



Rulemaking 101 – Process and Judicial Review

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What is Rulemaking?

The agency process for formulating, amending, or repealing a rule





Governing Law

- ▶ Administrative Procedure Act (APA) 1946
 - 5 U.S.C. Chs. 5 and 7

- ▶ Substantive statutes
 - Govern if specify procedure
 - E.g., OSH Act, TSCA, CAA, FTCA

- ▶ Other procedural statutes, such as:
 - Regulatory Flexibility Act (RFA)
 - Paperwork Reduction Act (PRA)
 - Federal Advisory Committee Act (FACA)
 - Congressional Review Act (CRA)



Executive Branch Oversight

E.g.:

- ▶ EO 12866, Regulatory Planning & Review
- ▶ EO 13563, Improving Regulation and Regulatory Review
- ▶ EO 13132, Federalism



Practice Tips

- ▶ It's all about FAIRNESS!
 - Limiting executive power and preventing “secret law”
 - Due process: notice & opportunity to be heard
- ▶ What laws govern the rulemaking at issue?



APA Publication Provisions

5 USC §552(a)

- *Federal Register* publication required for --
 - Agency organization statement, procedures, other information
 - Substantive and procedural rules
 - Statements of general policy
 - Interpretations of general applicability
 - Amendment, revision, or repeal of the foregoing
- Public not bound if agency fails to publish
 - Exception: actual and timely notice



APA Publication Provisions

5 USC §552(a)

- Available for public inspection and copying:
 - Final opinions and orders from adjudications
 - Statements of policy and interpretations not published in the Federal Register
 - Administrative staff manuals and instructions to staff that affect a member of the public
 - Index and copies of all FOIA records likely to become the subject of subsequent requests

- FOIA



The Rulemaking Process



Types of Rulemaking

- ▶ Agency statement of future effect, designed to implement, interpret, or prescribe law or policy.
- ▶ Informal Rulemaking (5 U.S.C. § 553)
 - Notice & comment (N&C) rulemaking
- ▶ Formal Rulemaking (5 U.S.C. § 556 & 557)
 - Adjudicatory hearing
 - Appropriate for agency fact finding
 - Rarely used unless required by another statute
- ▶ Hybrid Rulemaking
 - Combination of both
 - Required by some statutes (e.g., OSH Act)



Informal Rulemaking – Overview

- ▶ Notice of proposed rulemaking (NPRM) in Federal Register (FR)
- ▶ Public comment
- ▶ Final rule published in FR
- ▶ Imposition of additional procedures --
 - By statute? – OK
 - By Executive Order, rule or agency practice? – OK
 - By courts? – *Not* OK (*Vermont Yankee*)



ANPRM

(Advance Notice of Proposed Rulemaking)

- ▶ Not mentioned in APA
- ▶ Agency may request comments prior to NPRM
- ▶ Good way to float novel ideas, narrow or redirect proposal
- ▶ Agencies may also solicit ideas or gather information through less formal means



Notice and Comment Process

5 U.S.C. § 553

- ▶ NPRM must include:
 - Legal authority for the rule
 - Either terms or substance of proposed rule or a description of subjects and issues involved
- ▶ Agency must provide opportunity for public comment
- ▶ Agency must consider relevant comments



NPRM

- ▶ Usually preamble and regulation text.
 - Interested parties must be fairly apprised of the proposal
 - Meaningful notice and reasonable specificity
- ▶ May propose several alternatives
- ▶ Solicits comments on issues raised



Exceptions to Notice & Comment

- ▶ Military or foreign affairs exempt from 553
- ▶ Agency management or personnel matters, public property, loans, grants, benefits, or contracts
- ▶ Good cause to skip prior public comment
- ▶ Interpretive rules, general statements of policy (i.e., guidance), or procedural rules



Good Cause Exception

- ▶ Agency finds good cause to skip prior notice and comment (N&C) procedure
 - Impracticable, unnecessary, or contrary to the public interest
 - Narrowly construed
- ▶ Agency must publish good cause statement in the preamble to the final rule.

Types of Rules

Legislative
(substantive)
rules



Subject to APA N&C
procedures

Interpretive rules
Statements of policy
Procedural rules



Subject to publication
requirement, but
not N&C



Legislative Rules

- ▶ New law: Creates new rights or duties
- ▶ Modify or add to the legal norm
- ▶ Force and effect of law
- ▶ Binding on all



Interpretive Rules

- ▶ Advise public of agency's interpretation of its statutes or regs
- ▶ Do not independently have force and effect of law
 - Legal force is derived from the law or reg being interpreted
 - Do not create new law
 - Not independently enforceable



Legislative vs. Interpretive

- ▶ Legislative:
 - Can create new duties or rights

- ▶ Interpretive:
 - Reminds or advises public of existing duties
 - May clarify prior legislative rule, but cannot enact substantive change



Legislative vs. Interpretive

Example:

- Saying what CAA § 112 “average emission limitation achieved by the best performing 12% of existing sources” standard *means* (interpretive)

Vs.

- *Setting emission standards* under same (legislative)



Statements of Policy

- ▶ Advise public prospectively of the manner in which agency will exercise a discretionary power (e.g., enforcement)
- ▶ Not legally binding (i.e., guidance)



Legislative Rule vs. Statement of Policy

- ▶ Does the guidance create additional requirements or establish a binding norm? (legislative)
- ▶ Does the agency retain discretion to apply the guideline or not? (statement of policy)
 - Agency practice matters



Procedural Rules

- ▶ Relate to agency's organization, procedures, or practices
- ▶ Do not alter rights or interests of outside parties
- ▶ Do not encode “substantial value judgment”
- ▶ Examples: elimination of expedited approval process; rejection of incomplete application; agency rulemaking procedures



Practice Tips

- ▶ Look to DC Circuit cases
- ▶ Some language too vague to be interpreted without N&C procedure
 - “in the public interest”
 - “just and reasonable”
 - “fair and equitable”
 - “as the Secretary deems appropriate”



The Comment Period

- ▶ APA requires opportunity to submit “written data, views or arguments”
- ▶ No required minimum comment period under APA
 - E.O. 12866 says should be not less than 60 days “in most cases”
 - Reality: often 30 days
 - 15 day FR Act minimum for public meetings cited in AG Manual as “a general statutory standard of reasonable notice.”
- ▶ FR notice specifies deadline for comments



Practice Tip

- ▶ Counsel agency to consider a longer comment period, if possible, for complex rules.
 - Interested parties may need more time to digest and analyze a complex proposal
 - Agency decision-making and rationale may benefit from more thoughtful comments



Oral Communications

- ▶ APA does not address permissibility of meetings and other informal contacts before, during or after comment period
- ▶ “Ex parte” communications not prohibited in notice and comment rulemaking. See *Sierra Club v. Costle*, 657 F.2d 298 (DC Cir 1981)
- ▶ Agencies usually have policies regarding such communications growing out of concerns about appearances of impropriety



Practice Tip

- ▶ Counsel agency to maintain record of post-comment period contacts
 - Meeting agendas, summaries
 - Copies of post-comment materials and letters
- ▶ Counsel agency to meet with more than one side



Practice Tip: Drafting Effective Comments

- ▶ Explain issue clearly and thoroughly
- ▶ Suggest reg text language
- ▶ Use descriptive captions
- ▶ Praise what agency got right
- ▶ Provide independent scientific, legal, and economic impact analyses
- ▶ Offer specific alternatives consistent with rule's purpose and statutory objectives



Effective Comments

- ▶ Alternatives: Ask for something the agency can actually do
 - Logical Outgrowth/Scope of the Notice
 - Would not require statutory change or changes to regs not within scope of NPRM
 - Suggest standards that are enforceable
 - Spell out solution that works for your client AND addresses agency's concerns
- ▶ Give agency basis for final rule conclusions
- ▶ Someone must raise issue in comments or it can't be raised on review



Effective Comments

Not a vote!

One well argued and documented comment may serve as the basis for a rulemaking even if thousands of others say they do not want a rule but provide no rationale for their opposition



The Final Rule: Contents

- ▶ Concise general statement of basis and purpose (APA)
- ▶ Discussion of changes from the NPRM, why
- ▶ Responses to significant issues
- ▶ Reg text to appear in CFR
- ▶ Regulatory Impact Statement



The Final Rule: Effective Date

- ▶ APA: at least 30 days from publication
- ▶ Exception (shorter):
 - Substantive rule granting exemption, relieving restriction
 - Interpretive rule
 - Good cause found by agency and articulated in preamble to final rule
- ▶ Changing effective date is substantive and requires N&C
- ▶ Congressional Review Act can delay eff. date



Direct Final Rule

- ▶ Invented by EPA for noncontroversial rules, now used by many agencies
- ▶ A final rule, effective in X days, UNLESS adverse comments are received w/in that time. NPRM usually published simultaneously.
- ▶ If adverse comments are received, DFR is rescinded, agency considers comments and moves toward final rule



Interim [Final] Rule

- ▶ Commonly used if NPRM skipped for good cause
- ▶ Usually seeks additional, post-promulgation comments
- ▶ Typically effective upon publication
- ▶ Reviewable just like any other final rule
- ▶ Can serve as basis of subsequent final rule if original good cause claim was valid



Technical Correction Rule

- ▶ New final rule fixing error(s) in previous final rule
- ▶ No inherent agency power to correct errors; need to satisfy “good cause” exception if no NPRM



The “Logical Outgrowth” Doctrine

- ▶ Governs how much the agency can change its mind from NPRM to final rule
- ▶ Basic rule: no APA violation if final rule is within the scope, and a “logical outgrowth,” of NPRM
 - Final rule can be substantially different from the NPRM as long as agency “fairly apprised” the public of the possibility of changes of the type that occurred
 - Notice is inadequate if interested parties could not reasonably have anticipated the final rule from the NPRM



Application of Logical Outgrowth

- ▶ Note: Courts evaluate whether final rule is “logical outgrowth” of the proposed rule, NOT of the comments
 - Comments suggesting a different approach for the final rule or criticizing potential alternatives is *indicative* but not *dispositive* that public could predict that approach would be in the final rule



Application of Logical Outgrowth

- ▶ Agencies nearly always describe and solicit comment on potential alternatives in preamble to NPRM in order to select alternative at final rule stage
 - Whether public “adequately apprised” of such alternatives often turns on specificity of description
 - Ex: if Agency proposes Option “A” or “B”, may not pick “A” and “B” without explicit statement in proposal
- ▶ If Agency wants to select new alternative for which notice not adequate in NPRM, may issue supplemental notice or “NODA”



The “Administrative Record”— What Is It?

- ▶ ALL & ONLY information the agency relied upon to develop the rule
- ▶ ALL & ONLY information the court can rely on in judicial review
- ▶ Agency mostly gets to decide what will be included in the record except for public comments and supporting materials



Administrative Record – What’s In It?

- ▶ NPRM and Final Rule
- ▶ Agency’s Own Research (e.g., Background Information Documents)
- ▶ Other Information, Data, Research, and Supporting Documentation
- ▶ All Public Comments and Supporting Materials
- ▶ Transcripts/Notes of Public Hearings or Public Meetings
- ▶ Notes of Other Meetings with Outside Parties
- ▶ “Response to Comments” Document (Typically)



Use of Scientific Data and Other Information

- ▶ NPRM should describe any data (and any methodology to obtain the data), studies, or assumptions supporting the agency's proposal
 - Agency must also make such internal data or studies, along with rest of contents of Administrative Record, publicly available.
- ▶ Failure to make information available before end of public comment period = inadequate notice.
 - But Agency can add “supplemental” studies or data to the Administrative Record that provided additional support for proposal



NODA

- ▶ Notice of Data Availability
- ▶ How agencies get comment on new information that becomes available after a comment period closes
- ▶ Not second bite at other issues
- ▶ Can be used for industry-supplied data.



Practice Tip

- ▶ Useful for private counsel to review record
 - See what other commenters are saying (rebut? hints as to direction of final rule)
 - May not support agency (useful in commenting or judicial review)
 - “Legislative history” for compliance counseling
- ▶ Sometimes record documents not available by beginning of comment period -- seek extension
- ▶ All agency dockets on Web – www.regulations.gov



Practice Tip

- ▶ Instruct agency to print and maintain copies of any information for which it provides an internet citation in the preamble.
 - Websites frequently change
 - Printed copies ensure complete rulemaking record and record the date of a website that might change



Practice Tip

- ▶ Encourage agency to articulate guiding principles for the regulation
 - Helps agency see forest through the trees, rescues those in the weeds
 - Principles should be consistent with statutory authority
 - Policy choices and responses to comments should be consistent with guiding principles
 - Preamble provides courts and regulated entities guidance and interpretation of reg's meaning and agency intent



Practice Tip

- ▶ Read impact statement carefully
 - Ensure that it accurately characterizes the rule
 - Discrepancies can fuel litigation



Petition for Rulemaking

- ▶ Request for the issuance, amendment, or repeal of a rule
- ▶ Agency decision not to initiate rulemaking is given high level of deference



Judicial Review



Overview

- ▶ What law governs?
- ▶ What court?
- ▶ When to file?
- ▶ Sue or intervene?
- ▶ Stay pending complete review?
- ▶ Hurdles to overcome
- ▶ Standard of review
- ▶ What if you win?



What Law Governs?

- ▶ Many regulatory statutes have judicial review provisions. These control where they exist.
- ▶ APA § 10 applies otherwise (5 USC §§ 701–706)
- ▶ APA § 10 does not create jurisdiction in pure sense, but creates a right of action that triggers jurisdiction under 28 U.S.C. § 1331



What Law Governs?

APA § 10(e), 5 U.S.C. § 706

- Court shall compel agency action unlawfully withheld or unreasonably delayed; and
- Hold unlawful and set aside agency action, findings, and conclusions found to be –
 - Arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law;
 - Contrary to constitutional right, power, privilege, or immunity;
 - In excess of statutory jurisdiction, authority, or limitations, or short of statutory right;
 - Without observance of procedure required by law



What Law Governs?

- ▶ APA creates presumption of judicial review for final agency action not otherwise reviewable. Exceptions:
 - Review specifically precluded by statute, *e.g.*, Medicare contains more than 25 provisions precluding judicial review of rules
 - “[C]ommitted to agency discretion by law” (5 U.S.C. § 701(a)(2); *see Heckler v. Chaney*, 470 U.S. 821 (1985))
- ▶ “Finality” discussed below



What Law Governs?

- ▶ Exhaustion of administrative remedies required?
 - Some statutes specify procedure to be followed before lawsuits can be filed challenging a rule. *See e.g., Shalala v. Illinois Council On Long Term Care, Inc.*, 529 U.S. 1 (2000).
 - E.g., CAA § 307(d)(7)(B) requires challengers to first file a petition for reconsideration if the grounds for challenge arose after the comment period closed or it was impracticable to raise the issue then

What Court?

- ▶ APA says “a court of competent jurisdiction,” which usually means federal district court; which one depends on venue law (*see* 28 U.S.C. § 1391)
- ▶ Hobbs Act vests original jurisdiction in Courts of Appeals for certain challenges to certain agency actions (*see* 28 U.S.C. § 2342)
- ▶ Many environmental statutes specify venue for particular issues.
 - D.C. Circuit often specified for nationally applicable rules (e.g., RCRA, CERCLA, CAA)
 - Relevant circuit for CAA regional rules
 - CWA: circuit in which person resides or transacts business; may have a choice



When to File?

- ▶ APA sets no deadline. General SOL for claims against US is 6 years (28 USC § 2401(a)).
- ▶ Statutory review provisions typically establish jurisdictional filing *windows*
 - Set # of days after “promulgation”
 - Note, however, that rule is deemed published for *State Farm* purposes when on public display at OFR.
 - Exception to some “window” statutes: “Grounds arising after”



Sue or Intervene?

- ▶ Can file own complaint (district court) or petition (circuit court)
- ▶ Or intervene in someone else's case
 - Must have an interest in the case that could be adversely affected by a decision, and
 - None of the existing parties to the case will adequately represent your interest, and
 - Must be timely
 - Although there is no analog to Fed. R. Civ. P. 24 in F.R.A.P., appeals courts rely on same criteria

Sue, Intervene, or File Amicus Brief?

- ▶ Can intervene in attack on agency rule
 - Adverse impact of rule
 - But can have standing problems (more later)
 - Fear bad precedent (difficult to sustain)
- ▶ Much more difficult to intervene in support of agency rulemaking
 - Can still have standing problems depending on Circuit
 - Doubtful if “rule” constitutes “property” or “transaction” for Rule 24(a) purposes
- ▶ Problems:
 - Intervenors typically excluded from settlement negotiations
 - But intervenors may be subject to *res judicata*



Interim Relief

- ▶ Agency or court can stay rule pending review under APA § 705 unless authorizing statute precludes
- ▶ Temporary Restraining Order & Preliminary Injunction
- ▶ Challenger has to meet requirements for injunction:
 - Likelihood of success on merits
 - Harm to challenger if stay not granted
 - Harm to others if stay is granted
 - Public interest

Finality

- ▶ “Final” agency action? Usually no question with rules. Note everything an agency does is NOT “agency action.” *See Norton v. So. Utah Wilderness Alliance*, 542 U.S. 55 (2004).
- ▶ Some question with interpretive rules or guidance/policy statements (and recall preambles).
- ▶ *Bennett v. Spear*. Issue is whether document:
 - Marks consummation of decisionmaking process; and
 - Determines rights & obligations; legal consequences flow from it
 - Court uses pragmatic test to determine whether action is binding. *Appalachian Power Co. v. EPA*, 208 F.3d 1015, 1022 (D.C. Cir. 2000)



Ripeness / Enforcement

- ▶ APA allows collateral challenge to rule as defense to enforcement action
- ▶ *Pre*-enforcement review permissible if issue is ripe. Two questions (*Abbott Laboratories v. Gardner*, 387 U.S. 136, 148–156 (1967)):
 - Is the issue “fit for judicial decision”? Purely legal? Sufficiently “crystallized”?
 - What is hardship on challenger if review deferred?



Ripeness / Enforcement

- ▶ Sometimes pre-enforcement review expressly authorized (*e.g.*, judicial review provisions)
- ▶ “Window” provisions also cut it off
 - May preclude collateral challenges as defenses to an enforcement action
 - Typically substantive attacks OK, procedural attacks not
 - When in doubt, file.



Standing

- ▶ Original theory: Constitution Art. III “cases or controversies”; ensure litigants have personal stake, really care about outcome, fight hard and well
- ▶ Requires:
 - Injury-in-fact
 - Causation
 - Redressability
- ▶ Also “zone of interests” test – “prudential” (not Constitutionally based)

Types of Standing

- ▶ Traditional Standing
- ▶ Informational Standing
- ▶ Moribund Taxpayer Standing
- ▶ Moribund Procedural Standing
- ▶ Competitive Standing
- ▶ Representational Standing
- ▶ Associational Standing
- ▶ Environmental Standing
- ▶ Intervenor Standing
- ▶ Constitutional Standing
- ▶ Congressional Standing



Standing

- Injury
 - *Lujan v. Defenders of Wildlife* (general plans to view wildlife abroad not sufficiently concrete)
 - Is increased *risk* of injury injury-in-fact?
 - No -- *Summers v. Earth Island Institute* (only a chance, not a likelihood)
 - Yes -- *Monsanto Co. v. Geertson Seed Farms* (incurred costs to avoid risks)
 - No purely “procedural injury” (*Summers*)
- Zone of interests
 - *HWTC* (RCRA not intended to protect business interests of waste treatment industry)

Standing for Intervenorors

- D.C. Circuit requires intervenors to show standing; Fifth and Eleventh Circuits do not. *But See Diamond v. Charles, supra.*
- Even when supporting the government; government often opposes supporters
 - *E.g., Sherley v. Sebelius* (Stem Cell Case)
- Result: no standing or no interest if only stake is fear of bad precedent
 - *E.g., Purcell v. BankAtlantic Fin. Corp.*, 85 F.3d 1508 (11th Cir. 1996)



Standard of Review

- ▶ Rulemaking procedures: No deference
- ▶ Substance of rule: Deference to agency interpretations and decision-making



Standard of Review

- ▶ Did agency follow proper procedure?
 - E.g., did agency provide notice and take comment?
 - E.g., was final rule a “logical outgrowth” of NPRM?
- ▶ Error has to be prejudicial to challenger



Standard of Review

- ▶ Did agency actually have rulemaking authority under the authorizing statute?



Standard of Review

- Is the rule consistent with the authorizing statute?
- *Chevron* Step 1: Is the statute clear?
 - If so, court applies the statute's clear terms



Standard of Review

- *Chevron* Step 2: If the statute is unclear, is the agency's interpretation reasonable?
 - Theory: defer to agency because Congress charged it with interpreting statute
 - Not “most reasonable” or court's preferred interpretation
 - *Brand X*: Reasonable agency interpretation trumps prior judicial interpretation



Standard of Review

- ▶ Policy statements: Only get *Skidmore* “respect” based on “power to persuade” (*United States v. Mead Corp*)
- ▶ Agency’s interpretation of its own rules: Receives deference (*Seminole Rock/Auer*)



Standard of Review

- ▶ Did the agency violate some *other* statute?
 - National Environmental Policy Act
 - Regulatory Flexibility Act (requires agency to consider impact on small business)
 - Agency's authorizing statute

- ▶ Did the agency violate the Constitution?
 - Courts attempt to avoid deciding constitutional questions



Standard of Review

Arbitrary & Capricious Review

- ▶ Courts are highly deferential to agency decision-making
- ▶ Are fact findings supported by substantial evidence?
- ▶ Did agency articulate a rational connection between facts found and choice made?
- ▶ Did agency respond to significant issues raised in comments?
- ▶ Based upon review of administrative record
 - Not post-hoc rationalization



Standard of Review

Arbitrary & Capricious, con't

- ▶ Did agency:
 - Fail to consider a factor the statute requires?
 - Consider a factor the statute disallows?
 - Depart from prior policies/precedents without explanation?

- ▶ Courts impose same degree of scrutiny to rules changing or rescinding earlier rules
 - *State Farm* (air bags)
 - *FCC v. Fox* (fleeting expletives)



If Challenge Succeeds

- APA 706: “The reviewing court shall . . . hold unlawful and set aside” agency action found to be arbitrary/capricious, in excess of statutory authority, etc.
- “Vacatur” vs. “Remand” –
 - If court vacates rule (or portion of rule), rule is gone.
 - But remains in effect until court issues “mandate.”
 - If court remands rule (or portion), rule stays in effect while agency provides additional justification or revises.



APA Resources

- ▶ A Guide to Federal Agency Rulemaking by Jeffrey S. Lubbers
- ▶ Federal Administrative Procedure Sourcebook
 - Contains APA, AG Manual on APA (1947), Fed. Reg. Act, FACA, RFA, etc.
- ▶ 1941 AG Report on APA
 - <http://www.law.fsu.edu/library/admin/>
- ▶ Federal Register Document Drafting Handbook



Questions?