

The Regulatory Process

What is a regulation?

Regulations, or rules, are a primary vehicle with which agencies implement specific laws and general agency objectives. They are specific standards or instructions concerning what can or cannot be done by individuals, businesses, and other organizations.

Where does the authority to issue regulations come from?

The Constitution grants the legislative branch the power to pass laws. The executive and judicial branches are tasked with administration and adjudication, respectively.

Over the years, this separation of powers has blurred somewhat, and executive branch agencies are frequently granted authority for writing as well as administering and enforcing regulations (or Administrative Laws) by Congress. In granting this authority, Congress may state goals for a specific issue that the agency is mandated to meet, such as the Clean Water Act requirements on the EPA to reduce well-defined waterborne contaminants. Alternatively, Congress has granted broad powers to an agency to determine within a certain field what is to be regulated and how to accomplish it. For example, the Occupational Safety and Health Act directs OSHA to issue “occupational safety and health standards.” Recently, some broader delegations of power have been questioned under the “non-delegation doctrine.”

How are regulations made?

The [Administrative Procedure Act of 1946](http://www.sba.gov/advo/laws/sum_apa.html) (APA) (http://www.sba.gov/advo/laws/sum_apa.html) outlines the processes agencies must follow when writing regulations. The APA describes two types of rulemaking – formal and informal. Formal rulemaking is used by agencies responsible for economic regulation of industries, and is only required when a statute other than the APA specifically states that rulemaking is to be done “on the record.” Formal rulemaking involves hearings and the presentation of formal documentation to support the rule in front a commission or judge. Generally speaking, formal regulation is rare except in cases of “ratemaking” by a regulatory commission (such as the Federal Energy Regulatory Commission).

Informal rulemaking, or notice and comment rulemaking, is the most common process used by agencies for writing, or “promulgating” regulations. In informal rulemaking, the agency or department first proposes a rule or standard and invites public comment through a Notice of Proposed Rulemaking (NPR or NPRM). In some cases, the agency will even issue an Advance Notice of Proposed Rulemaking (ANPR or ANPRM).

How does the public get involved?

While interested parties (e.g., lobbying organizations and those affected by the rule) are often aware of an agency’s regulatory plans and communicate with it during the development of a proposed rule, the APA requires agencies to provide broad public notice of its intended actions by publishing an NPRM in the *Federal Register* (<http://www.gpoaccess.gov/fr/index.html>). The *Federal Register* notice specifies a period for public comment that can range from 30 to 120 days or more, depending on the complexity of and interest in the proposal. The public is invited to submit their comments on the rule during this period. These comments are collected in the “rulemaking record.”

After the comment period closes, the agency reviews the comments and publishes its final rule. According to the APA, the final rule must be based on the “rulemaking record.” Otherwise the agency could be sued and the regulation overturned for being “arbitrary and capricious.” In this manner public participation in agency rulemaking is guaranteed.

What is the President's role?

The president of the United States is the chief executive responsible for executive branch agency actions. Every president since President Nixon has established procedures for executive review of agency regulations. President Clinton's [Executive Order 12866](http://www.archives.gov/federal_register/executive_orders/1993_clinton.html) (E.O. 12866) (http://www.archives.gov/federal_register/executive_orders/1993_clinton.html) requires, among other things, that a regulatory analysis, including a statement of need for the regulation, assessment of alternative regulatory approaches, and a cost-benefit analysis, be performed on all rules deemed to be of significant economic impact (*i.e.* impose a cost burden of \$100 million or greater per year).

E.O. 12866 also requires that significant rules be reviewed by the [Office of Information and Regulatory Affairs \(OIRA\)](http://www.whitehouse.gov/omb/inforeg/regpol.html) (<http://www.whitehouse.gov/omb/inforeg/regpol.html>), in the Office of Management and Budget (OMB), before publication in the *Federal Register*. Each proposed or final rule must meet specific informational requirements before it passes the OIRA review, providing a consistent format for regulations that is designed to reduce the costs to the public of obtaining this information.

OIRA posts on its Internet site a list of [rules under review](http://www.whitehouse.gov/library/omb/OMBREGS.html) (<http://www.whitehouse.gov/library/omb/OMBREGS.html>) at any given time. Once OIRA has completed its review of a rule, the agency may then publish it in the *Federal Register* for public comment.

Does Congress have a role in issuing regulations?

Executive agencies exert their regulatory authority under delegation from Congress. Congress, however, monitors the activities of the various agencies through oversight committees, each of which is designated to a specific agency. Through oversight hearings, oversight committee members can hear the testimony of agency representatives concerning the regulatory actions of their agency. If Congress is displeased with the manner in which an agency is implementing its mandates, it can attempt to guide the process through regulatory oversight, or it can pass another law with new directives, but that can be a cumbersome and lengthy process. In recent years, Congress has passed a number of legal requirements governing factors the executive branch must evaluate, information it must provide, and procedures for review of regulations by parties other than the issuing agency.

Some of the most important regulatory review laws are:

- [Paperwork Reduction Act \(PRA\)](http://www.cio.noaa.gov/itmanagement/pr.html) (<http://www.cio.noaa.gov/itmanagement/pr.html>), which established OIRA within OMB to review the paperwork and information collection burdens imposed by the federal government.
- [Regulatory Flexibility Act \(RFA\)](http://www.sba.gov/advo/), which requires agencies to assess the impact of a regulation on small businesses and provides for review by the [Small Business Administration \(SBA\)](http://www.sba.gov/advo/) (<http://www.sba.gov/advo/>).
- [Small Business Regulatory Enforcement Fairness Act \(SBREFA\)](http://www.sbaonline.sba.gov/advo/laws/law_lib.html) (http://www.sbaonline.sba.gov/advo/laws/law_lib.html), which enforces requirements for small business impact analyses under RFA.
- [Congressional Review Act \(CRA\)](http://www.sba.gov/ombudsman/) (<http://www.sba.gov/ombudsman/>), contained in SBREFA, which requires rule-issuing agencies to send all mandated documentation that is submitted to OMB to both houses of Congress as well, and allows Congress to overturn regulations within a specified time with a Congressional Resolution of Disapproval.

- [Unfunded Mandates Reform Act \(UMRA\)](http://www.sba.gov/advo/laws/sum_unf.html)(http://www.sba.gov/advo/laws/sum_unf.html), which limits the ability of regulatory agencies to place burdens on state, local, and tribal governments.
- [Omnibus Consolidated and Emergency Supplemental Appropriations Act of 1999 \(section 638\(a\)\)](http://www.ncsl.org/statefed/omni99.htm)(<http://www.ncsl.org/statefed/omni99.htm>), which requires OMB to report to Congress yearly on the costs and benefits of regulations and recommendations for reform.
- Truth in Regulating Act of 2000 gives Congress the authority to request that GAO conduct an independent evaluation of economically significant rules at the proposed or final stages.

Do agencies regulate through other avenues?

In addition to formal and informal rulemaking as defined by the APA, standards and rules that businesses and individuals must follow are also established outside this rulemaking process. Standards may be set through policies, guidelines, executive orders, and through enforcement cases. For example, businesses are guided by the kinds of cases that an agency brings. Enforcement cases help define what the FTC, for example, may view as deceptive advertising.

How can the public keep track of regulations?

Keeping track of regulations and regulatory activities is challenging. The *Unified Agenda* (<http://ciir.cs.umass.edu/ua/>) lists the rulemaking plans of each agency. It is published each year in October and in April. However, this information becomes outdated quickly and may not be the most up-to-date given the relative infrequency of its publication. It should be seen as a very general and broad outline for regulatory activity. By incorporating up-to-the minute news and information, we hope RegRadar will help us all keep more informed about regulatory issues on a real time basis.

For a more detailed description of the regulatory process, see “A Guide to Federal Agency Rulemaking” by Jeffrey S. Lubbers and published by the [American Bar Association](http://www.abanet.org) (<http://www.abanet.org>).