



A Basic Guide to Federal Rulemaking and Small Business

Federal regulations can be confusing and burdensome to small business. They are the result of a multistep process that usually begins when Congress identifies a problem in need of intervention at the federal level. Some examples are outbreaks of food-borne illnesses, transportation accidents, or immigration policy; all of these may affect people in many states. When rules are made, small businesses have opportunities to offer their comments, experiences, and alternative solutions thanks to a law called the Regulatory Flexibility Act (RFA).

The chart shows the rulemaking steps and the small business consideration that is built into the process as a result of the RFA.

What is a Federal Regulation?

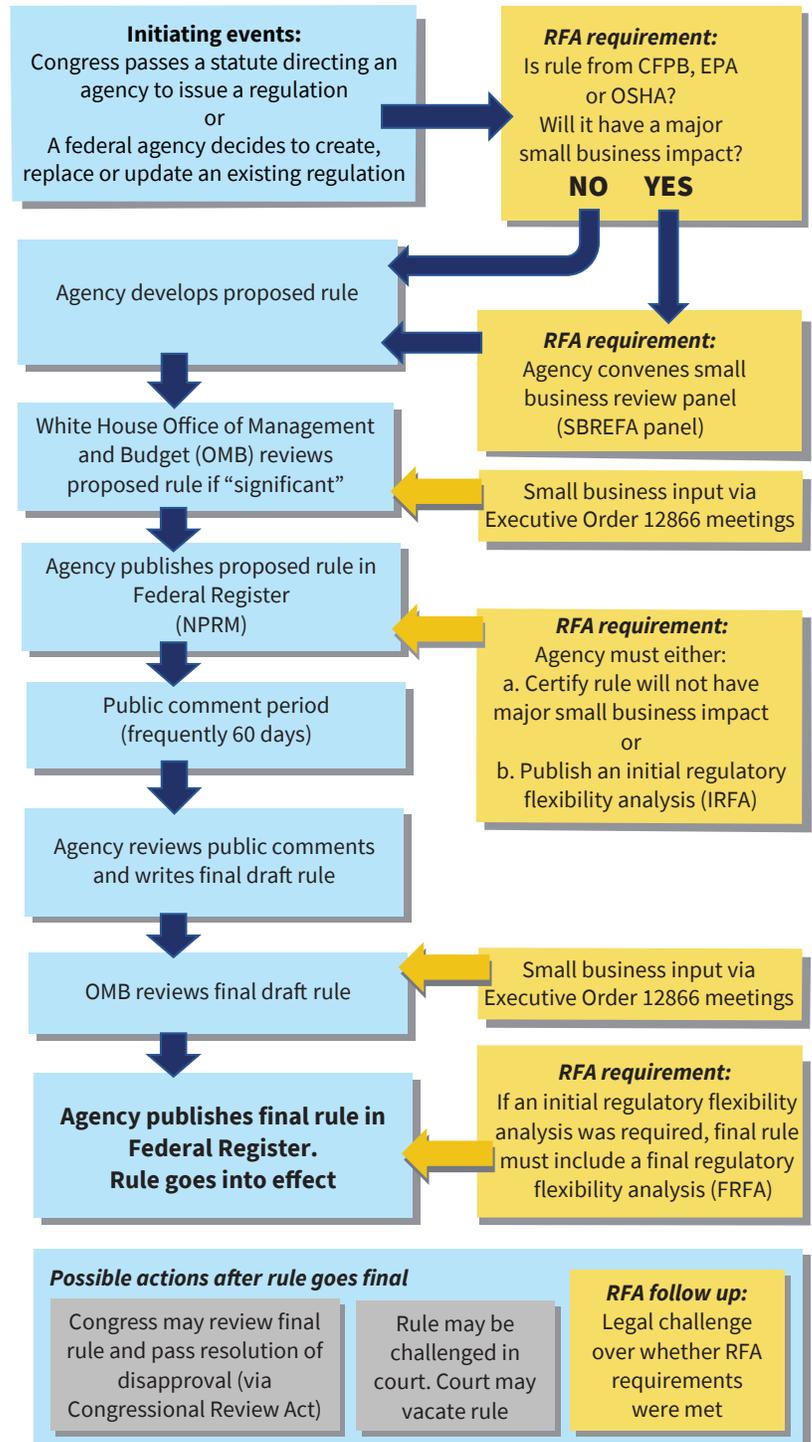
Generally, when Congress passes a law, it directs a federal agency to create regulations to interpret, explain, or put the law into an everyday context to accomplish its purpose. So, a federal “regulation,” or “rule,” is a specific detailed requirement or direction written by a federal agency that provides instructions on how to follow the law. Regulations often spell out the actions the law requires, those that it prohibits, and any penalty for failure to comply.

A law called the Administrative Procedure Act, which President Harry S. Truman enacted in 1946, establishes the process for federal agencies to make rules. This process is termed “notice-and-comment

rulemaking.” It contains public alerts that a rule is in the works, as well as windows of time when the public is able to provide input.



The Federal Rulemaking Process and Small Business Consideration



Steps to a New Regulation

1. Congress directs an agency to write regulations.

A statute often sets a date by which the law will take effect. The agency tapped to write the rules creates a schedule for completing this job. An agency may also decide to update an existing rule.

2. Small business panel needed? A special requirement applies to three agencies: the Consumer Finance Protection Bureau, Environmental Protection Agency, and Occupational Safety and Health Administration. When one of them begins considering a new regulation that will have a significant impact on small entities, it must convene a small business review panel to consider approaches to regulation. (These are also called “SBREFA panels” after the law that requires them).

3. Advance notice of proposed rulemaking. An agency may also gather information by announcing that it is considering a new rule in a publication called the *Federal Register*. Any interested individual or group may submit comments and provide their thoughts on the agency’s initial ideas.



4. Agency develops proposed rule. The proposed rule is the agency’s plan of action to address the problem and accomplish the goals of the authorizing statute.

5. White House reviews significant proposed rules.

The Office of Information and Regulatory Affairs (OIRA), a component of the White House Office of Management and Budget, reviews and coordinates rules written by the executive branch agencies that will cost the economy \$100 million or more. Most agencies submit their rules prior to publication of the proposed and final rule. Rules issued by independent agencies are not reviewed. These include the Federal Communications Commission, Federal Trade Commission, and Securities Exchange Commission.

While a proposed rule is under review, any affected entity can ask for a meeting to provide information on how the rule might affect them. Advocacy can assist a small entity in preparing for these meetings. This review of significant rules is part of Executive Order 12866, “Regulatory Planning and Review.”

6. Agency publishes the proposed rule. The notice of proposed rulemaking (NPRM), or proposed rule, is the official document that announces and explains the agency’s plan of action to address the problem and accomplish the goals. Generally, this plan must be published in the *Federal Register*. The RFA requires agencies to evaluate whether a proposed rule will have an impact on small entities. Following the analysis, the

agency may do one of two things: certify that the rule will not have a significant impact, or supply an analysis of the small business impact. (This is called the initial regulatory flexibility analysis or IRFA).

7. Public comment period. The public is invited to comment on the agency’s proposed rule for a specified time period. Small businesses are free to comment on the accuracy of the agency’s impact analysis and to submit their own estimates of what the impact would be. They may also suggest alternative, flexible ways of accomplishing the goal of the rule. The RFA requires the Office of Advocacy to monitor whether agencies are properly considering small entities and alternatives in rulemaking. Advocacy provides comments on agency proposals based on small business input and the office’s own economic research. The public may also have opportunities to participate in hearings and meetings on a rulemaking. Advocacy issues email and online alerts announcing such gatherings.

8. Agency writes final draft rule. After the comment period closes, the agency analyzes input and compiles the final draft.

9. White House reviews final draft rule. Agencies submit major rules in final draft form to OIRA for review. While a draft final rule is under review, any affected small entity can ask for an E.O. 12866 meeting with OIRA to discuss how the rule might affect them.

10. Final rule published. After the comment period closes, the agency considers public comments and all other input, then it develops the final rule. The agency publishes the final rule in the *Federal Register*. The final rule is lengthy. In addition to stating all the requirements of the rule in detail, it contains the purpose and justifications of the rule, summaries of the comments received, and the effective date or dates. The RFA requires the rule to contain a final regulatory flexibility analysis if an initial analysis had been required, plus responses to Advocacy’s public comments.



Exceptions to Notice-and-Comment Process

In certain cases, agencies issue rules without notice and comment. Reasons for this may include military or foreign affairs functions, internal agency procedures, contracts, interpretive rules, guidance, or for good cause, such as a national emergency. In such cases agencies may issue **interim final rules** or **direct final rules**, to which the RFA does not apply.

COMMENT LETTER HOW-TO

Small businesses can express their concerns or support for a proposed rule directly to an agency during an open comment period. You can also comment via a trade association or other representative. And you may share your input with Advocacy for background in the office's comments.

Find the proposed rule on www.regulations.gov.

Read the rule then decide how it would affect you. Note the comment deadline, and arrange to file comments in a timely fashion.

What makes a good comment letter?

Agencies value comments that provide detailed cost information and alternative ways of achieving a statutory goal. The length of the letter is not the most important factor; providing data and detail is.

Here are some useful questions to get you started:

- What impact would the rule have on your business if it were to take effect? Provide actual cost numbers or be as specific as possible.
- Do you see discrepancies between the agency's description of how the rule will work and the practical impact you see based upon how your business or industry operates in the real world?
- Is there confusing or misleading language that the agency should clarify?
- Are there areas that are beneficial to your business or industry? If so, compliment the agency, so rulemakers will know what they are getting right.

Effective comment letters include these items:

1. Your full name and address.
2. Correct reference to the name of the rule you are commenting on.
3. An explanation of what is at stake for you and your business in this rulemaking process.
4. Details and examples of how the rule will affect your business, customers, production, policy, and products.
5. Clear requests or recommendations to improve the rule, for instance:
 - To delay it for a certain number of days to provide more time to comply;
 - To revise a particular part of it;
 - To exclude a part of the industry that may not be contributing to the problem the rule seeks to address.
6. A summary of your comments.
7. A word of thanks to the agency for considering the rule's small business impact.



Where to send the comment letter.

Most comment letters are filed online at <https://regulations.gov>. They can also be mailed, faxed, or emailed. The address is listed in the proposed rule in the *Federal Register*, available at www.federalregister.gov.

Do not forget.

Be sure to note the comment deadline. They are different for each rule.

HOW DO PUBLIC COMMENTS AFFECT THE FINAL RULE?

The notice-and-comment process enables anyone to submit a comment on any part of the proposed rule. This process is not like a ballot initiative or an up-or-down vote in a legislature. An agency is not permitted to base its final rule on the number of comments in support of the rule over those in opposition to it. At the end of the process, the agency must base its reasoning and conclusions on the rulemaking record, consisting of the comments, scientific data, expert opinions, and facts accumulated during the pre-rule and proposed rule stages. To move forward with a final rule, the agency must conclude that its proposed solution will help accomplish the goals or solve the problems identified. It must also consider whether alternate solutions would be more effective or cost less.

If the rulemaking record contains persuasive new data or policy arguments, or poses difficult questions or criticisms, the agency may decide to terminate the rulemaking. Or, the agency may decide to continue the rulemaking but change aspects of the rule to reflect these new issues. If the changes are major, the agency may publish a supplemental proposed rule. If the changes are minor, or a logical outgrowth of the issues and solutions discussed in the proposed rules, the agency may proceed with a final rule.

Source: "A Guide to the Rulemaking Process," Office of the Federal Register, 2011. https://www.federalregister.gov/uploads/2011/01/the_rulemaking_process.pdf

REGULATORY REFORM AND REVIEW

Ten-Year Review

Section 610 of the RFA requires agencies to review rules that have or will have a significant small entity impact within 10 years of their promulgation. Rules must be reviewed to determine whether they should be continued as is, amended, or rescinded to minimize their impact on small entities.

Regulatory Reform and Deregulation

President Trump has made private-sector deregulation a top priority. Executive Order 13771 requires that any new regulation be balanced by removing at least two other regulations, and that costs of new regulations be offset by eliminating costs of existing ones. Executive Order 13777 created a framework for reform.

Advocacy has launched the Regional Regulatory Reform Roundtable initiative to help agencies un-



derstand which rules are most burdensome for small businesses. Roundtables are being held across the country to let small businesses discuss the challenges they face with various rules and which ones

they would most like to see reformed. Advocacy has followed up in letters and meetings with rulemaking officials, and some successes have already occurred.

Note that the multistep notice-and-comment rulemaking process is also used when existing rules are changed or withdrawn. The agency proposes a regulatory action to revise or remove a rule. And the small business impact of these actions must be considered as well.

Regulatory Reform Resources

Send Your Regulatory Reform Input to Advocacy Tell us about the regulations your business has compliance concerns with on our website: <https://advocacy.sba.gov/regulatory-reform/regulatory-reform-input/>

Read About Our Progress Toward Regulatory Reform Advocacy's report, "What Small Businesses Are Saying and What Advocacy Is Doing About It," tracks our regional roundtables and reports on the reform progress that has been made so far. <https://advocacy.sba.gov/regulatory-reform/regulatory-reform-follow-up/>

THE OFFICE OF ADVOCACY

The Office of Advocacy was created by Congress in 1976 to represent small business interests before government agencies. The leader of the office is the Chief Counsel for Advocacy, who is nominated by the President and confirmed by the Senate.

In 1980, the Regulatory Flexibility Act (RFA) was enacted. The RFA established the principle that government agencies must consider the effects of their rules on small entities, and where possible, they must provide flexibility to reduce negative impacts. As the watchdog of this important law, Advocacy works with agencies on behalf of small business to help the agency reduce small business burdens while still accomplishing the goals of the regulation.

On the official level, Advocacy is required to monitor federal agencies' consideration of small entities in rulemaking. On a practical level, Advocacy pores through thousands of pages of regulations, alerts small businesses to those that affect them, and conveys small business concerns to agencies.



Stay Connected with Advocacy

Follow Advocacy to learn about proposed regulations, open comment periods, roundtables, meetings, and Advocacy's public comments.

Listserv <https://advocacy.sba.gov/connect/>

Website <https://advocacy.sba.gov/>

LinkedIn www.linkedin.com/company/u-s-small-business-administration-office-of-advocacy

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