

# Federal Rulemaking Process

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# Federal Rulemaking Process

- What is the Federal Rulemaking Process?
- Why Is Rulemaking Necessary?
- History of Federal Rulemaking
- Steps in the Process
- Summary



# What is the Federal Rulemaking Process?

- Federal regulation is a basic tool of government to implement public policy
- Generally, starts with an act of Congress
- The terms “rule” or “regulation” often used interchangeably
- During the past 70 plus years, Congress and various Presidents have developed an elaborate set of procedures and requirements to guide the federal rulemaking process.

# Why is Rulemaking Necessary?

- In the 1930s, Congress made federal agencies responsible for issuing detailed regulations
- Previously no central regulatory publication system existed
- No efficient way for citizens to know about regulations that affected them
- By law, anyone can participate in the rulemaking process by commenting in writing on rules FDA proposes

# History of Federal Rulemaking

- **Federal Register Act – 1935**

- Established a uniform system for handling agency regulations by requiring:
  1. the filing of documents with the Office of the Federal Register,
  2. the placement of documents on public inspection,
  3. publication of the documents in the Federal Register, and
  4. (after a 1937 amendment) permanent codification of rules in the Code of Federal Regulations

- **Administrative Procedure Act -1946**

- The APA was written to bring regularity and predictability to agency decision making

# History of Federal Rulemaking

- **National Environmental Policy Act -1969**
  - Requires environmental impact statement of proposed rules
- **Paperwork Reduction Act - 1980**
  - Agencies Must Justify:
    - the need and intended use of the information,
    - estimating the burden that the collection will impose on respondents,
    - showing that the collection is the least burdensome way to gather the information.
- **Regulatory Flexibility Act -1980**
  - Federal agencies must assess the impact proposed regulations on “small entities”

# History of Federal Rulemaking

- **Small Business Regulatory Enforcement Fairness Act - 1996**
  - Permit judicial review and to permit small entities to participate in EPA and OSHA rulemaking before a proposed rule with a significant impact on small entities is published
- **Congressional Review Act – 1996**
  - Agencies must file final rules with each house of Congress and GAO
  - Submit cost-benefit analysis to GAO and each house of Congress
- **Unfunded Mandates Reform Act – 1995**
  - Established new procedures that Congress fully considers the potential effects of unfunded federal mandates before imposing them in legislation
  - Call for the Congressional Budget Office to provide statements to authorizing committees about bills containing mandates and, if so, the cost of those mandates

# History of Federal Rulemaking

- **Information Quality Act – 2001**

Amended the Paperwork Reduction Act to:

- OMB issue government-wide guidelines that to ensure and maximize quality and objectivity of information disseminated by Federal agencies.
- Instruct agencies to establish administrative mechanisms allowing affected persons to seek and obtain correction of information maintained and disseminated by the agency.
- Required agencies to report periodically to the Director of OMB on the number and nature of complaints received and how such complaints were handled by the agency.

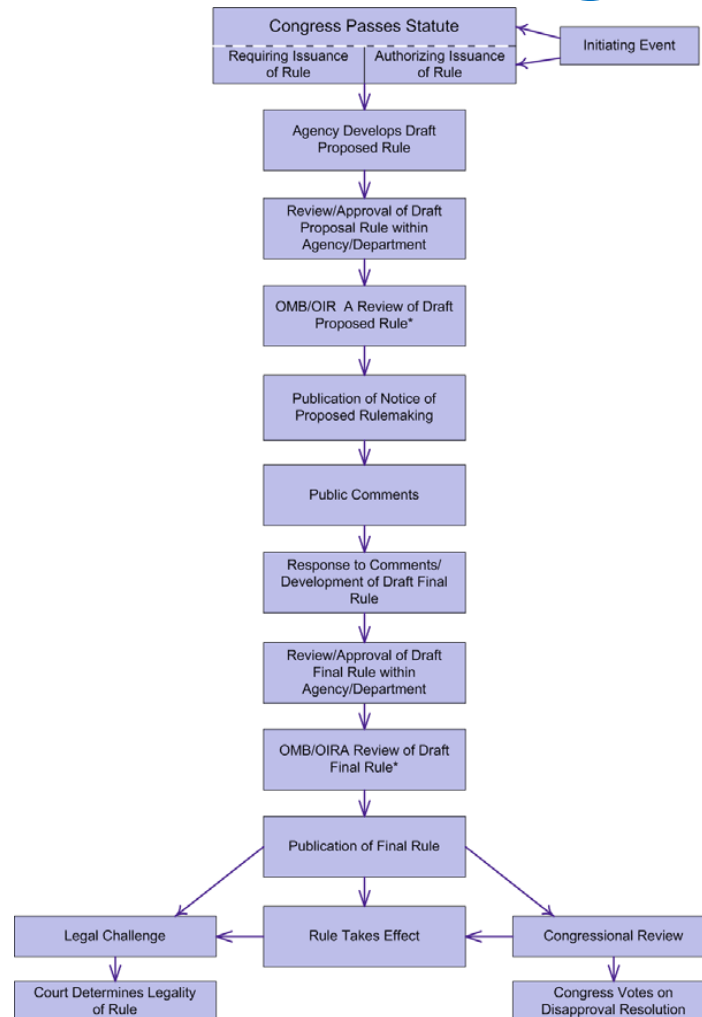


# History of Federal Rulemaking

- There have been many rulemaking laws passed by Congress in the last 70 years
- Agencies must follow these laws and any associated guidance when developing regulations



# Federal Rulemaking Process



**Source:** CRS.

\* The Office of Management and Budget's (OMB) office of Information and Regulatory Affairs (OIRA) reviews only significant rules, and does not review any rules submitted by independent regulatory agencies.

# Federal Rulemaking Process

## 1.) Congress Passes a Statute that Requires a Rule or Authorizes the Issuance of a Rule

- Example:
  - Section 204 Enhancing Tracking and Tracing of Food and Recordkeeping (Food Traceability Rule) of the Food Safety Modernization Act of 2011.<sup>1</sup>
  - <sup>1</sup> <https://www.fda.gov/food/food-safety-modernization-act-fsma/full-text-food-safety-modernization-act-fsma>

# Federal Rulemaking Process

2.) Agency Develops a Proposed Rule

3.) Review and Approval of Draft Proposed Rule within Agency and Department

## Federal Rulemaking Process

4.) Office of Management and Budget (OMB) and  
Office of Information and Regulatory Affairs (OIRA)  
Review of Draft Proposed Rule

- This review assures all the Acts and guidance have been followed in the process

# Federal Rulemaking Process

## 5.) Publication of Notice of Proposed Rulemaking

- Published the day the comment period begins
- Federal Register published every weekday
  - [regulations.gov](https://www.regulations.gov)
- Describes planned regulation and provides background
- Announces comment period

# Federal Rulemaking Process

- 6.) Public Comments

- Example:

- Three Public Meetings Held after Issuance of Proposed Food Traceability Rule<sup>2</sup>

- November 06, 2020
    - November 18, 2020
    - December 02, 2020

- Extension of initial public comment period

- “Requirements for Additional Traceability Records for Certain Foods” (Food Traceability Proposed Rule) published on September 23, 2020
    - 120 - day initial comment period
    - Extended by request to February 22, 2021

<sup>2</sup> <https://www.fda.gov/food/workshops-meetings-webinars-food-and-dietary-supplements/public-meetings-discuss-fsma-proposed-rule-requirements-additional-traceability-records-certain>

# Federal Rulemaking Process

- **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.
  - Final rule not based on the number of comments in support of the rule versus those that oppose it.
  - Agencies must base their 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.
  - Agencies must conclude that its proposed solution will help accomplish the goals or solve the problems identified.
  - Agencies must consider whether alternate solutions would be more effective or cost less.



# Federal Rulemaking Process

## 7.) Response to Comments and Development of Final Rule

- All comments to the proposed rule must be considered regardless of the source

## 8.) Review and Approval of draft Final Rule within Agency and Department

## Federal Rulemaking Process

### 9.) Office of Management and Budget (OMB) and Office of Information and Regulatory Affairs (OIRA) Review of Draft Proposed Final Rule

- Assures all the Acts and guidance have been followed in the process

# Federal Rulemaking Process

## 10.) Publication of Final Rule

- Preamble includes summary, effective date, and supplementary information

## 11.) Rule Takes Effect

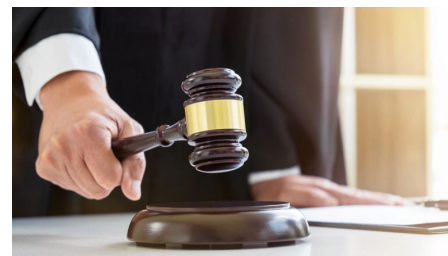


**FEDERAL REGISTER**  
The Daily Journal of the United States Government

# Federal Rulemaking Process

## 12.) Legal Challenge – When do Courts Get Involved in Rulemaking?

- Example:
  - FDA Sued in October 2018 to compel the agency to implement the traceability provisions in the FDA Food Safety Modernization Act (FSMA).
  - Consent order by district court June 2019.
  - FDA committed to:
    - designate the list of high-risk foods and issue a proposed rule that would establish recordkeeping requirements for these foods by September 8, 2020,
    - issue the final rule by November 7, 2022.



# Summary

- During the past 70 years, Congress and various Presidents have made numerous attempts to add structure, economy, efficiency, accountability, and greater public access and transparency to the regulatory process.
- Congress has enacted laws that require procedure, review, and/or analysis of draft rules by the rulemaking agencies or by outside parties.
- FDA is required to follow the laws and guidance for rulemaking

