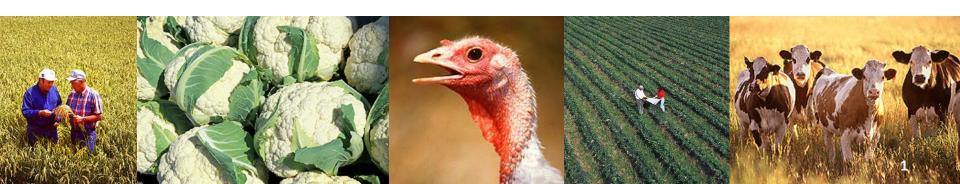


Rulemaking

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Purpose



- Responds to feedback that stakeholders need a clearer understanding of the rulemaking process.
- Explains what it takes to turn NOSB recommendation into a final change to the regulations.
- Describes when and how public can engage in this process along the way.

Legal Authority for Rules



- Statutes passed by Congress, signed into law by President, provide the authority for federal agencies to write regulations that implement the laws.
- An agency may issue rules only within scope of its authorizing statute.
- Must be issued in accordance with Administrative Procedure Act.

The Simplified Rulemaking Process



 Publish Proposed Rule in the Federal Register.

 Provide interested parties an opportunity to submit written data, views, or opinions about the proposed rule.

Publish a Final Rule in the Federal Register.

How does NOP initiate a rulemaking?



- We are required to prepare, submit and receive approval on a regulatory workplan for every stage of rulemaking.
 - Summarizes objectives, possible alternatives, and effects of action to policy officials (non-technical)
 - Provides information needed for "designation" of significance
 - Communicates to OMB and public about agencies regulatory plan

Office of Management & Budget

- USDA ORGANIC
- Office of Information and Regulatory Affairs (OIRA)
 - Operates as an "information aggregator" across government
 - Facilitates interagency coordination & communication
 - Considers costs and benefits of regulations
 - Ensures public engagement in process
 - Ensures compliance with relevant statutes

How does OMB determine which regulations to review?



OMB "designates" every planned regulatory action through a workplan:

- Not significant: OMB does not review rule*;
- Significant or EconomicallySignificant: OMB reviews the rule.

Significance



OMB reviews rules that are:

- Likely to have an annual effect on the economy of over \$100 million or more, or adversely affect the economy, a sector of the economy, jobs, or competition;
- Creates serious inconsistency or interferes with an action of another agency;
- Materially alter the budgetary impact of existing programs; or
- Raises novel legal or policy issues.

*Rules that have an effect of \$100M or more on the economy are Economically Significant rules, often considered "major" and triggers Congressional Review Act.

How do stakeholders know what rules agencies are working on?



- Once OMB approves a workplan, this information is published:
 - In the fall in a "Regulatory Plan"; and
 - Every spring and fall an "Agenda of Regulatory and Deregulatory Actions".
- This "Unified Agenda" is how agencies announce future rulemaking activities update the public on pending and completed regulatory actions.

Executive Orders & Other Requirements



- EO 12866 & 13563 Regulatory Impact Analysis
 - Costs, benefits, alternatives
- Regulatory Flexibility Act
- Paperwork Reduction Act
- EO 13175 Consultation with Tribal Governments
- Civil Rights Impact Analysis
- EO 12988 Civil Justice Reform

Great! Whew. We finished a draft. How do we clear rules for publication?



Not Significant Action

Office of General Counsel

Deputy Administrator

Administrator

Undersecretary

Secretary

Significant Action

Office of General Counsel

Deputy Administrator

Administrator

Office of Budget and Program Analysis

Office of Risk Assessment and Cost Benefit Analysis

Assistant Secretary, Civil Rights

Office of Chief Economist

Office of Chief of Information

Office of Tribal Relations

Undersecretary

Secretary

OMB – includes interagency review.

90-day review; can be extended.

(Congressional Review Act)

Why does rulemaking take so long?

USDA ORGANIC

- Review of NOSB recommendation
- Draft Regulatory Workplan for OMB Designation
- Conduct and Draft Required Analyses
- Draft Proposed Rule
- Clearance & Federal Register Publication
- Comment Period
- Comment Analysis
- Workplan Addendum for OMB Designation
- Revise Required Analyses
- Draft Final Rule
- Clearance & Federal Register Publication
- Effective Date of Final Rule

Proposed Rule Stage

Final Rule Stage

How can public comments affect the final rule?



- The notice-and-comment process enables anyone to submit a comment on any part of a 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.

How can public comments affect the final rule?



- 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.
- If the rulemaking record contains persuasive new data or sound policy arguments, 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.

How are rules incorporated into the regulations?



- The Code of Federal Regulations (CFR) contains all of the generally applicable rules of the Federal government with current or future effect.
- On the day a final rule is published in the Federal Register, Federal Register staff process the material for codification into the CFR.
 - Rules that are immediately effective are integrated into the "Electronic Code of Federal Regulations" (e-CFR) database (ecfr.gpoaccess.gov).
 - Rules with delayed effective dates are placed in amendment files and linked from the main e-CFR database.

Why is the whole process important!



- Courts can find a rule unlawful if:
 - It is arbitrary, capricious, an abuse of discretion, or not in accordance with the law;
 - It is in excess of the agency's statutory authority; and/or
 - The agency did not follow the proper procedure in promulgating the rule.

Resources



- A Guide to the Rulemaking Process
 - Office of Federal Register
- The Office of Information and Regulatory Affairs: Myths and Realities
 - Commentary By Cass R. Sunstein
- The Regulatory Plan and Unified Agenda
 - Office of Management & Budget