Day 8: The Regulatory Environment

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Road map

- The regulatory process
- Science and risk analysis
- Cost-benefit analysis

Regulation

Translating law into practice

"... how public administrators balance individual freedom and government control" (Kettl 372).

Three Models

Economic Theory

Regulations driven by needs of business

Political Incentives Theory

See Next Slide

Public Interest Theory

Regulation occurs in response to social movements, to protect public from business

Political Incentives Model (Wilson)

Issues and Interests Define Each Other

	Benefits	
Costs	Diffuse	Concentrated
Diffuse	Gradual expansion	Benefactor mobilizes
Concentrated	Opposition mobilizes	Stalemate; alternative victories

Type: Economic

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- Implications for admins: Need to decide how far to go
- Examples?

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UBER

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Role of Government

A Continuum

- Completely unregulated
- Market forces with some gov't controls
- Gov't controls at state and local level (fragmented)
- Gov't controls at national level, implemented by states and localities
- Total national control (development and implementation)

How do we decide?

Approaches to Regulation

1. Self-regulation
2. "Command and control"
3. Incentives: taxes, effluent charges, etc
4. Common property rights
5. Privatize commons

Again, how do we decide?

Source of Authority

- Constitution (Commerce Clause)
- Congress
- Common Law: private property preeminence; adversarial justice
- "Regulation is grounded in law, but it's shaped by politics" (Kettl 373)

Statutory Mandates

Vague/Broad Language

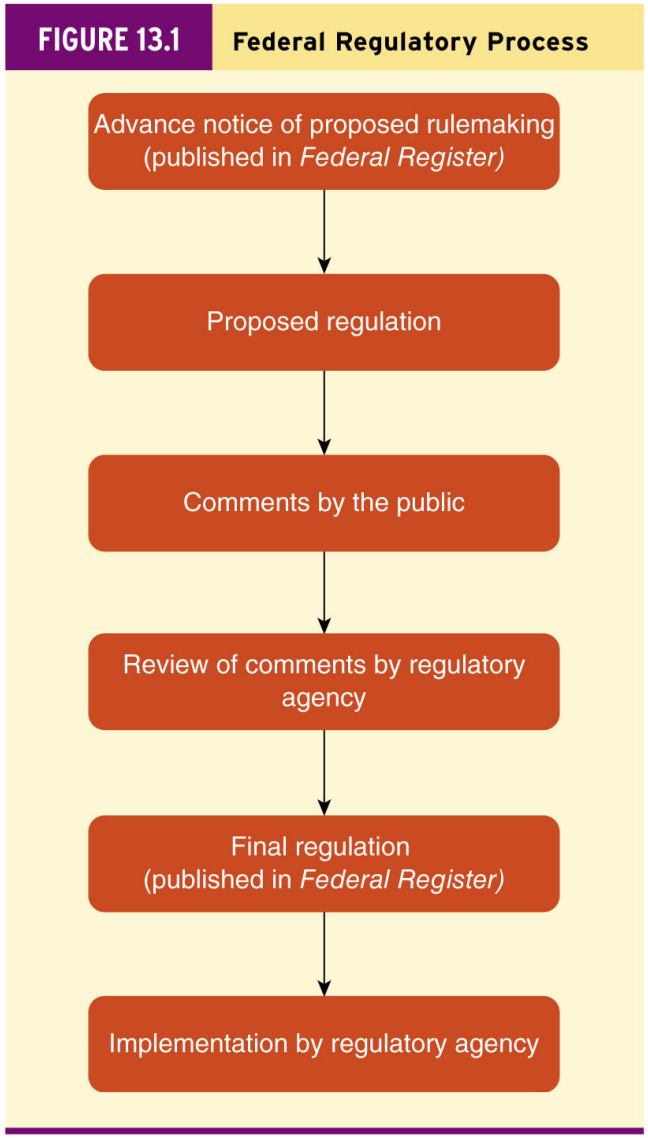
- "just and reasonable rates"
- "eliminate unfair and deceptive practices"
- "reasonably be anticipated to endanger"
- Result?

Be the Regulator

1. *For the purpose of establishing national primary and secondary ambient air quality standards, the Administrator shall within 30 days, publish, and shall from time to time thereafter revise, a list which includes each air pollutant–*
   - A *emissions of which, in his judgment, cause or contribute to air pollution which may reasonably be anticipated to endanger public health or welfare;*
   - B *the presence of which in the ambient air results from numerous or diverse mobile or stationary sources; and*
   - C *for which air quality criteria had not been issued, but for which he plans to issue air quality criteria under this section.*

Clean Air Act (42 U.S.C. §7408)

Process (Simplified)



Process (Real)

The Reg Map

Informal Rulemaking

Step One
Initiating Events

Agency Initiatives
Agency initiatives for rulemaking originate from such things as:
- Agency priorities and plans
- New scientific data
- New technologies
- Accidents

Required Reviews

Statutory Mandates

Recommendations from Other Agencies/External Groups/States/Federal Advisory Committees

Lawsuits

Petitions

OMB Prompt Letters

Step Two
Determination Whether a Rule Is Needed

Administrative Procedure Act Provisions
Under the Administrative Procedure Act provisions that are included as part of the Freedom of Information Act at 5 U.S.C. 552, agencies are required to publish in the *Federal Register*:
- Substantive rules of general applicability
- Interpretive rules
- Statements of general policy
- Rules of procedure
- Information about forms
- Information concerning agency organization and methods of operation

Step Three
Preparation of Proposed Rule

Proposed Rule
A notice of proposed rulemaking proposes to add, change, or delete regulatory text and contains a request for public comments.

Administrative Procedure Act Provisions
Under the Administrative Procedure Act provisions at 5 U.S.C. 553, rules may be established only after proposed rulemaking procedures (steps three through six) have been followed, unless an exemption applies. The following are exempted:
- Rules concerning military or foreign affairs functions
- Rules concerning agency management or personnel
- Rules concerning public property, loans, grants, benefits, or contracts
- Interpretive rules
- General statements of policy
- Rules of agency organization, procedure, or practice
- Nonsignificant rules for which the agency determines that public input is not warranted
- Rules published on an emergency basis

Note: Even if an exemption applies under the Administrative Procedure Act provisions, other statutory authority or agency policy may require that proposed rulemaking procedures be followed.

Optional Supplementary Procedures to Help Prepare a Proposed Rule

Advance Notice of Proposed Rulemaking
An advance notice of proposed rulemaking requests information needed for developing a proposed rule.

Negotiated Rulemaking
Negotiated rulemaking is a mechanism under the Negotiated Rulemaking Act (5 U.S.C. 561-570) for bringing together representatives of an agency and the various interests to negotiate the text of a proposed rule.

Step Four
OMB Review of Proposed Rule

OMB Review Under Executive Order 12866
OMB reviews only those rulemaking actions determined to be "significant."

Independent agencies are exempt from OMB review.

Step Five
Publication of Proposed Rule

Administrative Procedure Act Provisions
The Administrative Procedure Act provisions at 5 U.S.C. 553 require proposed rules to be published in the *Federal Register*.

Step Six
Public Comments

Comments
Under the Administrative Procedure Act provisions of 5 U.S.C. 553, an agency must provide the public the opportunity to submit written comments for consideration by the agency.

As required by Public Law No. 107-347, agencies must provide for submission of comments by electronic means and must make available online the comments and other materials included in the rulemaking docket under 5 U.S.C. 553 (c).

Executive Order 12866 established 60 days as the standard for the comment period.

The holding of a public hearing is discretionary unless required by statute or agency policy.

Step Seven
Preparation of Final Rule, Interim Final Rule, or Direct Final Rule

Final Rule
A final rule adds, changes, deletes, or affirms regulatory text.

Special Types of Final Rules

Interim Final Rule
An interim final rule adds, changes, or deletes regulatory text and contains a request for comments. The subsequent final rule may make changes to the text of the interim final rule.

Direct Final Rule
A direct final rule adds, changes, or deletes regulatory text at a specified future time, with a duty to withdraw the rule if the agency receives adverse comments within the period specified by the agency.

Step Eight
OMB Review of Final Rule, Interim Final Rule, or Direct Final Rule

OMB Review Under Executive Order 12866
OMB reviews only those rulemaking actions determined to be "significant."

Independent agencies are exempt from OMB review.

Step Nine
Publication of Final Rule, Interim Final Rule, or Direct Final Rule

Congressional Review Act (5 U.S.C. 801-808)
An agency must submit most final rules, interim final rules, and direct final rules, along with supporting information, to both houses of Congress and the General Accounting Office before they can take effect.

Major rules are subject to a delayed effective date (with certain exceptions).

Action by Congress and the President could have an impact on the rule.

Administrative Procedure Act Provisions
Under the Administrative Procedure Act provisions that are included as part of the Freedom of Information Act at 5 U.S.C. 552, agencies are required to publish final rules, interim final rules, and direct final rules in the *Federal Register*.

Federal Register Act (44 U.S.C. 1501-1511)
The Federal Register Act at 44 U.S.C. 1510 (implemented at 1 CFR 8.1) requires rules that have general applicability and legal effect to be published in the *Code of Federal Regulations*.

Specific Analyses for Steps Three and Seven

Regulatory Planning and Review (E.O. 12866)
Would the rule have a $100 million annual impact, raise novel issues, and/or have other significant impacts? → **If yes** — Prepare economic impact analysis.

Regulatory Flexibility Act (5 U.S.C. 601–612)
Is a notice of proposed rulemaking required by law? → **If yes**
Would the rule "have a significant economic impact on a substantial number of small entities"? → **and yes** — Prepare regulatory flexibility analysis.
Note: Under limited circumstances analyses also are required for certain interpretive rules involving internal revenue laws (5 U.S.C. 603, 604).

Paperwork Reduction Act (44 U.S.C. 3501–3520)
Does the rule contain a "collection of information" (reporting, disclosure, or recordkeeping)? → **If yes** — Prepare information collection clearance package for OMB review and approval, and prepare request for public comments.

Unfunded Mandates Reform Act (2 U.S.C. Chs. 17A, 25)
Does the rulemaking process include a proposed rule? → **If yes**
Does the rule include any Federal mandate that may result in the expenditure (direct costs minus direct savings) by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million in any one year (adjusted annually)? → **and yes** — Prepare unfunded mandates analysis (unless an exclusion applies).

Federalism (E.O. 13132)
Is the rule a discretionary rule that has federalism implications and imposes substantial unreimbursed direct compliance costs on State and local governments? → **If yes** — Prepare federalism summary impact statement.
Does the rule have federalism implications and preempt State law? → **If yes** — Prepare federalism summary impact statement.

Indian Tribal Governments (E.O. 13175)
Is the rule a discretionary rule that has tribal implications and imposes substantial unreimbursed direct compliance costs on Indian tribal governments? → **If yes** — Prepare tribal summary impact statement.
Does the rule have tribal implications and preempt tribal law? → **If yes** — Prepare tribal summary impact statement.

National Environmental Policy Act (42 U.S.C. 4321–4347)
Is the rule categorically excluded from review? → **If no**
Does the rule constitute a major Federal action that could significantly affect the quality of the human environment? → **and yes** — Prepare environmental assessment or environmental impact statement, as appropriate.

National Technology Transfer and Advancement Act (15 U.S.C. 272 note)
Does the rule contain provisions for which the use of voluntary standards is applicable? → **If yes** — Adopt voluntary consensus standards or explain why not.

Governmental Actions and Interference with Constitutionally Protected Property Rights (E.O. 12630)
Does the rule regulate private property use for the protection of public health or safety? → **If yes** — Prepare takings analysis.
Is the rulemaking a proposed regulatory action that has takings implications (other than regulating private property for the protection of public health and safety)? → **If yes** — Prepare takings analysis.

Protection of Children from Environmental Health Risks and Safety Risks (E.O. 13045)
Is the rulemaking a "covered regulatory action"? → **If yes** — Prepare analysis of the environmental health or safety effects on children.

Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use (E.O. 13211)
Is the rulemaking action a "significant energy action"? → **If yes** — Prepare statement of energy effects.

Using The Reg Map

The Reg Map is based on general requirements. In some cases, more stringent or less stringent requirements are imposed by statutory provisions that are agency specific or subject matter specific. Also, in some cases more stringent requirements are imposed by agency policy.

In a typical case, a rulemaking action would proceed from step one through step nine with a proposed rule and a final rule.

However, if a rulemaking action is exempt from the proposed rulemaking procedures under the Administrative Procedure Act provisions (explained under step three) or under other statutory authority, an agency may:

- promulgate a final rule omitting steps three through six, or
- promulgate an interim final rule omitting steps three through six, but providing a comment period and a final rule after step nine.

Also, if an agency determines that a rule likely would not generate adverse comment, the agency may promulgate a direct final rule, omitting steps three through six, but with a duty to withdraw the rule if the agency receives adverse comments within the period specified by the agency.

Drafting Requirements for Rulemaking Documents

Regulatory Planning and Review (E.O. 12866)
Rulemaking documents must comply with the specified regulatory philosophy and principles of regulation.

Civil Justice Reform (E.O. 12988)
Rulemaking documents must be written in clear language designed to help reduce litigation.

Presidential Memorandum on Plain Language (63 FR 31885)
Rulemaking documents must comply with plain language principles.

Federal Register Publications
Rulemaking documents must comply with the Federal Register regulations (1 CFR). Additional guidance and requirements are contained in the Federal Register's *Document Drafting Handbook*.

Agendas for Rules Under Development or Review

Unified Regulatory Agenda
The Unified Regulatory Agenda provides information concerning agency rules under development or review.

The Unified Regulatory Agenda is published in the *Federal Register* in the spring and fall of each year.

Regulatory Plan
The Regulatory Plan provides information concerning the most important significant regulatory actions that the agency is planning to take.

The Regulatory Plan is published in the Unified Regulatory Agenda in the fall of each year.

Regulatory Flexibility Agenda
The Regulatory Flexibility Agenda provides information concerning any rule that an agency expects to prepare or promulgate that is likely to have a significant economic impact on a substantial number of small entities.

Agency regulatory flexibility agendas are published as part of the Unified Regulatory Agenda in the spring and fall of each year.

Procedure, Procedure, Procedure

- Fair procedure is important
- Often makes process less efficient
- Courts more often than not review procedure, not substance of rulemakings when they are challenged
- Requirements for standing: injury, ability of court to remedy

Resources for Regulation

Science and Risk Analysis

Key points from Smith:

1. Analysis is as political as it is scientific - conflict of values
2. Modeling future events inevitably includes uncertainty
3. Interpretations vary across scientific disciplines regarding pollution risk/harm
4. Focuses on "acceptable" risk, not potential alternatives to risky activity

Resources for Regulation

Cost-Benefit Analysis

- Striving for certainty
- Some costs and benefits cannot be quantified
- How much is a human life worth (2016)?

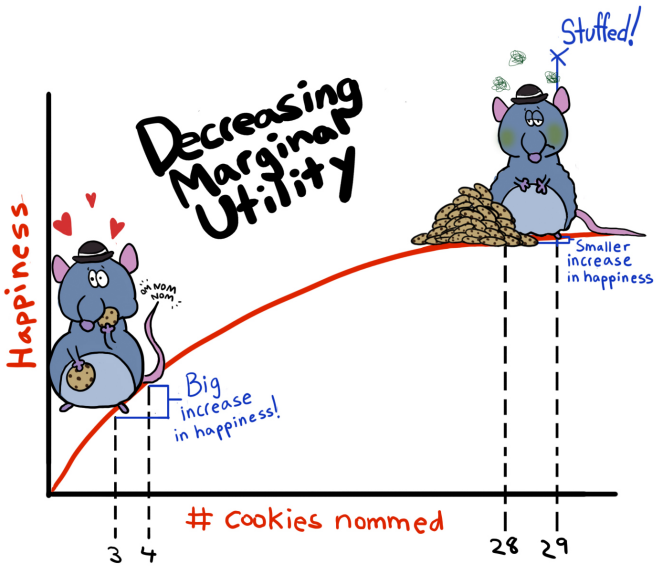
Resources for Regulation

Cost-Benefit Analysis

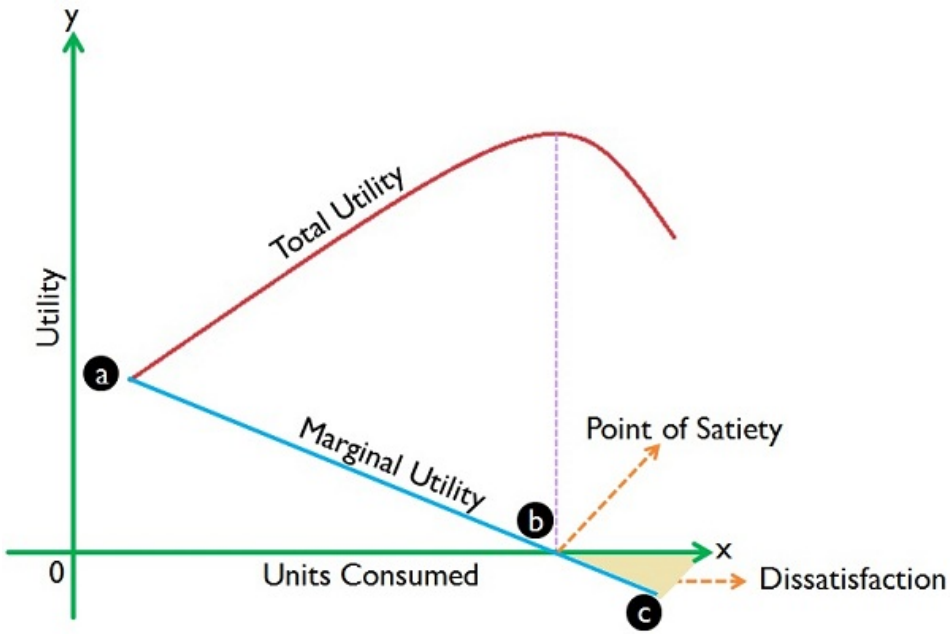
- Striving for certainty
- Some costs and benefits cannot be quantified
- How much is a human life worth (2016)?
  - EPA: $10 million
  - USDA: $8.9 million
  - FDA: $9.5 million
  - DOT: $9.6 million

Resources for Regulation

Marginal Utility



Source: economnomnomics.com, CC BY-NC 2.5



Source: Surbhi S. (2016)

Final Point

Do not forget that both science and politics/policy involve values. Need to understand value conflicts, not just scientific evidence.