THE ESSENTIAL GUIDE TO THE REGULATORY PROCESS

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A regulation or a rule is the primary vehicle with which agencies use to implement specific laws and general agency objectives. They are specific standards or instructions concerning what individuals, businesses, and other organizations can or cannot do.

Regulations influence nearly every aspect of daily life, yet most people know very little about the impact of regulations or the process by which regulations are created.

The regulatory space is notoriously opaque relative to the legislative process. Even so, it has a tremendous impact on the way lobbyists, companies, and regular people operate on a daily basis.

“In 2011, the federal government printed 82,129 pages of rules and announcements in the Federal Register. At a reading rate of 4 minutes per page, 2.6 people would have to read for 40 hours per week for a year just to keep up with the new rules and pronouncements.” – Dudley and Brito
THE REGULATORY PROCESS: 
FROM LAW TO REGULATION

1. **CONGRESS WRITES A BILL**
   Congress passes legislation granting a government agency the authority to issue regulations based on the passed law.

2. **THE PRESIDENT APPROVES OR VETOES THE BILL**
   If both houses of Congress approve a bill, it goes to the President who can either approve or veto the bill. If approved, the new law is then called an act or statute.

3. **THE ACT IS CODIFIED IN THE U.S. CODE**
   After an act is passed, the House standardizes the text and publishes it in the United States Code (U.S.C.). It is then officially a part of the collection of the general and permanent laws of the United States.

4. **PUTTING THE LAW TO WORK**
   Once a law is official, it is put into practice. Laws do not usually include all the details necessary to explain how individuals, businesses, or state and local governments might follow that law. The U.S.C., for example, does not tell you what ingredients can be in toothpaste or what the quality of water is in a shower. So, Congress authorizes certain government agencies to create regulations that bring laws to life.

5. **A FEDERAL AGENCY THEN PROPOSES A RULE DESIGNED TO CARRY OUT THE INTENT OF LAW.**
   If a rule is subject to public comment, the agency responds by either withdrawing, modifying or maintaining the rule.

6. **THE OFFICE OF MANAGEMENT AND BUDGET'S OFFICE OF INFORMATION AND REGULATORY AFFAIRS REVIEWS THE AGENCY'S PROPOSED RULE**
   and later the final rule.

7. **THE PROPOSED RULE IS POSTED IN THE FEDERAL REGISTER,**
   opening it to public comment for about 60 days. The final rule is also posted before being sent to the Government Publishing Office.

8. **THE FEDERAL AGENCY THAT ORIGINATED THE PROPOSED RULE REVIEWS PUBLIC COMMENTS**
   posted in the Federal Register and incorporates changes into a final rule.

9. **THE GOVERNMENT PUBLISHING OFFICE PRINTS THE CODE AND PUBLISHES IT ONLINE**
   After the Federal Register posts the final rule, it becomes effective in no less than 30 days – except in cases of exemption, relief of restriction or if the rule addresses an emergency.
FREQUENTLY ASKED QUESTIONS

WHY DOES CONGRESS DELEGATE RULEMAKING TO AGENCIES?

The main reason that rulemaking is delegated to agencies is because agencies have a significant amount of expertise that enable them to fill in the technical details of a program to implement a law. Congress does not have the depth in all issue areas necessary to both create laws and implement the practical rules for those laws. This allows Congress to focus on big-picture issues.

DOES CONGRESS PLAY ANY ROLE IN AGENCY RULEMAKING?

Yes. Congress is able to monitor agency activities through oversight hearings and oversight committee meetings.

HOW DO PEOPLE EXERT INfluence OVER AGENCY RULEMAKING?

Many interested parties (lobbyists, trade associations, etc.) often try to learn about a rule before it is proposed in the Federal Register (FR) so that they can exert influence over the initial development of the rule. Once the rule has been proposed, smaller or less influential parties, as well as the public, get involved by commenting on rules during the comment period.

WHAT IS A “GUIDANCE”?

Guidance documents assist the public in their compliance with rules coming out of agencies. These specifically refer to the agency's thinking on a specific topic or policy that helps guide how they enforce said regulations.
REGULATORY GLOSSARY

**CFR Citation** – This citation refers to a specific section of the CFR. It is usually used in the context of what is being modified or changed by a rule. Ex. 27 CFR 478

**Code of Federal Regulations (CFR)** – The CFR is the codification of the general and permanent rules published in the Federal Register by the departments and agencies of the Federal government. Each volume is updated once every calendar year and titles are issued in chunks on a quarterly basis.

**Comments** – When someone says "comments" or "comment period" they are referring to the part of the rulemaking process when all people and organizations can submit their opinions or research on a specific rule.

**Completed Actions** – Actions or reviews the agency has completed or withdrawn since publishing its last agenda. This would also include anything the agency began and completed between issues of the Unified Agenda.

**Economically Significant** – For a rule to be deemed economically significant, the rule will have an annual impact on the economy of $100 million or more, or will have any material adverse effect on the "economy, productivity, competition, jobs, the environment, public health, or State/local/tribal governments".

**EO 12866** – "Regulatory Planning and Review", requires covered agencies to prepare an agenda of all regulations under development or review.

**EO 13771** – "Reducing Regulation and Controlling Regulatory Costs", requires each agency to identify for the elimination of two prior regulations for every one new regulation issued.

**Federal Register (FR)** – The FR is the daily journal of the Federal government and it contains Federal agency regulations, proposed rules and notices of interest to the public, executive orders, proclamations, and other Presidential documents.

**FR Citation** – This citation is used when referring to either a specific document from the Federal Register or for a rule in its totality (rules are collections of documents). Ex. 83 FR 9239

**Interim Final Rule** – This is a rule published first as a final rule with the opportunity to comment at the time the rule is made public. These often occur when a statute (a passed law) requires an agency to act within a specified time shortly after the law is passed.

**Long Term Actions** – Items under development but for which the agency does not expect to have a regulatory action within 12 months after publication of the current edition of the Unified Agenda.

**Notice** – Notices are documents published in the Federal Register that describe proposed rulemaking, updates, settlements, meetings, workshops, and many other important agency activities.
OMB/OIRA – The Office of Information and Regulatory Affairs (OIRA) is an office within the Office of Management and Budget (OMB). Its primary responsibilities include reviewing drafts of proposed and final rules, ensuring the rules reflect the priorities of the president, reviewing rules it deems significant and examining the costs and benefits of rules. Not all agencies are required to submit their proposed rules through OIRA.

Prerule Stage – Actions agencies undertake to determine how or whether to initiate rulemaking. This occurs ahead of a Notice of Proposed Rulemaking and may include Advance Notices of Proposed Rulemaking and reviews of existing regulations.

RIN – A RIN or Regulation Identified Number is assigned to identify each regulatory action listed in the Unified Agenda. They are included in the headings of Rule and Proposed Rule documents and can be used to track the publication history of a regulatory action.

Unified Agenda – The semiannual publication of all the regulatory actions federal agencies are considering. It is sectioned by the Cabinet-level department and independent agency. Agencies can then further divide into sub-agencies and place their actions into one of five stages: pre-rule, proposed rule, final rule, completed action, or long-term action.

U.S. Code (U.S.C.) – The United States Code is a consolidation and codification of all general and permanent laws of the U.S. The U.S.C. is divided into 50 titles, each covering a broad area of Federal law.