternatives. These should be added to the direct benefits and costs as appropriate.

With this information, you should be able to assess quantitatively the benefits and costs of the proposed rule and its alternatives. A complete regulatory analysis includes a discussion of non-quantified as well as quantified benefits and costs. A non-quantified outcome is a benefit or cost that has not been quantified or monetized in the analysis. When there are important non-monetary values at stake, you should also identify them in your analysis so policymakers can compare them with the monetary benefits and costs. When your analysis is complete, you should present a summary of the benefit and cost estimates for each alternative, including the qualitative and non-monetized factors affected by the rule, so that readers can evaluate them.

As you design, execute, and write your regulatory analysis, you should seek out the opinions of those who will be affected by the regulation as well as the views of those individuals and organizations who may not be affected but have special knowledge or insight into the regulatory issues. Consultation can be useful in ensuring that your analysis addresses all of the relevant issues and that you have access to all pertinent data. Early consultation can be especially helpful. You should not limit consultation to the final stages of your analytical efforts.

You will find that you cannot conduct a good regulatory analysis according to a formula. Conducting high-quality analysis requires competent professional judgment. Different regulations may call

for different emphases in the analysis, depending on the nature and complexity of the regulatory issues and the sensitivity of the benefit and cost estimates to the key assumptions.

A good analysis is transparent. It should be possible for a qualified third party reading the report to see clearly how you arrived at your estimates and conclusions. For transparency's sake, you should state in your report what assumptions were used, such as the time horizon for the analysis and the discount rates applied to future benefits and costs. It is usually necessary to provide a sensitivity analysis to reveal whether, and to what extent, the results of the analysis are sensitive to plausible changes in the main assumptions and numeric inputs.

A good analysis provides specific references to all sources of data, appendices with documentation of models (where necessary), and the results of formal sensitivity and other uncertainty analyses. Your analysis should also have an executive summary, including a standardized accounting statement.

[xxv] There are limitations to the information in the Unified Agenda. As the Regulatory Information Service Center (RISC) of the General Services Administration noted in its introduction to the December 2004 agenda:

> Agencies prepared entries for this publication to give the public notice of their plans to review, propose, and issue regulations. They have tried to predict their activities over the next 12 months as accurately as possible, but dates and schedules are subject to change. Agencies may withdraw some of the regulations now under development, and they may issue or propose other regulations not included in their agendas. Agency actions in the rulemaking process may occur before or after the dates they have listed.
>
> The Regulatory Plan and Unified Agenda do not create a legal obligation on agencies to adhere to schedules within it or to confine their regulatory activities to those regulations that appear in this publication.

(December 14, 2004; 69 FR 72645, at 29976)

The rulemaking activities of each agency appear in the Unified Agenda under one of five headings according to the rulemaking stage of the activity. According to RISC, the stages are:

> 1. Prerule Stage -actions agencies will undertake to determine whether or how to initiate rulemaking. Such actions occur prior to a Notice of Proposed Rulemaking (NPRM) and may include Advance Notices of Proposed Rulemaking (ANPRMs) and reviews of existing regulations.
>
> 2. Proposed Rule Stage -actions for which agencies plan to publish a Notice of Proposed Rulemaking as the next step in their rulemaking process or for which the closing date of the NPRM Comment Period is the next step.
>
> 3. Final Rule Stage -actions for which agencies plan to publish a final rule or an interim final rule or to take other final action as the next step in their rulemaking process.
>
> 4. Long-Term Actions -items under development but for which the agency does not expect to have a regulatory action within the 12 months after publication of this edition of the Unified Agenda.
>
> 5. Completed Actions -actions or reviews the agency has completed or withdrawn since publishing its last agenda. This section also includes items the agency began and completed between issues of the Agenda.

(Id., at 29977)

[xxvi] Trade secrets and "commercial or financial" information are covered by Exemption 4 of the Freedom of Information Act, 5 U.S.C. § 552(b)(4). Material may be withheld as "commercial or financial" information under two circumstances. First, if the information was provided to the Government voluntarily, it is confidential for the purpose of the Exemption if it is of a kind that would customarily not be released to the public by the entity

submitting the information. Second, if the information was provided to the Government on a mandatory basis, it is confidential if disclosure would be likely either to impair the Government's ability to obtain necessary information in the future; or (2) to cause substantial competitive harm to the entity submitting the information.

Persons submitting documents confidentially must assert their claim to confidential treatment when the documents are submitted. The agency then makes a determination as to whether exemption 4 applies. This exemption applies during all stages of the rulemaking process. As noted in this paper, not all agencies accept documents containing trade secrets or confidential commercial information for use in their rulemakings.

[xxvii] In addition to the exemption discussed in endnote 25 for trade secrets and confidential commercial or financial information (exemption 4), exemptions are also provided for other matters such as inter-agency or intra-agency memorandums or letters (exemption 5), and for records or information compiled for law enforcement purposes (exemption 7). (5 U.S.C. § 552(b)(5) and (7)).

[xxviii] In the case of a "major rule," the CRA provides that such a final rule may not take effect sooner than the end of the 60-day period following the submission of the rule to Congress. A "major" rule is defined for the purposes of the CRA as a rule that the OIRA finds will result in any of the following:

> (a) an annual effect on the economy of $100,000,000 or more;
>
> (b) a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or
>
> (c) significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of United States-based enterprises to compete with foreign-based enterprises in domestic and export markets.

Except as otherwise provided in statutes concerning particular types of product regulations, a major rule typically would not be scheduled to go into effect shortly after its publication in the Federal Register. This is because the time needed to bring the affected products into compliance would make it necessary for the issuing agency to specify an effective date that is significantly later than the date of issuance. In those typical cases, the CRA would not cause a delay in the implementation of a major rule (unless, of course, Congress disapproved the rule).

[xxix] The importance of the administrative record to the judicial review of rulemaking is reflected in Rule 28 of the 2004 Federal Rules of Appellate Procedure. A portion of that rule is set forth below. All of the rules can be found at http://judiciary.house.gov/media/pdfs/printers/108th/appel2004.pdf.

> **Rule 28. Briefs**
>
> **(a) Appellant's Brief.** The appellant's brief must contain, under appropriate headings and in the order indicated:
>
> …
> (3) a table of authorities—cases (alphabetically arranged), statutes, and other authorities—[cited in the brief,] with references to the pages of the brief where they are cited;
> …
> (5) a statement of the issues presented for review;
> (6) a statement of the case briefly indicating the nature of the case, the course of proceedings, and the disposition below;
> (7) a statement of facts relevant to the issues submitted for review with appropriate references to the [administrative] record …;
> (8) a summary of the argument, which must contain a succinct, clear, and accurate statement of the arguments made in the body of the brief, and which must not merely repeat the argument headings;

(9) the argument, which must contain:

(A) appellant's contentions and the reasons for them, with citations to the authorities and parts of the [administrative] record on which the appellant relies; and

(B) for each issue, a concise statement of the applicable standard of review (which may appear in the discussion of the issue or under a separate heading placed before the discussion of the issues);

(10) a short conclusion stating the precise relief sought.

[xxx] An argument made by counsel for the government during the judicial review of a Final Rule is a post hoc rationalization if it was not made by the issuing agency when it issued the rule.

[xxxi] Administrator Procedure Act provisions re judicial review. Section 706 of Title 5, U.S.C. provides:

> To the extent necessary to decision and when presented, the reviewing court shall decide all relevant questions of law, interpret constitutional and statutory provisions, and determine the meaning or applicability of the terms of an agency action. The reviewing court shall --
>
> . . . .
>
> (2) hold unlawful and set aside agency action, findings, and conclusions found to be –
>
> (A) arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law;
>
> (B) contrary to constitutional right, power, privilege or immunity;
>
> (C) in excess of statutory jurisdiction, authority, or limitations or short of statutory right;
>
> (D) without observance of procedure required by law; . . . .

[xxxii] In *Motor Vehicle Manufacturer's Ass'n of United States v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43-44, 103 S.Ct. 2856, 2866-2867, 77 L.Ed.2d 443 (1983), the U.S. Supreme Court described the scope of review as follows:

> The scope of review under the "arbitrary and capricious" standard is narrow and a court is not to substitute its judgment for that of the agency. Nevertheless, the agency must examine the relevant data and articulate a satisfactory explanation for its action including a "rational connection between the facts found and the choice made." *Burlington Truck Lines v. United States*, 371 U.S. 156, 168, 83 S.Ct. 239, 245-246, 9 L.Ed.2d 207 (1962). In reviewing that explanation, we must "consider whether the decision was based on a consideration of the relevant factors and whether there has been a clear error of judgment." *Bowman Transp. Inc. v. Arkansas-Best Freight System*, *supra*, 419 U.S., at 285, 95 S.Ct. at 442; *Citizens to Preserve Overton Park v. Volpe*, *supra*, 401 U.S., at 416, 91 S.Ct., at 823. Normally, an agency rule would be arbitrary and capricious if the agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise. The reviewing court should not attempt itself to make up for such deficiencies: "We may not supply a reasoned basis for the agency's action that the agency itself has not given." *SEC v. Chenery Corp.*, 332 U.S. 194, 196, 67 S.Ct. 1575, 1577, 91 L.Ed. 1995 (1947). We will, however, "uphold a decision of less than ideal clarity if the agency's path may reasonably be discerned." *Bowman Transp. Inc. v. Arkansas-Best Freight System*, *supra*, 419 U.S., at 286, 95 S.Ct. at 442. See also *Camp v. Pitts*, 411 U.S. 138, 142-143, 93 S.Ct. 1241, 1244, 36 L.Ed.2d 106 (1973)(per curiam). For purposes of this case, it is also relevant that Congress required a record of the rulemaking proceedings to be compiled and submitted to a reviewing court, 15 U.S.C. 1394, and intended that agency findings under the Motor Vehicle Safety Act would be supported by "substantial evidence on

the record considered as a whole." S.Rep. No. 1301, 89th Cong., 2d Sess. p. 8 (1966); H.R.Rep. No. 1776, 89th Cong., 2d Sess. p. 21 (1966), U.S.Code Cong. & Admin.News 1966, p. 2716.

Appendix

Practical Information about Public Participation

This appendix provides practical information about some of the opportunities for public participation in rulemaking-related activities.

Request for Confidential Treatment of Information. Persons who wish to request confidential treatment of information they plan to include in the submissions listed below should carefully identify that information, request confidential treatment of it, and explain the basis under the FOIA for the agency's providing that treatment. Prior to submitting such information to an agency, persons should consult with the agency about any special rules it may have established regarding the making of such requests.

Submissions that can be made anytime

Submission of Information and Arguments to an Agency. The public's opportunity to influence an agency's rulemaking related activities is not limited to submitting information and arguments during periods for commenting on rulemaking proposals published in the Federal Register. At any time, the public may submit information and arguments to an agency in an attempt to influence the agency's decisions on rulemaking related activities. These decisions include such pre-rulemaking matters as what regulatory problems should be included in the agency's rulemaking priority plan, what research should be conducted to aid in developing regulatory proposals to address those problems, and whether to initiate rulemaking on a particular problem.

Comment on Agency's Peer Review Agenda. Beginning in 2005, each agency is required to publish and invite public comment on an agenda describing all of its influential scientific information planned for dissemination in the foreseeable future and setting forth its plans for peer reviewing that information. (The first edition of an agency's agenda will be required to include only scientific information that is highly influential.) The agendas must be updated and published not less than every six months. The public will be invited to comment on the adequacy of the agenda, e.g., whether the public believes that all planned or ongoing scientific information that should be classified as influential has, in fact, been so classified, and whether the agency's peer review plans for each entry in the agenda are appropriate.

Request Correction of Information Disseminated by Agency. A member of the public may write to an agency to request correction of scientific, financial, statistical and other information disseminated by the agency if (s)he believes that the information does not meet OIRA's or the agency's guidelines regarding information quality, objectivity, utility and integrity. The request should clearly identify the information and explain why and how it should be corrected.

Petition Agency for Initiation of Rulemaking. Agencies typically issue regulations specifying the required contents of petitions for rulemaking. Regardless of what information is specified in such regulations, a petitioner is likely to improve the chances of having its petition

granted to the extent that the petitioner provides the information and analysis that the agency will ultimately need if it grants the petition and initiates a rulemaking to adopt the requested regulatory provisions.

It may be useful for a potential petitioner to consult in advance with the agency (s)he plans to petition. Some agencies may be willing to supplement their general guidance with specific suggestions as to what information the agency would consider to be most useful in assessing the merits of the petition (s)he plans to submit.

Submissions during a Rulemaking

Submission to Agency of Comments on Notices. The invitation by an agency for the submission of comments on one of its ANPRMs, NPRMs or SNPRMs provides the public with an opportunity to:

- Provide the agency with information that will enhance the agency's knowledge about matters discussed in the notice;
- Challenge the agency's interpretation of law, interpretation and application of data and research, factual assumptions, analytical methodologies, tentative factual, technical and policy conclusions, practicability assessments, and assessments of the benefits and other impacts of the proposal; and
- Suggest alternatives to the proposed requirements and test procedures.

A person will increase the effectiveness of his/her comments to the extent that (s)he:

- Explains his/her views and reasoning as clearly as possible.
- Provides empirical evidence, wherever possible, or test data to support his/her views. By supporting his/her arguments with facts, a commenter increases the likelihood of successfully persuading agencies to accept those arguments. An agency may regard an argument unaccompanied by supporting facts as being unsubstantiated and therefore give it little weight. Since the agencies are expected to rely on sound science to resolve technical factual issues in their rulemaking documents, they look especially for the public comments that are supported by sound science.
- Explains the basis for and calculations (s)he used in developing any estimates (s)he makes regarding costs of compliance.
- Provides specific examples to illustrate his/her concerns.
- Offers specific alternatives to the proposed regulation, including the regulatory text needed to implement those alternatives, and analyzes the relative merits of the proposal and alternatives.

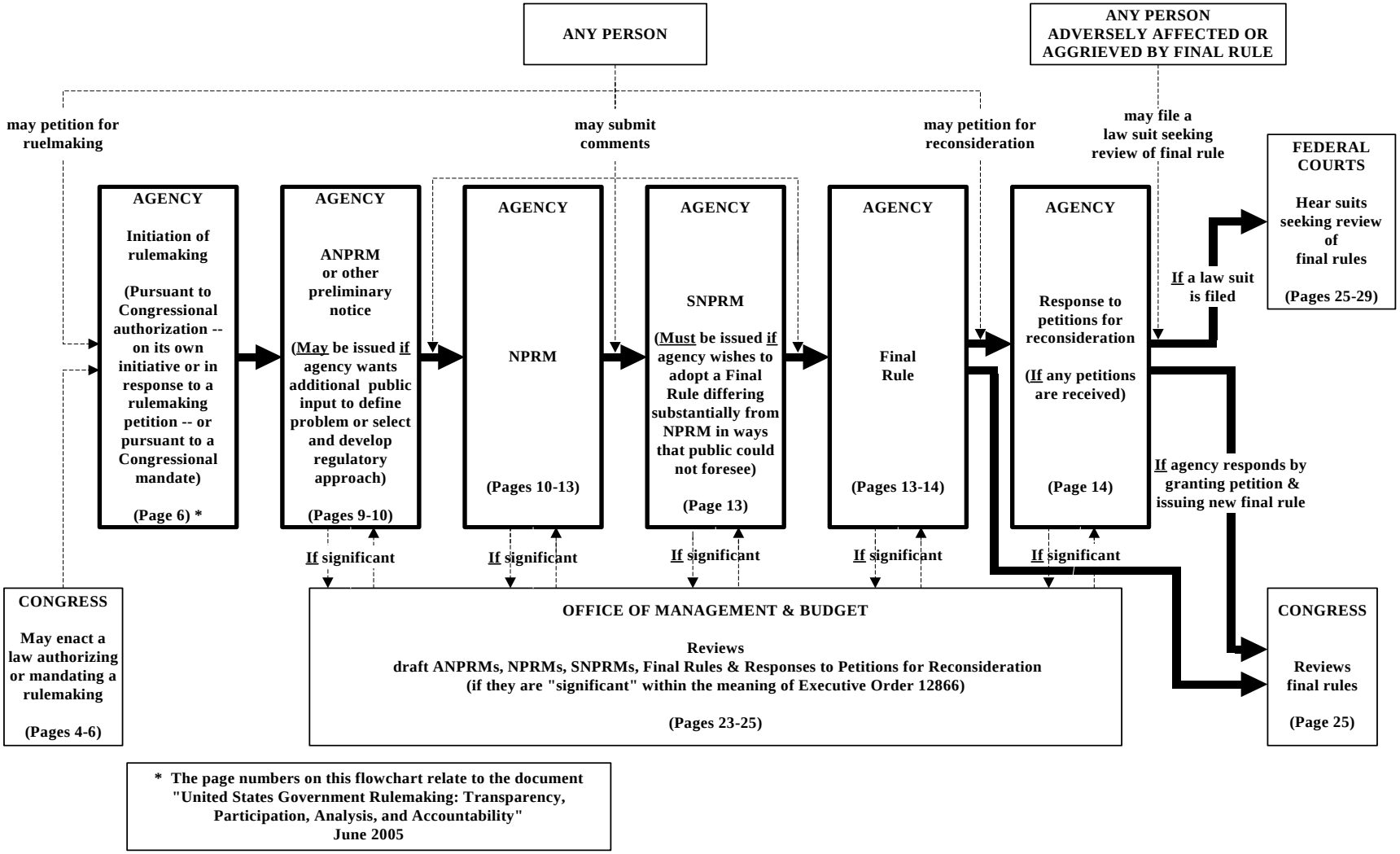
Petition Agency for Extension of Time to File Comments. Particularly in rulemakings that are not subject to statutorily or judicially mandated deadlines, agencies are willing to consider reasonable requests for extending comment periods on a rulemaking proposal. For example, depending on the circumstances that exist in a particular rulemaking, an agency may grant an extension to accommodate the need of petitioners for more time to conduct tests based on proposed new procedures or test devices (e.g., vehicle dynamometers and anthropomorphic dummies) for testing product performance and to analyze the test results.

Submissions after the Issuance of a Final Rule

Petition Agency for Reconsideration of a Final Rule. A person wishing to ask an agency to reconsider and change a Final Rule will increase his/her chances of success to the extent that (s)he is able to submit new facts and arguments in support of the desired change. A petition that essentially repeats what the person said in comments on the NPRM that preceded the Final Rule may be rejected by some agencies on the grounds that it is repetitious.

Index

Informal (Notice and Comment) Rulemaking Procedures of U.S. Regulatory Agencies



* The page numbers on this flowchart relate to the document "United States Government Rulemaking: Transparency, Participation, Analysis, and Accountability" June 2005