



# How to Determine the Need to Regulate

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Neil Eisner  
Assistant General Counsel  
U.S. Department of Transportation



# U.S. Rulemaking Responsibility/Authority

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



# Statutory Delegation

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



# Identification of Need for a Regulation

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- 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
  - Etc.
- Petitions from the public
- Policy initiatives
- Investigative agency recommendations
- Etc.
- Role of risk assessments



# Consideration of Legal Requirements

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



# Consideration of Alternatives

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- 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

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



# Risk Assessments

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- 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

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- 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

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- 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



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- 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

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- 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?

# The Logic of the Decision -- Continued



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- 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

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- 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