



Background on the Rulemaking Process

IV. Rulemaking

To understand how the laws and executive orders that govern the regulatory process interact with agency activities, it is important to know how agencies develop regulations.

An agency's work does not consist solely of rulemaking, of course. Agencies recommend legislation to Congress and help draft bills. Some agencies adjudicate and settle cases, issue cease and desist orders or try civil penalty actions. And once programs are put into place and regulations published, agencies must ensure they are implemented.

Also, many other forces besides legislation may propel agencies to initiate rulemaking or take other actions: Public opinion, presidential politics, industry influence, natural disasters, and many others.

Thus, separating out the rulemaking process from all other agency activities can be somewhat misleading since agencies and their staffs have many responsibilities, only some of which have to do with drafting rules. And rulemaking itself is seldom a simple process.

A. Gathering Information

Gathering information is basic to agency work. Federal agencies cannot make decisions or regulate without information to guide them. Information comes from studies, surveys, and other kinds of data collection-sometimes conducted by the agency itself, collected from other agencies, private companies and public organizations, and sometimes data collection is contracted out to consultants.

When an agency proposes to collect information, it sends its research proposal and supporting documentation to the Office of Information and Regulatory Affairs (OIRA) at the White House Office of Management and Budget (OMB). At the same time, the agency sends a public notice to the *Federal Register* regarding the request that has been forwarded to OMB.

Within OIRA, agency proposals are reviewed by desk officers who have responsibility for specific agencies. These same desk officers review both paperwork and regulatory proposals.

The OIRA desk officer will review the proposal and will allow an agency to undertake an information collection activity, if he or she is satisfied the collection of information is:

- "the least burdensome necessary for the proper performance of the agency's functions to comply with legal requirements and achieve program objectives";
- "not duplicative of information otherwise accessible to the agency"; and
- of "practical utility." (5 C.F.R. 1320.9)

If OIRA approves the agency proposal, the agency is given an "OMB control number," which must be displayed on every form and which is good for no more than three years. If the agency wants to keep collecting the information after the expiration of the OIRA approval, it must resubmit the information

collection proposal for OIRA review. If OMB does not approve, the agency may not collect the information.

For basic information requests (i.e., non-regulatory paperwork), the Paperwork Reduction Act gives OIRA 90 days to review the request. If the review goes over 60 days, OIRA must notify the agency. If the review exceeds 90 days, the proposal is to be automatically approved for a year.

Once approved by OIRA, the agency can conduct its studies or surveys and accumulate the information necessary to make program or policy decisions.

B. Regulatory Planning Process

As agency personnel begin working on issues which may lead to regulations, they have to comply with the requirements of Executive Order 12866, Regulatory Planning and Review. Independent regulatory agencies are subject to planning requirements as well.

To comply with E.O. 12866, an agency must prepare semiannually an agenda of all its proposed regulations. The agendas of all agencies are published collectively as the Unified Agenda of Federal Regulatory and Deregulatory Actions (Unified Agenda). The Unified Agenda is typically published in April and October of each year.

The Unified Agenda is to include regulatory actions in the prerule, proposed rule, and final rule stages as well as long-term and completed actions. Due to the length of the rulemaking process, many regulations repeatedly appear in the Unified Agenda.

Rulemakings listed in the Unified Agenda are to include, among other things, a summary of the rule, the legal authority for the rulemaking, and any legal deadline for promulgation of the rule.

E.O. 12866 also requires each agency to prepare a Regulatory Plan of the "most significant regulatory actions" the agency anticipates pursuing. The Plan is included in the fall publication of the Unified Agenda.

The Plan is more focused than the Unified Agenda. Whereas the Unified Agenda is to include "all regulations under development or review," the Plan includes only "significant" regulations. Significant regulations, those expected to have "an annual effect on the economy of \$100 million or more," require a more detailed submission of information to OIRA. Significant regulations are pared even further so that only the most important are included in the Plan. Additional requirements associated with each rule in the Plan include a statement of need and may include a summary of legal basis, alternatives to the proposed regulation, anticipated costs and benefits, and risks.

The anticipated costs and benefits section should provide a brief description of the impact the regulation is expected to have on agencies, industry, and the public. When possible, agencies often include dollar amounts to quantify these expectations, and often a quantified net impact on the economy.

Even as an agency is developing its regulatory plan, it is also in the midst of on-going activities. By the time the Regulatory Plan has been published, an agency may well want to begin work on issues not included in the Regulatory Plan. These, too, will have to be submitted to OIRA for review. The agency cannot act until the review is completed, unless there is an "unanticipated" emergency or statutory or judicial deadline.

C. Writing the Rule

The process of writing regulations varies considerably among federal agencies. Some have detailed procedures for rulemaking; others operate more informally. The time it takes from initial drafts of a regulation to publication as a final rule can range from a few months to several years. Most often, it takes a few years to complete a regulation because of the complexity of the issues, the collection of appropriate information, and the inherent delays built into the regulatory process. It usually involves considerable staff time and financial costs.

Often a program office within an agency is assigned the main responsibility for drafting a regulation. The program office is staffed by professionals who generally possess technical knowledge and experience with the subject of the regulation.

An alternative to the program office writing the rule is a team or working group assembled from different agency offices. These may include the office of the general counsel, regional and field personnel, policy planners and economists.

Specific laws sometimes dictate these procedures. For example, if a proposed rule would affect the environment significantly, agency personnel are required to send a copy of their proposal to agencies having environmental jurisdiction. Comments from those agencies will accompany the proposal through the agency review process.

Although many agency professionals have graduate degrees and specific technical expertise, they may still need the assistance of scientists or academics from outside the agency. These consultants may be hired to review agency proposals or to conduct studies for information lacking in the agency.

Not infrequently, agency personnel have discussions with representatives of the regulated industry or other interest groups. Industry representatives might be asked, for instance, to estimate the projected costs for a regulatory proposal. State officials may be asked about the mechanics of operating a program that they will have to administer.

On occasion agencies will attempt to formalize the process of consulting with interested parties by engaging in "negotiated rulemaking." Negotiated rulemaking attempts to move interested parties to compromise among themselves and help the agency develop a widely accepted regulatory proposal. The Negotiated Rulemaking Act of 1990 outlines the framework for the procedure, and Congress occasionally mandates its use when passing a law. However, due to the difficulty of incorporating the views of diverse groups of stakeholders, agencies do not often pursue negotiated rulemaking.

The internal agency steps involved in drafting a rule include gathering and evaluating data, participating in inter- and intra-agency meetings, drafting the proposed rule that will go into the *Federal Register*, and preparing background material and option papers for the agency decision-maker. An agency may also analyze public comments if any interested parties have submitted comments in the pre-rulemaking stage.

Agencies can sometimes skip some of these steps if there is an emergency (such as an immediate threat to public health and safety). The agency may also have to speed up the process due to a congressional or court order to issue a regulation by a specific deadline. In the interests of speed, an agency might publish an "interim" regulation, to be followed by a final regulation.

The drafting of a rule is a long process of inter- and intra-agency reviews and edits. Agency staff incorporates collected information, the views of other government bodies, the opinions of stakeholders and public comments where appropriate.

After a rule is drafted, it undergoes the centralized review process described in Section III. Once this process is complete, the rule is published in the *Federal Register* as a notice of proposed rulemaking (NPRM).

The NPRM will rarely describe the consultations between agency officials and their OIRA desk officer over the proposed rule. If an agency withdraws a proposed rule after OIRA review, there will of course be no NPRM published.

The public may request drafts of proposed rules sent to OIRA for review after they have been published in the *Federal Register*. Simple comparisons of a draft with a final rule will not reveal why any changes were made or who initiated them.

D. Publication in the *Federal Register*

After a proposed rule is reviewed by OIRA, it is published in the *Federal Register*. As required by the Administrative Procedure Act (APA), the NPRM must contain a description of the agency's rulemaking process, legal authority for the proposed rule, and the text or summary of the rule. The NPRM will announce what the agency intends to do and will also solicit comments on specific questions related to the rulemaking.

E. Notice-and-Comment Period

Generally, an agency will also announce a comment period, during which time interested parties can submit written comments either supporting or opposing the proposed regulation or offering ideas for changes. These comments can be simple or contain detailed arguments. Anyone can submit comments on a proposed rulemaking.

The publication in the *Federal Register* of an NPRM, or an advanced notice of proposed rulemaking (ANPRM), serves as an invitation for public participation in the rulemaking process.

The NPRM will likely be the first detailed presentation of the proposed rule. Agencies may already have published some description of the regulatory proposal in the Regulatory Plan or the Unified Agenda, but the NPRM is likely the first time the public is able to see the whole rule.

The APA only requires agencies to solicit written comments from the public. However, a number of agencies also hold hearings on proposed rules either because of the agency's desire to do so or because of a requirement in the statute the agency is enforcing.

The NPRM will describe how comments should be prepared and when they are due at the agency. The public is generally allowed access to the material and information the agency has collected in preparation for the filing, unless the Freedom of Information Act exempts a document.

Some rulemakings are exempt from the notice-and-comment period. Rules that are exempt from APA notice-and-comment period requirements are those dealing with military or foreign affairs and those "relating to agency management or personnel or to public property, loans, grants, benefits or contracts." Agencies may voluntarily waive an exemption if they so choose.

Comments received and the results of any hearing (when applicable) are put into a "rulemaking record," also known as the agency docket. The record should also include all the information collected in the course of agency research and investigation. The existence and organization of such a record is important if a court reviews the final agency decision and tries to determine the basis for the decision.

Searching through an agency's rulemaking record for information on how the agency reached its decision can be difficult since staff may have compiled hundreds (even thousands) of pages. While some agency rulemaking files are well organized, tabulated and indexed, searching through others may be, as one circuit court judge said, like "a safari through uncharted lands without benefit of a guide."

As part of e-rulemaking efforts, agency dockets are increasingly available online through the agency websites. However, much like the hard copy records, these online versions can often be difficult to navigate.

Not only does a poorly organized record make researching the rulemaking decision difficult, it may result in a court decision against the agency. Courts have invalidated rules when the record failed to demonstrate factual support for the rule or failed to show that the agency considered all relevant data.

To submit your own comments, please visit our [Comment on a Rule](#) page.

F. Review of Comments

Once the comment period ends, the agency reviews public comments received and may revise the rule.

The agency then goes through its final internal review process, which usually involves those same offices brought into the process earlier — the Secretary, the general counsel, program office, policy and planning staff, etc. They may be represented on a team or they may be asked only to sign off on the final proposal.

G. Publication of the Final Rule

When the agency makes its final rulemaking decision, it must again submit the final rule to OIRA for review. If it is a major rule it must also be accompanied by a final Regulatory Impact Analysis. OIRA will review the costs and benefits of the rule and determine if the rule fits the administration's regulatory priorities under E.O. 12866.

This final OIRA review may involve further negotiations with the agency, and the agency must again wait for the conclusion of OIRA review. For more on review of rules by OIRA, see [Section III](#).

The final rulemaking notice will contain the text of the final rule as well as a statement of its basis and purpose. In a preamble, there will be a summary and analysis of the issues raised during the earlier stages in the process. If the rule is "major," the notice will also include an announcement of the availability of the final Regulatory Impact analysis and a legal memo on the agency's authority. Both the RIA and the memo must be placed in the rulemaking record.

Once the final rule has been published, an agency usually must wait at least 30 days before implementing it. While Congress or a court may occasionally give an agency a deadline for starting or completing rulemaking, most often agencies are free to set their own schedules. These are sometimes reflected in the timetables contained in the Regulatory Plan and the Unified Agenda.

For major rules the Congressional Review Act (CRA) grants Congress a 60-day window to review the rule. Congress may also review non-major rules, however those rules are not subject to further delay in the way major rules are. Congress is allowed to nullify the rule by simple majority. Since the enactment of the CRA in 1996, Congress has rarely considered the strategy and used it successfully only once.

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