Mercatus Center at George Mason University REGULATORY STUDIES PROGRAM

REGULATORY OVERSIGHT: THE BASICS OF REGULATORY IMPACT ANALYSIS

By Richard Williams and Jerry Ellig

INTRODUCTION

Congress delegates some of its power to federal agencies, allowing them to exert authority through regulations or rules that implement laws and general agency objectives. This is no light delegation of responsibility as federal agencies must accomplish significant public objectives, such as protecting people from financial fraud, keeping the air clean, and preventing terrorist attacks.

Regulation, however, is one, but not the only, option for addressing problems. Pursuing regulation without carefully examining the range of options available risks the implementation of a second-rate solution that does not achieve the desired significant public objective. As such, federal agencies must act first and foremost as effective problem-solvers. An agency needs to define the outcome the agency seeks to achieve, understand the root causes of the problem that stands in the way of achieving the desired outcome, identify a wide variety of options to solve the problem, and assess the pros and cons of each option before making a decision on a course of action.

Thus, both the legislative branch, through the Unfunded Mandates Reform Act, and the executive branch, through Executive Order 12866, direct agencies to perform regulatory impact analysis (RIA) on many proposed regulations.¹ Executive agencies must produce an RIA for any regulation the Office of Management and Budget designates as "significant."² Analytical requirements are especially rigorous for "economically significant" regulations, defined as regulations that "have an annual effect on the economy of \$100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local or tribal government or communities."³ RIAs should provide agency policy makers with evaluations of the size and nature of the problems, possible solutions, and assessments of the solutions that identify the relationship between benefits and costs.

RIAs provide members of Congress the same information. Since the RIA serves as the agency's most rigorous assessment of a regulation's intended effects, congressional oversight committees can use the RIA as a starting point for investigating whether the regulation achieved its intended outcomes and at

¹ Unfunded Mandates Reform Act of 1995, Pub. L. 104-4, 109 Stat. 48; Executive Order 12866, *Federal Register* 58:190 (Oct. 4, 1993), 51735–44.

² A "significant" regulation is one that is "economically significant" (see below) or creates a serious inconsistency with another agency's action, has a material effect on the federal budget, or raises novel legal or policy issues. E.O. 12866, Sec. 3(f).

³ E.O. 12866, Sec. 3(f)(1).

what cost. Members also can use that information to assess whether a regulation should be challenged under the Congressional Review Act.

RIA BASICS

Agency economists perform preliminary and final RIAs, and RIAs often go through multiple layers of internal and external agency review.⁴ Not all agencies, however, are subject to the same RIA standards. In some cases, statutes may actually prohibit an agency from considering an RIA when making decisions about a regulatory course of action. For example, the Clean Air Act forbids the Environmental Protection Agency from considering costs when setting standards, although it can use economic evidence when enforcing the standards.⁵ To date, independent agencies, such as the Federal Communications Commission, the Commodity Futures Trading Commission, and the new Consumer Financial Protection Bureau, have not been brought under the economic executive orders. Thus, independent agencies are not required to perform an RIA before developing or issuing regulations.

Notices of proposed rulemaking include preliminary RIAs, either in a section of the notice of proposed rulemaking or in a separate document. Sometimes an agency does both, producing a separate RIA document and including a summary of the document as a section of the notice of proposed rulemaking. In other cases, the preamble to the proposed rule may contain a good deal of the agency's regulatory analysis even if it is not clearly labeled as the RIA. The publication of a final rule includes a final RIA.

RIAs contain four primary elements:

- 1. A statement of need for the regulation;
- 2. An assessment of alternative regulatory approaches;
- 3. A benefit-cost analysis; and
- 4. In some cases, a cost-effectiveness analysis.

At a minimum, an RIA should include:

- 1. Evidence demonstrating the existence of a significant, systemic market failure or other problem that government intervention might mitigate;
- 2. A discussion of the baseline—i.e., what happens to the problem if the government does nothing new. The baseline should estimate what the affected parties (businesses, consumers, etc.) are doing, what they know, and what they are likely to do in the immediate future;
- 3. A broad array of different options for solving the problem;
- 4. A discussion and estimation of the marginal benefits and costs of each of the options and each component of the options. The discussion should identify any assumptions and unquantified values clearly and discount future benefits and costs to today's values; and

⁴ For example, the Office of Risk Assessment and Cost-Benefit Analysis (ORACBA) within USDA reviews RIAs that are associated with health and safety. The Office of Information and Regulatory Affairs (OIRA) within the Office of Management and Budget (OMB) will review all RIAs the OMB deems "significant," which essentially means any RIA the OMB wishes to review. Numerous other executive branch entities, such as the Council of Economic Advisors or the Office of Science and Technology, may also be involved in reviewing RIAs or the entire regulatory proposal.

⁵ 42 U.S.C. §§ 7408–7409.

5. An estimate of the uncertainty in the benefit and cost estimates, including, some type of sensitivity analysis.

KEY QUESTIONS IN EXAMINING A REGULATORY IMPACT ANALYSIS

1. Does the agency use empirical evidence to define a significant, systemic problem?

In the RIA, the agency should define clearly the significant, systemic problem that it intends to address through the proposed regulation. Defining a problem means a great deal more than simply citing a statute or act of Congress. Agencies should provide a substantive description of the "failure" addressed or the "need" for new regulations, along with supporting evidence.

Is there a problem?

Most regulatory actions cite a few particular problems:

- Market Failure. Government intervention may be appropriate where markets fail to allocate resources to the uses that consumers value most highly. Market failures generally fall into one of four categories:
 - Externalities occur when one party's actions create significant uncompensated costs or benefits for another party.
 - Public goods are resources that have two attributes: (1) it is not possible to exclude users who have not paid to use the resource, and (2) the resource cannot be used up. The market may under-provide public goods because the inability to exclude non-payers makes provision of those goods unprofitable; for example, new discoveries might not be made if inventors cannot gain a patent to protect property and profit rights. Sometimes exhaustible resources get treated as a public good (or "commons") even though they can be used up; ocean fisheries open to all that get over-fished provide one contemporary example.
 - A firm with monopoly power has the ability to reduce output and increase prices. "Natural monopolies" exist when economies of scale are so great that a market can be served at lowest cost with a single producer. In such cases, without some form of intervention, prices would be higher and quantity produced lower than in a competitive market.
 - When market participants have inadequate information, markets may not allocate resources efficiently. However, few would argue that perfect information is necessary or desirable, because information itself is a good that costs something to produce and disseminate. More recent empirical analysis shows that perfect information is not even optimal for a well-functioning market.

These categories are so broad that virtually any market may be said to have a "failure." Thus evidence that a significant failure exists, that the market is unlikely to self-correct in the near future, and that the government can correct the failure should accompany any claim of a market failure.

• Government Failure. Even when a government could theoretically correct a market failure, the political nature of arriving at solutions often prevents a government from doing so. Governments tend to reward those with concentrated interests (firms or activist groups) at the expense of those who must bear dispersed costs (e.g., a general rise in prices for consumers). In addition, there are

often unknown preferences or unintended consequences of which government is not aware prior to taking action. In these types of cases, a new regulation may seek to solve a problem that can be traced to government failure. Federal actions to protect interstate commerce, for example, can counter political pressures in states to protect local business interests at the expense of consumers and out-of-state sellers. Alternately, a new regulation may seek to fix problems that were either unanticipated or ignored for political reasons at the time an old regulation was enacted. A great deal of the economic "deregulation" in the transportation and communications industries involved removal of government-enforced monopolies or cartels.

• Overriding Social Need. This category covers a broad array of issues that the government chooses to address even though neither market nor government failures exist. Most government actions under this rubric involve redistribution of income and other benefits in order to satisfy the decision makers' sense of fairness or justice. Some regulations of this type implement federal spending programs that transfer income. In other cases, agencies may design risk regulations to protect a small group of the highly exposed or the highly sensitive, even though such rules may impose overall costs that substantially exceed the benefits.

Is the defined problem "significant" and "systemic"?

It is not enough for an agency to define a problem; it must also show that problem merits federal regulation because it is significant and systemic. Federal regulation may be appropriate if the problem involves significant spillovers across state lines, if state or local regulations burden interstate commerce, or if such regulations are necessary to protect the rights of national citizenship. In general, however, regulations developed at the state or local level offer advantages of diversity in meeting citizens' local circumstances and preferences and encourage competition among governmental units to meet the needs of its citizens.

The agency must use published data and analysis to demonstrate the existence of a significant systemic problem that is not likely to be solved in the near future. The RIA should present credible empirical support for the problem's existence and not just anecdotes about a few bad actors.

Questions that help evaluate whether the problem is a "significant, systemic problem" include:

- Is this an issue that can be addressed by states or localities? Why or why not?
- Does the RIA adequately assess uncertainty about the existence and size of the problem?
- Does the RIA outline a coherent and testable theory that explains why the problem is systemic rather than anecdotal?
- What evidence does the agency present that supports its assertion of a significant, systemic problem?
- Has the agency considered whether regulations currently in place may not work or may have caused unexpected problems?
- Is the problem one that courts would consider "de minimis"?

2. Did the agency identify and evaluate the baseline and alternative solutions?

Once it defines a significant, systemic problem and gives evidence to support its case in the RIA, the agency should evaluate and present a wide range of viable approaches (non-regulatory to regulatory) to solving the problem. Unless it considers a broad range of alternatives, the agency may not identify the

best solution. (The alternatives identified might be minor variations of the chosen option, like different levels of stringency.)

In general, market-based and performance-oriented approaches are preferable to command-and-control standards. By harnessing market forces, market-based approaches are likely to achieve desired goals at lower social costs than command-and-control approaches. Where regulations create private rights or obligations, they also should encourage unrestricted exchange of these rights or obligations. Health, safety, and environmental regulations should address ends, rather than means. Performance standards or economic incentives are more effective than technology-based standards, which by dictating the means of achieving goals, discourages innovation to improve health, safety, and environmental quality.

Alternatives may include:

- Providing the public with more information to help people make better decisions
- Establishing a rule that prompts individuals to make an explicit choice in cases where they might not otherwise consider their options (e.g., automatic enrollment in a 401k account unless one chooses to opt-out)
- Providing a performance standard (like a safety level) rather than instituting command-and-control rules (e.g., dictating exactly what technology firms must install)
- Establishing market mechanisms, such as tradeable quotas in a fishery that prevent over-fishing
- Regulating more or less of an industry or group of industries—in particular, focusing the regulation only on those that contribute to the identified problem; this kind of solution might also be geographic in nature
- Selecting an effective date for the regulation that gives regulated entities more time to find the necessary resources to comply and enables them to spread the costs over more of their output
- Investing in more information if there is an incomplete understanding of the problem or there is no cost-effective solution

- Does the RIA explore multiple options to address the problem?
- Is the range of options considered narrow or broad?
- Does the RIA adequately address the baseline—what the state of the world is likely to be in the absence of further federal action?
- Does the RIA evaluate how alternate approaches would affect the amount of the outcome achieved?
- Has the agency analyzed options outside of its statutory authority? (Each agency should evaluate all options, including those that might inform Congress that a better option exists outside of the agency's current statutory authority.)
- Does the benefit-cost analysis contain a complete discussion of the benefits and costs of the chosen option but say relatively little about alternatives?
- Is this the right agency to address this problem?

- Does this agency have a history of success in solving similar problems?
- 3. Is there evidence that the proposed regulation will solve the problem?

In its benefit-cost analysis in the RIA, the agency should back up its rationale for choosing a particular course of action with solid evidence that its regulatory proposal will solve all or a significant portion of the problem that it has identified. That is, will the course of action achieve the desired outcome(s)?

An "outcome" is a result that directly affects citizens' quality of life. Fewer cancer deaths, fewer industrial injuries, and lower prices for consumers are all outcomes. Outcomes are not processes, activities, or outputs, which may affect outcomes but are not themselves directly outcomes. Processes, activities, and outputs are things like the number of regulations written, enforcement actions, or pollution control technologies installed. These are means to an end, not ends in themselves.

Acceptable evidence might include a scientific study (preferably more than one), a pilot program, or evidence from experience in states or other countries. If the rule has multiple requirements, the RIA should present evidence that shows that each requirement will work.

Questions for policy maker analysis:

- How well does the RIA identify the desired outcomes and demonstrate that the regulation will achieve them?
- How well does the RIA clearly identify ultimate outcomes that affect citizens' quality of life?
- How well does the RIA identify how these outcomes are to be measured?
- Does the RIA provide a coherent and testable theory showing how the regulation will produce the desired outcomes?
- Does the RIA present credible empirical support for the theory?
- Does the RIA adequately assess uncertainty about the outcomes?
- 4. Is the proposed solution worth the costs?

In the economic analysis, the option that "maximizes net benefits" (the option that has the largest difference between benefits and costs) is the one that has the best possible solution for the costs expended (absent other criteria). This may not be the least-costly option or the option that appears to generate the largest amount of benefits. Of course, unless all regulatory options have benefit and cost estimates, it is impossible to determine which option maximizes net benefits.

EO 12866 directs agencies to "propose or adopt a regulation only upon a reasoned determination that the benefits of the intended regulation justify its costs." Costs and benefits include qualitative factors that are difficult or impossible to quantify. Qualitative benefits or costs may be factors the agency has not figured out how to measure, such as the amount by which airport security has reduced the risk of terrorism. Agencies can also consider qualitative factors that are inherently subjective, such as equity. For these reasons, the executive order incorporates a more flexible decision rule than saying agencies can only regulate when the monetary value of quantified benefits exceeds the monetary value of quantified costs. Nevertheless, it is not sufficient that the agency merely speculate about qualitative effects; agencies

should be expected to offer evidence that the regulation is in fact likely to generate any qualitative benefits or costs discussed in the RIA.

Questions for policy maker analysis:

- Does the analysis identify and quantify incremental costs of all alternatives considered?
- Does the analysis identify all expenditures likely to arise as a result of the regulation?
- Does the analysis identify how the regulation would likely affect the prices of goods and services?
- Does the analysis examine costs that stem from changes in human behavior as consumers and producers respond to the regulation?
- Does the analysis adequately address uncertainty about costs and benefits?
- Does the analysis identify the approach that maximizes net benefits?
- Does the analysis identify the cost-effectiveness of each alternative considered?
- Does the analysis identify all parties who would bear costs and assess the incidence of costs?
- Does the analysis identify all parties who would receive benefits and assess the incidence of benefits?
- Do parts of the proposed regulation have costs exceeding benefits even though the overall regulation has benefits exceeding costs? Has the agency justified keeping those cost-exceed-benefits parts?
- Has the agency associated benefits and costs with legal requirements as opposed to changed behavior?

5. Did the agency use the RIA to inform its decision?

RIAs are not the sole determinate of "the solution." Nevertheless, RIAs offer unique information essential to informed decision-making and so should be performed before, not after, an agency makes a regulatory decision. After all, when an agency conducts a RIA after it has selected a particular regulatory approach, it has not acquired all of the necessary information for making an informed, balanced decision.

- Does the notice of proposed rulemaking explicitly claim that the agency accepted or rejected particular regulatory options due to information about the regulation's effectiveness, costs, or net benefits contained in the RIA?
- Does the RIA offer a thorough evaluation of benefits and costs of several very different regulatory alternatives?
- Does the RIA offer an in-depth assessment, supported by rigorous empirical evidence, that shows private markets are unlikely to solve the problem the regulation seeks to solve?
- Does the RIA quantify most of the important benefits and costs of several alternative approaches?

- Has the agency chosen the option with the greatest net benefits or cost effectiveness? If not, why?
- Do the RIA and the notice of proposed rulemaking explicitly address any economic factors that the legislation requires the agency to consider, such as net benefits, costs, or efficiency?
- Was the RIA completed before the agency made significant decisions about the regulation? Indicators that this did NOT occur include language showing that the regulation originated in recommendations of advisory committees or negotiations with stakeholders that likely occurred well before the RIA was completed, language indicating that the proposed regulation is the result of a court settlement, or language indicating that legislation prohibits the agency from considering costs, net benefits, or the RIA.

If an agency has used an RIA to inform its decision, most of the answers to these questions will be affirmative. Congressional decision makers might still disagree with the agency's judgment, but at least it will be clear how the agency used the RIA to arrive at its decisions. If the answers to many of these questions are "no," then further oversight investigation may be necessary to determine how the agency actually made its decisions and why the RIA and notice of proposed rulemaking do not transparently reflect the reasons for the decisions.

6. Will the proposed solution trigger unintended consequences (e.g., an increase in risks) that could make the overall problem worse or create another problem?

Unintended consequences may cause a proposed regulation to result in more harm than good. Failure to predict unintended consequences arises from incomplete analysis and constitutes one type of government failure.

One key unintended consequence is the risk/risk tradeoff. With risk/risk tradeoffs, reducing one risk may cause another risk to increase. One well-documented example of this is the consumer response to increased airline security after 9/11. The security measures may have reduced the risk of terrorism on airplanes, but they also prompted travelers to substitute driving for flying on short trips, increasing the risks of death in highway accidents. There are always risk/risk trade-offs because no risk-free product or activity exists.⁶

Of course, risk/risk tradeoffs can only be accurate if they are based on accurate estimates of risks, not conservative estimates. Health and safety regulations often build in overestimates of risk in order to err on the side of protection. Reasonable people can disagree as to whether this is a reasonable decision rule. But piling conservative assumptions on top of conservative assumptions in a risk assessment means that the risk assessment itself will fail to reflect reality.

Other kinds of unintended consequences may arise because analysts are not able to perfectly predict how people and firms are going to react to a new regulation. For example, when the Food and Drug Administration required producers of raw juices to put a warning on the labels, manufacturers either stopped making raw juices or pasteurized their products. There is no evidence that warning labels were ever used. The true cost of this regulation, therefore, was the increased cost to consumers associated with pasteurization and the reduction in competition—not the modest cost of warning labels.

- Did the agency analyze risk/risk tradeoffs?
- Does the analysis make conservative assumptions or use unwarranted conservative defaults?

⁶ Garrick Blalock, Vrinda Kadiyali, and Daniel H. Simon, "The Impact of Post-9/11 Airport Security Measures on the Demand for Air Travel," *Journal of Law & Economics* 50, no. 4 (November 2007): 731–56.

• Did the agency fully assess benefits or costs that would stem from likely behavioral changes induced by the regulation?

7. Is there a thorough discussion of the science that is relevant to the proposed regulation? Has the agency separated science from policy decisions?

EO 12866 directs regulatory agencies to base their decision on "the best reasonably obtainable scientific, technical, economic, and other information concerning the need for, and consequences of, the intended regulation." Therefore, RIAs should incorporate scientific findings into benefit-cost analysis. If the science used to identify and calculate benefits or costs is not correct, then the benefits or costs will not be correct either.

The natural sciences (as well as social sciences like economics) can furnish information that is useful to decision makers, but science cannot determine the decision. Science tells us what is, not what ought to be. In 1983, the National Academy of Sciences recommended, "Regulatory agencies should take steps to establish and maintain a clear conceptual distinction between assessments of risks and the consideration of risk management alternatives, that is, the scientific findings and policy judgments embodied in risk assessments should be explicitly distinguished from the political, economic, and technical considerations that influence the design and choice of regulatory strategies." While agency managers must consider all scientific findings, including risk assessments, benefit-cost analysis, etc., risk managers must also take into account factors like legal precedent, equity, and fairness when they make regulatory decisions.

One attempt at ensuring that agencies base their decisions on the best available scientific evidence is the Information (Data) Quality Act (see appendix), which allows stakeholders to challenge the quality, objectivity, utility, and integrity of the information disseminated by an agency. However, as there is no judicial remedy for this challenge and the agency itself resolves the challenges, Congress, in its oversight capacity, should pay close attention to the data under consideration when such challenges exist.

Questions for policy maker analysis:

- Has the agency left out part of the science that argues against its definition of the problem or its chosen solution?
- Have challenges been made under the Information (Data) Quality Act?
- Have the agencies clearly identified where they have made assumptions? Have they made unverified assertions?
- Where agencies discuss hazards and severity of hazards, do they discuss or analyze the probability or likelihood of them occurring?
- Have agencies identified the full extent of uncertainty in their data and models?
- Have the data and models received independent peer review? Did the agency choose the peer reviewers or did a neutral third party choose them?

8. Has the agency examined how the proposed regulation, alone or in combination with other regulations, will affect the ability of U.S. firms to compete internationally?

Regulations are not costless. They can have a direct effect on the competitiveness of U.S. businesses in the global marketplace. Regulations can raise the price of production in the United States to the point that it negatively affects manufacturers' abilities to export goods. Regulations also can make it too expensive

for firms to continue production in the United States, causing them to relocate production facilities, and the jobs they create along with them, overseas.

- Has the agency identified and analyzed whether or not the proposed regulation might create barriers to domestic or international trade (e.g., barriers to entry)?
- Have they analyzed all relevant costs?
- Has the International Trade Administration in the Department of Commerce expressed concern about the regulation?

GLOSSARY

alternatives: other possible solutions. A good analysis of alternatives should describe the actual mechanisms by which the problem could be solved, present evidence that this is likely to occur, and assess how people and firms are likely to respond to those mechanisms.

baseline: the projection of what changes are likely to take place in the next several years if the government takes no new action. For example, expected higher oil prices will lead consumers to purchase cars with higher gas mileage. A thorough baseline analysis can identify potential market solutions that may address the problem in whole or in part without new government intervention. It also estimates what the affected parties (consumers, businesses, etc.) are doing, what they know, and what they are likely to do in the immediate future.

benefit-cost analysis: a study that compares the pros and cons of a regulation and its alternatives. The benefits may include both quantified and non-quantified effects. The costs are not just monetary outlays, but anything society must give up (quantified and non-quantified) in order to accomplish the regulation's goals.

command-and-control standards: regulations that dictate the methods actors must employ to achieve goals, which have the effect of discouraging innovation to improve health, safety, and environmental quality

cost-effectiveness analysis: a study that compares the cost of a regulation and the cost of alternatives that achieve the same goal

de minimis: so small or minimal in difference that it does not matter or the law does not take it into consideration

discount future benefits and costs to today's values: a means to adjust cost and benefit figures from different years to reflect the fact that people tend to place less value on future benefits and costs than on current benefits and costs. A discount rate is used to calculate all relevant future costs and benefits in "present value" terms.

economic incentives: factors that motivate certain courses of action. Incentives can be monetary or nonmonetary; what matters is that they affect the choices people make.

economically significant regulations: regulations that have an annual effect on the economy of \$100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local or tribal government or communities

externality: a significant cost or benefit, not transmitted through prices, incurred by a party who did not agree to the action causing the cost or benefit

government failure: incentive or information problems in government that lead to decisions that fail to promote economic efficiency or the public interest. Examples include the tendency to reward those with concentrated interests (firms or activist groups) at the expense of those who must bear dispersed costs (e.g., a general rise in prices for consumers), failure to consider consequences of policies that occur after the next election, and failure to consider unintended consequences of legislation.

inadequate information: a form of market failure that occurs when market participants lack information that would materially affect their decisions, even though that information could be produced or disseminated at relatively low cost.

incremental benefits (or costs): the change in cost associated with a change in a regulation or in the amount of some activity. "Incremental" is sometimes used as a synonym for "marginal" (see below). But in technical economics, marginal refers to a very small change, whereas incremental refers to any designated size of change.

marginal benefits (or costs): the change in benefit or cost associated with a small change in a regulation or in the amount of some activity. "Marginal" is sometimes used as a synonym for "incremental" (see above). But in technical economics, marginal refers to a very small change, whereas incremental refers to any designated size of change.

market failure: a situation in which markets fail to allocate resources to the uses that consumers value most highly

monopoly power: exclusive control of a commodity or service in a particular market, enabling a firm to reduce output and increase prices

net benefits: the total amount of benefits created by a regulation minus its costs

outcome: a result that directly affects citizens' quality of life, e.g. fewer cancer deaths, fewer industrial injuries, and lower prices for consumers

overriding social need: in the absence of a market or government failure, policy makers may choose take action that appeals to their own sense of fairness or justice, often resulting in redistribution of income and other benefits

performance standards: regulations, particularly pertaining to health, safety, and environmental issues, that identify the outcomes to be achieved, leaving flexibility to actors as to how to accomplish those ends

public goods: resources that have two attributes: (1) it is not possible to exclude users who have not paid to use the resource, and (2) the resource cannot be used up. The market may under-provide public goods because the inability to exclude non-payers makes provision unprofitable; for example, new discoveries might not be made if inventors cannot gain a patent to protect property and profit rights.

qualitative benefits or costs: benefits and costs that are difficult or impossible to quantify; these may be factors the agency has not figured out how to measure, or they may be inherently subjective

regulatory impact analysis (RIA): a report that evaluates the size and nature of a problem, possible solutions, and the pros and cons (benefits and costs) of different solutions.

risk: a situation in which there are multiple possible outcomes, and their probabilities can be estimated

risk/risk tradeoff: reducing one risk may cause another risk to increase; for example, airline security measures post 9/11 may have reduced the risk of terrorism on airplanes, but they also prompted travelers to substitute driving for flying on short trips, increasing the risks of death in highway accidents

sensitivity analysis: a technique used to determine how different values of an independent variable will impact a particular dependent variable under a given set of assumptions; it is used to assess how outcomes could be different if key input values or assumptions are different from what the analysts predict.

uncertainty: a situation in which there are multiple possible outcomes, but their probabilities cannot be estimated. Also used to refer to situations in which not all of the possible outcomes are known.

unintended consequences: benefits or costs of a regulation that are not intended and often not recognized when the regulation was adopted. Productivity improvements that result from improvements in workplace

safety could be an example of an unintended benefit; risk/risk tradeoffs are often examples of unintended costs.

unquantified values: benefits or costs that are not quantified in an RIA. These may be inherently unquantifiable, or the agency may not have figured out how to quantify them yet.

KEY MERCATUS SCHOLARS



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Richard Williams is the Mercatus Center's Director of Policy Research. Dr. Williams is an expert in benefit-cost analysis and risk analysis, particularly associated with food safety and nutrition.



Bruce Yandle

Bruce Yandle is a distinguished adjunct professor of economics for the Mercatus Center's Capitol Hill Campus program and the dean emeritus of the Clemson College of Business and Behavioral Sciences.

ADDITIONAL RESOURCES

Federal Agencies

- A summary of rulemaking requirements can be found at U.S. Department of Transportation, "Rulemaking Requirements," http://regs.dot.gov/rulemakingrequirements.htm.
- A discussion of all requirements for the rulemaking process can be found at U.S. Department of Transportation, http://regs.dot.gov/docs/Rulemaking%20%20Requirements%20April%2009%20Edited%20by%20Neil%20E.pdf
- To find out what rulemakings are underway, what comments have been submitted to agencies, and which proposed regulations are under review by OIRA, see http://www.regulations.gov/search/Regs/home.html#home.

The Mercatus Center

- Susan Dudley, *A Primer on Regulation* (Arlington, VA: Mercatus Center at George Mason University, December 6, 2005), http://mercatus.org/publication/primer-regulation.
- For a discussion of potential problems that may occur with regulations, see Richard Williams, "Regulatory Checklist: Common Pitfalls in Regulations" (working paper, Mercatus Center at George Mason University, January 2010), http://mercatus.org/sites/default/files/publication/Common%20Pitfalls%20in%20Regulations.pdf.
- Jerry Ellig and John Morrall, "Assessing the Quality of Regulatory Analysis: A New Evaluation and Data Set for Policy Research" (working paper, Mercatus Center at George Mason University, December 2010), http://mercatus.org/publication/assessing-quality-regulatory-analysis.
- Jerry Ellig, Patrick McLaughlin, "The Quality and Use of Regulatory Analysis in 2008" (working paper, Mercatus Center at George Mason University, June 2010), http://mercatus.org/publication/quality-and-use-regulatory-analysis-2008.

Other Non-Government Sources

- You also can sign up to be notified of when certain types of regulations are coming out at OpenRegs.com.
- To find out more about RIAs and their use worldwide, see John Morrall, U.S. Experience with Regulatory Oversight: History and Use of RIA, (presentation, Institute of Brazilian Issues, March 2010) http://www.gwu.edu/~clai/recent_events/2010/Spring_Regulatory_Program/Speaker%20Presentations/US_Experience_with_Regulatory_Oversight_2010.pdf.

APPENDIX

LEGAL REQUIREMENTS APPLICABLE TO ECONOMIC ANALYSIS

The Unfunded Mandates Reform Act of 1995 (UMRA), 2 U.S.C. agency §§ 1501 et seq.

Under this law, for rules that result in \$100 million (adjusted for inflation) or more in costs in one year, agencies are required to include an analysis of the costs and benefits and "identify and consider a reasonable number of regulatory alternatives and, from those alternatives, select the least costly, most cost-effective or least burdensome alternative that achieves the objective of the rule" or explain why it could not. OMB supplies Congress with an annual report on compliance with this act, specifically compliance with the least burdensome option requirement. An agency action can be judicially challenged for failure to prepare a written statement.

The Regulatory Flexibility Act (RFA), 5 U.S.C. §§ 601-612

The RFA requires a separate analysis at both the proposed and final rule stage of the rulemaking's likely impact on small entities, including firms and small governments.

The Small Business Regulatory Enforcement Fairness Act (SBREFA), 5 U.S.C. §§ 601 *et seq*. (Pub. L. Nos. 104-121, 110-28)

This act amended the RFA to:

- Allow for judicial review of final RFAs, efforts to collect small entity comments, certifications of no significant impact, and compliance with periodic reviews;
- Establish Small Business Development Centers;
- Establish Ombudsmen and Regional Boards to help register small business complaints;
- Provide for waivers of civil penalties and other exclusions and recovery of small business attorney fees when in litigation with the federal government;
- Require that agencies prepare a plain language guide for small businesses; and
- Require panels for EPA and OSHA to solicit comments on major rulemakings.

Information (Data) Quality Act of 2000, Pub. L. No. 106-554, § 1(a)(3) [Title V, § 515], codified at 44 U.S.C. § 3516 note.

For economic analysis, this act requires that data and models for "influential scientific information" receive peer review. More is required for "highly influential" scientific assessments (a potential impact of \$500 million in any one year).⁷ It also allows stakeholders to challenge the quality, objectivity, utility, and integrity of analysis and data in an administrative proceeding before the agency. Agencies sometimes take years to resolve challenges to their data and analysis. The act does not provide a judicial remedy. See: http://www.whitehouse.gov/omb/inforeg_agency_info_quality_links.

⁷ OMB, Final Information Quality Bulletin for Peer Review, December 15, 2004,

http://cio.energy.gov/documents/OMB_Final_Info_Quality_Bulletin_for_peer_bulletin%282%29.pdf; OMB, "Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies," September 24, 2001, http://www.whitehouse.gov/omb/fedreg_final_information_quality_guidelines.

Other Statutes and Acts of Congress

Many agency statutes have requirements for regulatory analysis. For the U.S. Department of Agriculture, the mandate for the Office of Risk Assessment and Benefit-Cost Analysis mandates benefit-cost analysis. Even some independent agencies have such mandates, including the Securities and Exchange Commission and the Consumer Product Safety Commission.

Executive Orders, Memos, and Circulars

Executive orders have the force and effect of law on members of the executive branch but can only be enforced by the executive branch.

• Executive Order 12866 (1993). Following on its predecessor from 1981 (E.O. 12291), this executive order requires agencies to prepare RIAs for significant rulemakings. The analyses are overseen by OIRA and compliance depends considerably on the will of the executive branch. OIRA has two functions with respect to rules: to ensure that the RIAs are done correctly and to ensure that the president's policies are carried out. OIRA puts itself on a clock to make decisions about rules, but it need not stay with that clock. It can accept rules, return them for reconsideration, or negotiate with agencies to change rules. Whether or not a rule will be reviewed—that is, whether it is "significant"—is entirely up to OIRA. When a rule is reviewed, it is generally examined by a desk officer. An OMB economist examines larger rules. Where there are risk assessments cited, they may also be reviewed by OMB scientists.

This executive order requires that agencies identify the problem it intends to address, how it intends to fix an existing problem with regulation, what alternatives there are to solve the problem, and the costs and benefits of those alternatives. Agencies are instructed to choose an alternative that is the most cost-effective at achieving the regulatory objective (similar to UMRA). The costs of the regulation must be "justified" by the benefits. This was purposely left vague, but it means that non-quantifiable benefits or costs can be included in the determination. See: http://www.whitehouse.gov/sites/default/files/omb/inforeg/eo12866.pdf .

- Executive Order 13422 (2007) (revoked by Executive Order 13497 (2009)). This executive order essentially put regulatory guidance under OIRA review.
- Executive Order 13563 (2011). Issued by President Obama, this executive order reaffirmed the principles and institutions for regulatory review in Executive Order 12866. It also directed agencies to undertake a comprehensive review of the benefits and costs of existing regulations.
- OMB Circular A-4. This instructs economists how to do economic analysis as required by the executive order. See: http://www.whitehouse.gov/omb/circulars_a004_a-4/.
- M-07-24, Memorandum for the Heads of Executive Departments and Agencies, Updated Principles for Risk Analysis, Office of Management and Budget and Office of Science and Technology Policy. This memorandum requires agencies to analyze the distribution of risks and the costs and benefits of risk-management strategies and outlines principles for risk assessment. See: http://www.whitehouse.gov/sites/default/files/omb/assets/omb/memoranda/fy2007/m07-24.pdf.