In making laws, Congress often leaves it to the executive branch (specifically, federal agencies) to figure out the nuts and bolts of how to achieve a law’s objectives. Important decisions about how to implement a law generally take the form of regulations.

Federal environmental laws, for example, call for clean air and clean drinking water but leave it to the Environmental Protection Agency (EPA) to determine, after looking at the science and hearing from the public, what the allowable concentration or pollution limit should be. The EPA and state environmental agencies then take steps, such as issuing permits to facilities like factories and power plants, to ensure compliance with pollution limits. Without federal and state agencies issuing regulations and taking other actions to implement the laws Congress has passed, many laws would have little or no practical effect.

Agencies don’t have a free hand in making or changing regulations; they must comply with the laws that authorize their actions. They must also follow laws that govern the process for developing regulations (rulemaking)\(^1\) and that establish additional requirements for regulatory design (e.g., minimizing paperwork,\(^2\) avoiding placing an undue burden on businesses\(^3\) or state and local governments\(^4\)). Additional steps may be required in order to satisfy presidential executive orders, including analyzing and disclosing the costs and benefits of regulations deemed “significant” based on cost or other factors.\(^5,6\)

### Legal Requirements for the Content of Regulations

Agencies must follow Congress’s directions in making or changing regulations. Congress typically tells an agency when or under what circumstances a rule should be written, what it should accomplish, and what the agency should consider in crafting it. If the agency doesn’t follow Congress’s directions, its decisions can be overturned by a court.

Federal law requires agencies to do a lot of homework before issuing a regulation: they must collect and analyze relevant scientific, technical, economic, and/or other information, and arrive at decisions that make sense in light of that information. If an agency fails to do either, a court can find it in violation of the law and tell the agency to go back to the drawing board.

### Legal Requirements for the Process of Making Regulations

Agencies generally must follow a process that gives the public—every one of us—a chance to learn about a proposed rule, say what we think about it, and compel the issuing agency to consider and respond to our views.

**Publishing a proposal.** With few exceptions, an agency must give the public notice of, and an opportunity to comment on, a proposed rule before the agency makes a final decision. To accomplish this, the agency issues a notice of proposed rulemaking in the Federal Register, the official journal of the federal government, accessible online at www.federalregister.gov. The agency may also post the notice or a link to the notice on its own website.

A proposal notice is—or should be—a gold mine of information. The agency is required to describe the action being proposed and the information on which it is based. It must also explain how, in its opinion, the proposed action is consistent with the relevant law and facts. Except for legally protected confidential information, all the information used by the agency must be available for public review and can usually be found in an electronic docket accessible online.

**Asking for public comment.** As part of the proposal notice, the agency lets the public know when, where, and how to submit comments. Agencies generally must give the public at least 30 days from the date the proposal is published in the Federal Register to comment. Under very limited circumstances, agencies can shorten the time for comment.

In some cases, agencies also hold public hearings where anyone can offer remarks; the proposal notice usually provides the dates and locations. Sometimes an agency holds a public hearing during the comment period.
Although not required, agencies may provide additional opportunities for public input. Representatives of businesses and public interest groups often ask to meet with agency officials, for example, and these requests are often granted. Agencies must document these meetings, including who attended and what views were aired, in a memorandum or other submission to the docket. This ensures all comments made to an agency are in the public record.

Issuing a final regulation or action. The agency must consider all the public comments it receives in making final decisions about a rule, and respond to all “significant” comments (i.e., those that provide new information or analysis or make reasoned arguments for how and why the proposal should be changed).

After deciding on a final regulation or action, the agency issues a notice of a final rule or action in the Federal Register. The notice or supporting materials must include an explanation of any changes made to the proposal and the agency’s responses to all significant comments. The agency may also prepare various technical and other documents to explain and support its decision and include those in the docket.

How Other Agencies and the White House Play a Role

For agencies, the public rulemaking steps described above are only part of the process. Presidential executive orders have added two rounds of interagency review so that White House and other federal agency officials have a chance to weigh in on drafts of “significant” proposed and final rules before they go public. Important goals of interagency review are coordination of federal agency actions and consistency of those actions with the president’s policies, to the extent permitted by law.

The Office of Information and Regulatory Affairs (OIRA) in the White House Office of Management and Budget (OMB) is the gatekeeper of the interagency review process and determines which rules are significant based on cost and other factors. OIRA usually meets with outside groups upon request and keeps a public log of those meetings. That log is accessible online at www.reginfo.gov/publicvd/oonl2866Search under the tab “Regulatory Review.” During these meetings, OIRA officials listen but generally do not engage in debate or discussion.

Engaging with OIRA can be useful. As a strictly legal matter, White House officials (including the president) are not authorized by most laws to make decisions about regulations. But the agency heads who are authorized to make these decisions work for the president. Because OIRA and other White House officials are often important advisors to the president, they can have considerable clout. Moreover, OIRA
Interagency review aims to coordinate federal agency actions and consistency of those actions with the president’s policies.

controls when the interagency review process begins and ends. That adds to the sway the White House has over a regulation’s outcome.

Your voice matters too. For advice on how to participate in the federal rulemaking process, refer to our companion piece at www.ucsusa.org/resources/participating-federal-rulemaking.

This toolkit was drawn from A Citizen’s Guide to the Federal Regulatory Process, written by a group of former employees of the Environmental Protection Agency. You can read the guide, and our companion toolkit on how to participate in the federal rulemaking process, at www.ucsusa.org/resources/participating-federal-rulemaking.

ENDNOTES
1. For example, the Administrative Procedure Act, 5 U.S.C. 551 et seq. See www.epa.gov/laws-regulations/summary-administrative-procedure-act.
5. For example: Executive Order (E.O.) 12866, Regulatory Planning and Review; E.O. 13563, Improving Regulation and Regulatory Review; E.O. 13132, Federalism; E.O. 13175, Consultation and Coordination with Indian Tribal Governments; E.O. 13045, Protection of Children From Environmental Health Risks and Safety Risks; E.O. 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use; E.O. 12898, Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations.
6. One tactic used by the Trump administration was changing cost-benefit analyses to make rules look less beneficial to the public. In proposing to rescind the EPA’s Waters of the US rule, for example, the administration changed the cost-benefit analysis that had shown the rule’s benefits would significantly exceed its costs. By removing some benefits (e.g., wetlands protection) from the equation, they tried to hide the fact that rescinding the rule would result in a net loss for the public. Pointing out this kind of flawed decisionmaking can be helpful in public comments.
7. E.O. 12866, which governs interagency review, provides for some transparency. It requires OIRA to place in a public docket any written comments received from other agencies during the interagency review process. It also requires agencies to identify for the public all changes made to a proposed or final rule that were made at the suggestion or recommendation of OIRA. Some statutes add further transparency requirements. In the case of the Clean Air Act, for example, the draft rules submitted for interagency review are made available to the public.

The Union of Concerned Scientists puts rigorous, independent science to work to solve our planet’s most pressing problems. Joining with people across the country, we combine technical analysis and effective advocacy to create innovative, practical solutions for a healthy, safe, and sustainable future.