

WTO TBT Committee
Workshop on Good Regulatory Practice
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U.S. Rulemaking Responsibility/Authority

Congress generally delegates to Executive Branch responsibility or authority to issue regulations



Statutory Delegation

- The statute may
 - Mandate action
 - Provide discretion
- It may also be
 - General
 - Specific
 - Conflicting
 - Vague or problematic



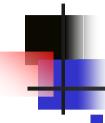
Identification of Need for a Regulation

- Agency identification of a problem
 - Inspector reports/agency oversight
 - Accidents, environmental problems, or other problems
 - Enforcement issues/problems
 - Requests for interpretation/exemption
 - Changes in state of the art
 - Review of existing regulations
 - Ftc.
- Petitions from the public
- Policy initiatives
- Investigative agency recommendations
- Etc.
- Role of risk assessments



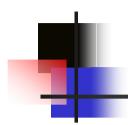
Consideration of Legal Requirements

- Treaties
- Statutes
- Executive Orders
- Regulations
- Etc.



Consideration of Alternatives

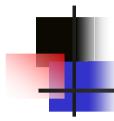
- Non-regulatory alternatives; e.g.,
 - Market place incentives
 - Tax incentives
 - Voluntary partnerships
- Regulatory alternatives; e.g.,
 - Information disclosure/labeling
 - International standards
 - Performance vs. design standard
 - Alternative methods of compliance
 - Phase-in
 - Tiering



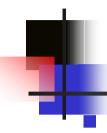
Continued - Consideration of Alternatives

- Substantive alternatives
 - Different ways to fix problem
 - Some may achieve more benefits
 - Some may cost more
- Role of economic and other analyses





- Determination
 - Probability of problem occurring (e.g., accident)
 - Probability of problem causing harm (e.g., death)
- Issues
 - Assumptions
 - Range and distribution of risks
 - Comparison to other risks
 - Risk tradeoffs
 - Peer review
 - Etc.
- Timing
 - Should be done prior to cost-benefit analysis



Cost-Benefit Analyses

- Determination
 - Costs and benefits of the regulation (and alternatives)
- Issues
 - Limitation/restrictions on use
 - Data
 - Assumptions
 - Indirect effects
 - Nonquantifiable costs or benefits
 - Value of life
 - "Tombstone mentality"
 - Cost effective vs. cost beneficial
 - Discount rate
 - Reasonable alternatives
 - Sensitivity analyses
 - Etc.



Continued - Cost-Benefit Analyses

- Decision
 - Generally: do benefits justify costs
- Timing
 - This should form the basis of decision:
 - Whether regulation is justified
 - What alternative should be chosen

Continual Reassessment of Need

- During development of rulemaking, agency continually reassesses need
- Agency justification reviewable by
 - Agency officials
 - OMB and other agencies
 - Public
 - Congress
 - Courts



The Logic of the Decision

- Is problem/policy goal clear?
- Will the action fix the problem?
- Are conflicts with other objectives and requirements explained and justified?
- Will the action promote or hinder innovation, competition, trade, and investment?
- Do data/analyses support decision? Are costs and market distortions minimized? Benefits maximized?



- Is the action sensible?
- Are assumptions reasonably explained and supported?
- Are there reasonable alternatives and explanations for rejection?
- Could action have unintended consequences?
- Is it clear, practical, and easily enforced?
- If problem continues, will agency be able to explain why its decision was reasonable?



Conclusion

- Well done analyses are exceptionally valuable decisionmaking tools
- If process is used correctly, regulations are much less likely to create trade barriers or other problems