Regulatory Planning and Review in the U.S.: An Overview

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Visiting Scholar
Resources for the Future
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• Visiting Scholar, Resources for the Future
• Served 4 Presidents while working in 3 federal agencies.
  – CEA 1997-1998,
    • Senior Economist for Environment & Regulation
  – FDA 2003-2009
    • Chief Economist, Associate Commissioner, Deputy Commissioner for Policy
• Economist and researcher
  – AEI and AEI-Brookings Joint Center 1998-2003
  – Numerous papers on health, safety and environmental regulation, e.g., Science, ES&T, JPE, Economic Inquiry, Energy Journal, Regulation
How to Achieve Government Policy Goals?

- **Spend** (make federal Budget request, seek Congressional appropriations)
- **Tax** (include in federal Budget, requires Congressional action)
- **Mandate** (may require Congressional action, or if there is already existing statutory authority, may entail issuance of *new regulation*).
Attractions of the Mandate

• “Off-budget”
  – Effects (both costs and benefits) are less transparent.
• If authorizing legislation already exists, a regulation is within President’s authority.
• More appropriate for complicated science-based risk-related issues that are pervasive in modern life, e.g.,
  – food and drug safety,
  – labeling,
  – air pollution.
An Example: Air Pollution: Revising the Ozone Standard

• In January 2010, EPA *proposed* a regulation to set new national ambient air quality standards for ozone, a regulation more stringent than issued by EPA in 2008 (2 years earlier)

• EPA proposed to strengthen *the 8-hour* “primary” ozone standard, designed to protect public health, to a level within the range of 0.060-0.070 parts per million (ppm).

• “The proposal to strengthen the primary standard places more weight on key scientific and technical information, including epidemiological studies, human clinical studies showing effects in healthy adults at 0.060 ppm, and results of EPA’s exposure and risk assessment.”
An Example: Air Pollution
A Role for Economic Analysis?

• “The costs of reducing ozone to 0.070 ppm would range from an estimated $19 billion to $25 billion per year in 2020. For a standard of 0.060 ppm, the costs would range from $52 billion to $90 billion.”

• “EPA estimates the value of health benefits of reducing ozone to 0.070 ppm would range from about $13 billion to $37 billion per year in 2020. For a standard of 0.060 ppm, the value of benefits would range from about $35 billion to $100 billion per year in 2020.”
Regulatory Planning and Review Policy and Practice

• Problem (control and authority)
• Process of Regulatory Planning and Review
• Role of Economic Analysis
• Strengths and weaknesses
The Problem

• Who makes what regulatory decisions, according to what criteria, and with what level of oversight?

• Regulatory review is important because cabinet and sub-cabinet officers are very rarely fired.
  – Once appointed, firing, or even public admonishment, is embarrassing to the WH.
  – Thus Presidents for decades have sought to retain control by instituting a process of review within the WH, of draft regulatory decisions.
The Process: E.O. 12866

– Signed by President Clinton, October 1993,
  • Replaced E.O. signed by President Reagan.
  • Used by President Bush and so far by President Obama.

– “The American people deserve a regulatory system that works for them, not against them: a regulatory system that protects and improves their health, safety, environment, and well-being and improves the performance of the economy without imposing unacceptable or unreasonable costs on society; regulatory policies that recognize that the private sector and private markets are the best engine for economic growth; regulatory approaches that respect the role of State, local, and tribal governments; and regulations that are effective, consistent, sensible, and understandable. We do not have such a regulatory system today.

– With this Executive Order, the Federal Government begins a program to reform and make more efficient the regulatory process.”

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Process: E.O. 12866 Has Twelve “Good Government” Principles, e.g.,

(1) Each agency shall **identify the problem** that it intends to address (including, where applicable, the failures of private markets or public institutions that warrant new agency action) as well as assess the significance of that problem.

(2) Each agency shall **examine whether existing regulations** (or other law) have created, or contributed to, the problem that a new regulation is intended to correct and whether those regulations (or other law) should be modified to achieve the intended goal of regulation more effectively.

(3) Each agency shall **identify and assess available alternatives to direct regulation**, including providing economic incentives to encourage the desired behavior, such as user fees or marketable permits, or providing information upon which choices can be made by the public.

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E.O. 12866 Has 12 Principles, e.g.,

(4) In setting regulatory priorities, each agency shall consider, to the extent reasonable, the degree and nature of the risks posed by various substances or activities within its jurisdiction.

(5) When an agency determines that a regulation is the best available method of achieving the regulatory objective, it shall design its regulations in the most cost-effective manner to achieve the regulatory objective. In doing so, each agency shall consider incentives for innovation, consistency, predictability, the costs of enforcement and compliance (to the government, regulated entities, and the public), flexibility, distributive impacts, and equity.

(6) Each agency shall assess both the costs and the benefits of the intended regulation and, recognizing that some costs and benefits are difficult to quantify, propose or adopt a regulation only upon a reasoned determination that the benefits of the intended regulation justify its costs.
<table>
<thead>
<tr>
<th>Rule [FR Cite]</th>
<th>Agency</th>
<th>Benefits</th>
<th>Costs</th>
<th>Other Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Right Whale Ship Strike Reduction [73 FR 60173]</td>
<td>DOC/NOAA</td>
<td>Not estimated</td>
<td>$105 million per year</td>
<td>Benefits: Reduction of right whale mortality which reduces the likelihood of extinction of this endangered species. Costs: Total costs include both direct and secondary economic effects.</td>
</tr>
<tr>
<td>Group Health Plans and Health Insurance Issues Under the Newborns and Mothers Health Protection Act [73 FR 62409]</td>
<td>HHS/CMS, DOL/EBSA and Treas/IRS</td>
<td>Not estimated</td>
<td>$119 - 238 million per year</td>
<td>Benefits: Increase in access to health plan coverage for postpartum care and monitoring of mothers and their newborns should reduce the risk of adverse health outcomes. Costs: Because the statute does not require a 48 or 96-hour stay, but instead gives the decision-making authority to the attending physician in consultation with the mother, it is expected that not all these births will result in additional hospital time. The RIA is available online at: <a href="http://www.regulations.gov/edmnpublie/component/main?main=DocumentDetail&amp;o=090000648076a419">http://www.regulations.gov/edmnpublie/component/main?main=DocumentDetail&amp;o=090000648076a419</a></td>
</tr>
</tbody>
</table>
Assessments of Costs and Benefits

Figure 2-2: Annual Benefits and Costs of Major Rules (1992-2008)

Annual Costs and Benefits (billions of 2001 dollars)

Year Rule Was Issued
Caveats: FY 2008 Rules

• 21 economically significant final rules in 12 month interval.

• Some with no (quantitative) estimates of
  – Costs (1 rule: Migratory Bird Hunting Regulations)
  – Benefits (6 rules: e.g., Right Whale Ship Strike Reduction)
  – Cost or benefits (1 rule: Default Investment Alternatives for Participant Directed Individual Account Plans)
OMB Circular A-4

• OMB Circular A-4,
  – Imposes requirements on regulatory agencies

• “Where all benefits and costs can be quantified and expressed in monetary units, benefit-cost analysis provides decision makers with a clear indication of the most efficient alternative, that is, the alternative that generates the largest net benefits to society (ignoring distributional effects). This is useful information for decision makers and the public to receive. . . .”

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A-4 Includes Three New Requirements

• Requires that agencies perform a formal quantitative analysis of uncertainty for rules with annual benefits or costs that exceed $1 billion,

• Requires that agencies present an annual stream of benefits and costs expected to result from the rule and provide estimates of net benefits calculated using both 3 and 7 percent.

• Requires that agencies prepare a cost-effectiveness analysis (CEA) for all major rulemakings for which the primary benefits are improved public health and safety.
RIA Performance In 13 Selected Very Significant EPA Rules

• Only 2 had a formal quantitative treatment of important aspects of uncertainty. (Seven had either no formal treatment of uncertainty or modeled of only 1 of three important aspects, e.g., concentration response).

• While all but one discounted at both 3% and 7%, 12 did not present streams of undiscounted benefits and costs.

• About half provided a cost-effectiveness analysis.
OIRA / OMB 2009 Report to Congress
Recommendations for Reform

• emphasizes the potential value of behaviorally informed approaches to regulation, including disclosure policies, prudent use of default rules, and simplification.
• suggests that regulatory impact analysis should be improved by increased clarity about costs and benefits, by greater use of retrospective analysis, and by taking account, where relevant, of the interests of future generations, of distributional effects, and of fairness.
• suggests the importance of using regulatory analysis as a tool of transparency and open government, by allowing public scrutiny of rules with reference to their anticipated and actual consequences.
The Process

• OIRA professional analysts evaluate draft agency analyses to see whether
  – Draft regulations comport with the principles in the EO & A4
  – Supporting analyses follow methods outlined in OMB circulars, regarding both substance (e.g., discount rates) and process (e.g., peer-review).

• OMB accepts requests from outside parties to meet to hear concerns with pending draft regulations, but these meetings are
  – in presence of representatives of regulatory agencies
  – held without disclosing the content of the draft rule to outsiders
  – disclosed officially to the public.

• Agency and OMB officials discuss (negotiate) text of regulation.
Role of Economic Analysis

• To inform government policy makers about efficiency implications.
• To comply with statutory requirements.
• To inform the public about expected effects of regulatory decisions.
RIAs: Informing Government Policy Makers About Efficiency Implications

• RIAs are well suited to provide such information. If the people in charge care about getting better RIAs they can ask agencies to conduct further analysis.

• But improving economic analysis as a management aid has an effect on efficiency only to the extent that decision-makers are committed to efficiency as an important objective.

• Evidence here is mixed.
RIAs: Complying with Statutory Requirements

• Agencies take seriously legal requirements for economic analysis under SBREFA or UMRA, or even under CWA BAT program, for example.
• Successful challenge of rules for inadequate economic analysis is rare.
• But statutorily mandated economic analysis of rules is rarely directly related to efficiency.
RIAs: Informing Congress and the Public

• Benefit-cost analysis when well done yields perhaps the best available summary of the effects of a regulation on national welfare.

• But how to judge “quality” of RIAs?

• There are two approaches:
  – review the results,
  – review the process.
RIAs: Informing Congress and the Public

• 1) Review results
  – Low hurdles of general applicability
    • assess different regulatory options (or alternatives),
    • discount benefits that occur later than the associated costs, and
    • use the same baseline to assess costs and benefits.
RIAs: Informing Congress and the Public

1) Review results

- Medium hurdles
  - Did the analysis assess an adequate set of alternatives?
  - Did the analysis use an appropriate baseline to describe the world that would occur in the absence of the regulation?

- Did it provide quantitative estimates of benefits and costs for all significant categories of benefits and costs?
- Did it provide a formal treatment of uncertainty?
RIAs: Informing Congress and the Public

• 2) Review process: Are there incentives for quality and good procedures for quality control?
  • Public comment
  • External independent qualified peer-review
  • Competition among institutions
  • Independence from political pressure
Strengths and Weaknesses

• Strengths:
  – Institutionalized commitment to economic analysis of regulations through transparent process open to public comment and according to established rules.
  – Acceptance within the Executive Branch and the policy community
  – Frequently good, credible analysis
Strengths and Weaknesses

• Weaknesses
  – Weak incentives or controls to ensure quality analysis and plenty of examples of quality inadequate for public accountability.
Suggestions / Recommendations

• The quality of economic analysis is likely to be higher if there are competing estimates.
• Insulation of analysts from political pressures is important.
• Some administrative arrangements may promote good analysis.
  – Public commitments to abide by best practices for RIAs.
  – Public commitments to complete analysis before decision-making.
• Some analysis, or some oversight of analysis, could be delegated to independent agencies.

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Selected References


Getting Good Expert Advice
Dead Cats and Melamine

• What Killed the Cats?
  • In March 2007, FDA learned that certain pet foods (used in a routine taste test) were sickening and killing cats.
  • FDA found contaminants in vegetable proteins imported into the US from China and used as ingredients in pet food.
  • Melamine? A small, nitrogen-containing molecule that has industrial uses, including as an industrial binding agent, flame retardant, and as part of a polymer in the manufacture of cooking utensils and plates. Melamine also used as a fertilizer.

• So why was this new contaminant present?
  – Adding melamine “transformed” flour to gluten, a more valuable product, because gluten was identified by protein content, measured simply as nitrogen levels, and melamine raised measured nitrogen levels.
Melamine in Animal Feed: 2007

• Massive animal food recall
  • 1174 separate shelf-keeping units,
  • >150 distinct brands,
  • about 16K public complaints to FDA of sick or dead animals.

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Melamine in Animal Feed: 2007

• Risks?
  – Published research scarce. FDA knew of a 1945 published article in which dogs were administered 125 milligrams of melamine/kilogram body weight. The study reported melamine to have a diuretic effect (increase the flow of urine), but no toxic effects were noted.
  – A 2007 study conducted in 4 cats demonstrated that given separately, neither melamine nor cyanuric acid caused renal failure. If, however, both compounds were given together, the cats developed signs of renal failure and intratubular crystals.

• Policy problem: How to identify safe animal food given that melamine-contaminated feed appeared to be in hundreds of products, eventually reaching Chinese infant formula?
Melamine in Animal Feed 2007

• May 25th, 2007: Interim Melamine and Analogues Safety/Risk Assessment
• June 7th 2007: Peer-Review Report
• June 14th 2007, FDA Science Board Meeting:
  – The Science Board “concurred with the findings in the report, including the probability of risk to humans, analysis of risk to the food supply, and methods used in the analysis.” The Science Board also reported they concurred with the findings in the peer-review.
• December 3rd, 2007: Status Report to FDA Science Board.

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Melamine in Animal Feed 2007

- August 2008: Melamine discovered in infant formula in China.
- October 2008: External Peer Review of the FDA/CFSAN Draft Report Interim Safety and Risk Assessment of Melamine and its Analogues in Food for Humans and Update
- November 28, 2008: Update: Interim Safety and Risk Assessment of Melamine and its Analogues in Food for Humans
  - “Thus, levels of melamine or one of its analogues alone below 1.0 ppm in infant formula do not raise public health concerns.”

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Outcome?

• Interim risk/safety assessment and final tolerance have largely withstood scrutiny.

• Prosecution:
  – 2/6/2010: 2 Nevada business owners sentenced to three years probation for distributing a melamine-tainted ingredient.
  – U.S. Magistrate Judge Maughmer also ordered Sally Qing Miller, 43, a Chinese national, and her husband, Stephen S. Miller, 57, to each pay a $5,000 fine.
  – In addition, Whipple ordered the Miller's company, Chemnutra, Inc., to pay $25,000.
Overview

• Why seek expert advice?
• How?
  – FACA requirements
  – Peer-review requirements
  – Managing conflicts of interest
Why?

• Why seek expert advice?
  – Genuinely expert advice is more likely to be right and rarely available in house.
  – Appearing to solicit expert advice will enhance confidence in any regulatory actions, at least to the extent that the advice is seen as
    • Genuinely expert
    • From balanced sources representing diverse views
    • Public and thereby subject to public comment and criticism
  – But solicitation of public advice may be governed by Federal Advisory Committee Act (FACA)

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How to Seek Expert Advice

- FACA applies if agency *establishes a committee or group* that includes *non-federal employees* and that will provide *group or consensus advice or recommendations* to federal officials.
FACA Meetings Are Well Regulated

- FACA
- FOIA, Government in the Sunshine Act
- 18 USC 208 (b)(3)
- FD&CA (Including FDAAA)
- Privacy Act
- Trade Secrets Act
How to Seek Expert Advice Outside of FACA

• Convene public meeting and / or open public docket:
  – Quick: not governed by FACA or even PRA.
  – Open:
    • Questions are public
    • Advice from the public is public but may not come only from experts and may not respect legal constraints faced by the agency.

• Convene non-public meeting
  – Industry execs
  – Public interest groups
  – Academic and scientific experts

• Conduct survey
  – Covered by PRA, therefore not quick.
FACA Requirements

• Committee must be chartered. Charters describe
  – Objectives and scope
  – Description of duties
  – Membership and designation
  – Number and frequency of meetings
  – Official to whom the committee reports
  – Designated Federal Official
FACA Requirements

• Meetings must
  – Be announced >15 days in advance
  – Be convened with (brief) agenda announced in advance
  – Allow for public comment
  – Be open to the public
    • Except for narrow exceptions, e.g., discussions of confidential business information (existence of a new drug application), or personnel matters
  – Be held with DFO in attendance
  – Have content disclosed through posting of minutes.
FACA Requirements

• Membership must be balanced in terms of points of view represented and the functions to be performed by the committee.

• Members are subject to ethics laws if they are appointed because of their personal knowledge, background or expertise.

• Members are not subject to ethics laws if they are appointed to represent the point(s) of view of a particular group or segment of the public.
Flexibility Under FACA

- Subcommittees are permissible provided they report to parent committee and not to the federal agency.
- Consultants are permissible and may be given temporary voting privileges.
- Agendas may or may not include an item suitable for a vote by the committee.
- Committee members may do “homework” assignments for the agency as part of their duties before the committee.
An FDA Perspective

• Runs about 60 meetings annually for about 50 committees and “panels” on many issues.

• 2008 Innovations
  – Availability of information given to AC members. 48 hours in advance.
  – When FDA convenes an AC meeting (draft guidance).
  – Centralized listing of all vacancies on FDA advisory committees because filling vacancies is challenging.
Peer Review Requirements

- OMB’s Final Information Quality Bulletin for Peer Review, 12/2004
- Agencies must subject "influential" scientific information to peer review prior to dissemination.
- An agency conducting a peer review of a highly influential scientific assessment must ensure that the peer review process is transparent by making available to the public
  - the written charge to the peer reviewers,
  - the peer reviewers’ names, the peer reviewers’ report(s), and
  - the agency’s response to the peer reviewers’ report(s).
- The agency must address reviewers’ potential conflicts of interest (including those stemming from ties to regulated businesses and other stakeholders) and independence from the agency.

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Peer Review Requirements

- Agencies must adopt or adapt the committee selection policies employed by the National Academy of Sciences (NAS) when selecting peer reviewers who are not government employees.
Managing Conflicts of Interest

• Intrinsically contentious
• 18 USC 208(b)(3) covering SGEs
  – “need for the individual’s services outweighs the potential for a conflict of interest created by the financial interest involved”
• FDAAA
  – Waivers may be granted only if “necessary to afford the committee essential expertise”
  – Establishes a declining cap now around 13 percent
  – Mandates screening at time of appointment and for meeting.
FDA COI Innovations

• 2008
  – Availability of information given to AC members. 48 hours in advance.
  – Procedures for determining COI and eligibility (a $50,000 cap) for “direct” interests.
  – When FDA convenes an AC meeting (draft guidance).

• 2010
  – Disclosure of specific interested entities (companies or agencies) (draft guidance)
Questions?

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