Rulemaking 101 – Process and Judicial Review

Andrew Emery
Principal
The Regulatory Group, Inc.
Arlington, VA

Jane Luxton
Partner
Pepper Hamilton
Washington, DC

Aditi Prabhu
Attorney-Adviser
Environmental Protection Agency
Washington, DC
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
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
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
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)
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.
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?
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
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

“Finality” discussed below
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
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

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
  - 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 Intervenors

• 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
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
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
- 1941 AG Report on APA
  ◦ http://www.law.fsu.edu/library/admin/
- Federal Register Document Drafting Handbook
Questions?