INTRODUCTION

Rulemaking is the policymaking process for Executive and Independent agencies of the Federal government. Government agencies write rules (e.g. regulations) to implement laws set forth by the U.S. Congress. Rules provide direction for all kinds of government activities such as defense, budgeting, program administration, and human capital management. Rules also provide protections for pollution control, workplace safeguards, veterans’ benefits, and food safety, to name a few.

Rulemaking is governed by the Administrative Procedure Act (APA) (5 U.S.C. Chapter 5). There are numerous other statutes, executive orders, or agency policies that may describe additional requirements. Once an agency decides that a regulatory action is necessary or appropriate, it develops and typically publishes a proposed rule in the Federal Register (FR). Next, agencies solicit public comments on the proposal. After the agency considers public feedback, conducts further research, and makes changes where appropriate, it then publishes a final rule in the Federal Register with a specific date on which the rule becomes enforceable. In issuing a final rule, the agency must describe and respond to the public comments it receives.

PRERULE STAGE

Origins of a rule
Statutes prompt agency rules. For example, Congress could delegate to an agency the authority to set minimum safety standards or mandate a baseline of technology standards. Other events can prompt a regulatory assessment. New scientific data, new technologies, accidents, lawsuits, public petitions, as well as agency priorities represent some reasons why an agency may decide to initiate the rulemaking process. Also, agencies use risk assessments to determine the likelihood of a problem to occur (e.g., industry accidents) or causing harm (e.g., workplace injuries).

Alternative regulatory actions
Agencies evaluate possible alternative regulatory solutions. For example, agencies evaluate whether the problem might be fixed without a compliance-based rule through alternative policy tools such as market incentives (e.g. consumer reactions), public-private partnerships (e.g. National Environmental Performance Track) or information disclosure (e.g., Toxics Release Inventory). Whenever possible, agencies try to use performance standards rather than design standards. These standards can be less burdensome, and still meet agency goals for effective safeguards.

Analysis
In addition, agencies use economic analyses (sometimes referred to as cost-benefit analyses, regulatory impact analyses, or regulatory evaluations) to help determine the best alternative and whether the benefits of the rule would justify its costs.
PROPOSED RULE STAGE

Notice of Proposed Rulemaking
After an agency researches the issues and determines the necessity of a new rule, it proposes a regulation, also known as a Notice of Proposed Rulemaking (NPRM). The proposal is listed in the Federal Register (FR) so that members of the public can consider it and submit comments. The proposed rule and supporting documents are also filed in official agency dockets on Regulations.gov. The docket is the file folder of the rulemaking documents, including studies not readily available to the public, as well as all public comments.

Contents of NPRM
The NPRM includes such information as the preamble, deadline for comments, how and where to file comments, and people to contact for information about the proposal. The preamble explains the need and the authority for the proposed rule, including a discussion of any statutory constraints. It explains any rule text and issues involved. Also, the preamble will often contain summaries of investigations or analyses. This includes how an agency chose its proposed solution. The agency may include specific questions or requests for data from the public.

Public comment period
Generally, agencies will allow 60 days for public comment. Sometimes they provide much longer periods. Agencies may receive anywhere from no comments to tens or hundreds of thousands of comments or more. They can be brief one-line or one-paragraph comments, or they may contain thousands of pages with detailed analysis.

Logical outgrowth test
The law recognizes that changes may be made to the proposed rule based on the public comments received. However, the courts have required any changes made in the final rule be of a type that could have been reasonably anticipated by the public – a logical outgrowth of the proposal. If the “logical outgrowth test” is not met, agencies must provide a second notice with an opportunity for public comment on the changes.

FINAL RULE STAGE

Post-comment period
After the comment period closes the agency reviews them and conducts a comment analysis. Next, agencies decide whether to proceed with the rulemaking process and issue a new or modified proposal. Sometimes they withdraw the proposal. Before reaching a final decision, agencies will make any appropriate revisions to the various supporting analyses prepared for the Notice of Proposed Rulemaking (NPRM).
**Preparing a final rule**
Any final rule must include preamble and rule text. The preamble includes a response to the significant and relevant issues raised in public comments as well as a statement providing the basis and the purpose of the rule. Typically, agencies respond to all public comments at one time by categories or themes in the preamble of the final rule, including a withdrawn proposal.

**Published final rule**
The final rule is published in the *Federal Register (FR)*. In addition, a copy is placed in the rulemaking docket along with the final version of any supporting documents. The Office of the Federal Register, on a rolling, annual basis, updates the *Code of Federal Regulations (CFR)* to reflect the additions, changes, or rescissions made by the rule text. The CFR contains all Federal agency rules currently in effect as of the date of its publication.