

Assessing Regulatory Costs and Benefits

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Synopsis: Efforts to reduce environmental hazards almost inevitably involve trading off expenditures on pollution abatement efforts with expenditures on other desired goods and services. As a result, many governments now require that agencies formally assess the impacts of their major environmental regulations, to determine whether the benefits of the resulting actions are likely to be commensurate with the costs. For example, when selecting among air pollution standards that vary in stringency, agencies may estimate the value of the associated mortality and morbidity risk reductions as well as the effects on the natural and built environment. These benefits can then be compared to the government and private industry expenditures required to comply with each set of standards. Such analyses may also present information on impacts that cannot be quantified or monetized and explore the uncertainty in the results. In addition, they can provide information on how the impacts are distributed across population subgroups, so that decision-makers can weigh the equity implications of the options as well as their economic efficiency. These analyses are one of many inputs into regulatory decisions, which must comply with legal requirements and often include substantial public involvement.

Keywords: Benefit-Cost Analysis; Compliance Costs; Cost-Effectiveness Analysis; Economic Analysis; Pollution Abatement; Regulation; Regulatory Impact Analysis; Quality-Adjusted Life Year; Willingness to Pay; Valuation.

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ASSESSING REGULATORY COSTS AND BENEFITS

Introduction

Efforts to reduce environmental hazards usually involve decisions to devote scarce resources to pollution abatement, which means that affected individuals, firms, and government agencies will not be able to use these resources to instead provide other desirable goods and services. As a result, many governments now require that agencies formally assess the impacts of their major environmental regulations, to determine whether it is likely that the benefits of their actions will be commensurate with the costs. These regulations may take a variety of forms, such as establishing permissible emission levels, creating tax incentives or trading systems, or requiring information collection and dissemination. Analyses of the benefits and costs of these actions are one of many inputs into the decision-making process.

In the United States (U.S.), the Office of Management and Budget (OMB) is responsible for reviewing proposed Federal regulatory actions and has developed guidelines for the accompanying analyses of costs and benefits. Historically, environmental regulations have represented the majority of the rules subject to the U.S. requirements for economic analysis, both in terms of the number of rules and the magnitude of the associated costs and benefits. Other countries, such as Canada and the United Kingdom (U.K.), as well as the European Union (E.U.), have developed similar processes and guidance for assessing environmental and other regulations.

Analytic Framework

Regulatory analyses estimate the costs, benefits, and other impacts of policy options for consideration by decision-makers and other interested parties. Their core is generally an economic analysis, which compares the costs and benefits of the options measured in monetary terms. In addition, a well-conducted analysis presents information on impacts that cannot be quantified or monetized and explores the uncertainty in the results. The estimates of total costs and benefits are often accompanied by information on how the impacts are distributed across key population subgroups (e.g., children, small businesses), so that decision-makers can weigh the equity implications of the options as well as their economic efficiency. In addition to providing summary measures of impacts, the analytic requirements establish a useful and rigorous framework for collecting, organizing, and reporting information on alternative policy choices. The information from these analyses is among the many factors considered in choosing among regulatory approaches, which may be constrained by legal requirements. These decisions also usually include substantial public involvement.

Environmental regulations are often designed to address inefficiencies in economic markets which occur when polluters do not bear the full social costs of their actions. Because the adverse effects of pollution on health and welfare are borne by other members of society, regulatory goals frequently involve ensuring that polluters take these external costs into account. For example, they may be required to meet specific emissions standards or to pay taxes for emissions.

Traditionally, benefit-cost analysis has been used to determine the net effect of these types of policies on overall societal well-being – regardless of who bears the costs or receives the benefits. It is based on the general principles of welfare economics, a key premise of which is that each individual is the best judge of his or her own welfare, often referred to as consumer sovereignty. Thus an individual's willingness to trade-off income (or wealth) for various improvements; i.e., his or her willingness to pay (WTP) for a good, service, health state, or environmental condition, is used to indicate its value. This value may exceed the market price, in which case the individual benefits from being able to acquire the improvement for an amount that is less than his or her WTP. If instead the market price exceeds an individual's WTP, he or she would not purchase the improvement. Individual WTP is summed across the affected population to indicate regulatory benefits; i.e., the value of a specific reduction in pollutant emissions and the resulting decreases in risks to human health and the environment.

A key component of these regulatory analyses involves identifying the option with the largest net benefits. From the perspective of overall social welfare, this is the preferred, or most economically efficient, policy option. Economists often argue that if regulatory decisions focus on investing scarce resources so as to maximize net welfare throughout the population, these decisions will collectively maximize overall well-being. Furthermore, they argue that it is preferable to directly address equity concerns through tax and income policies, rather than to use environmental (or other health and safety) regulations to promote changes in the distribution of monetary or other resources.

This separation between economic efficiency and equity has been hard to maintain in regulatory analysis, however, due to issues related to the perceived fairness of the analytic approach. For example, in the U.S., effects on human health and longevity are generally valued using population-wide averages, rather than values that vary depending on the preferences or characteristics of those affected, such as their age or income level. This approach reflects concern that doing otherwise might imply less than equal protection from environmental harms. Other countries sometimes diverge from this practice. For example, Canadian analyses at times adjust benefit values to reflect age-related differences in WTP for mortality risk reductions, and the U.K. guidance includes options for applying weights that address the distribution of income.

In addition to conducting benefit-cost analyses, agencies may assess the cost-effectiveness of potential interventions. Cost-effectiveness analyses involve dividing regulatory costs by a nonmonetary benefit measure, such as tons of pollution averted, to determine the cost per unit of benefit. Such assessments face several challenges. For example, while they provide information on the option that leads to the largest benefit per unit of expenditure, they do not indicate which option leads to benefits that exceed costs by the greatest amount. In addition, it is difficult to define effectiveness measures that encompass varied impacts. Although health researchers have developed quality-adjusted life year (QALY) measures to integrate consideration of different types of effects on morbidity and mortality, these measures are not entirely consistent with economic theory. Perhaps most importantly, they only reflect the trade-offs between different health states, not between expenditures on reducing health risks and other goods or services. In addition, non-health impacts, such as reductions in risks to ecological systems, are not incorporated into these benefit measures. Thus cost-effectiveness analysis is

often best viewed as a supplement to, rather than a substitute for, benefit-cost analysis of environmental policies.

Implementing benefit-cost analyses in the regulatory context involves several steps related to characterizing the affected universe with and without different policy interventions and determining the costs and benefits of each option. Typically, costs include the expenditures needed to comply with new requirements and their market effects, while benefits include the effects of reduced pollution on human health, the natural environment, and manufactured materials. The steps in these analyses are summarized in Figure 1 and briefly introduced below.

<< **Insert here, Figure 1, “Steps in conducting regulatory analysis.”** >>

- 1) **Estimate baseline conditions:** The first step in the analysis involves estimating current and future conditions in the absence of government intervention. It includes identifying and characterizing the potentially affected universe (e.g., the industrial facilities that may be required to implement new controls) and determining the pollution levels likely if no action is taken.
- 2) **Predict responses to each regulatory option:** The second step includes predicting the responses of the regulated entities to each regulatory (and non-regulatory) option under consideration. For example, this may include determining whether industrial facilities will install particular treatment technologies or change their production processes.
- 3) **Estimate changes in national costs:** The third step is to determine the total national costs attributable to each option, summing the costs of the predicted responses across those entities subject to the provisions. Conceptually, the correct approach to estimating these costs includes consideration of market impacts (e.g., changes in consumption due to price increases). However, in many cases these market effects are likely to be small, and analysts often simply sum compliance costs nationally.
- 4) **Estimate changes in national benefits:** The fourth step involves estimating the national benefits of the options, including the effects on human health and the natural and built environment. This is often the most complicated component of the analysis, because it requires assessing the link between changes in pollution levels and each health or environmental outcome of concern, taking into account how pollutants are transported through the environment and the resulting changes in exposure. The dollar values of these effects are then determined, based ideally on estimates of individual WTP. Ultimately, this step results in estimates of the physical changes (cases of illness or deaths averted, stream miles protected, corrosion averted, etc.) as well as of their monetary value.
- 5) **Assess distributional impacts:** While Steps 3 and 4 typically focus on the national effects of the regulations, decision-makers and stakeholders are also interested in the effects of the regulations or policies on specific groups, such as small businesses or sensitive sub-populations (e.g., children). Thus the analysis often identifies any disproportionate adverse effects.

Each of these steps involves a number of complex considerations, frequently requiring significant time and resources to complete. A well-conducted regulatory analysis will attempt to account for all costs and benefits that may be significant enough to affect the policy decision, discussing the implications of impacts that cannot be quantified and assessing related

uncertainties. It is not unusual for the analysis of a major U.S. environmental regulation to result in a several hundred page document that reflects work conducted by a large number of researchers over several years.

U.S. Government-Wide Guidance

In the U.S., the OMB (within the Executive Office of the President) is responsible for reviewing major Federal regulations and the supporting analyses. This role is rooted in the rapid expansion of environmental, health, and safety regulations in the late 1960s and early 1970s, which led to an increasing emphasis on evaluation. Initially, analytic requirements focused narrowly on specific types of impacts, particularly those related to the burden that environmental regulations impose on business. Over time, this focus broadened. In 1981, President Ronald Reagan issued Executive Order 12291, *Federal Regulation*, which substantially expanded the requirements for review and analysis and covered most major regulations. The requirements were updated in 1993 by President Clinton as Executive Order 12866, *Regulatory Planning and Review*. President George W. Bush then amended the requirements (under Executive Orders 13258 and 13422 in 2002 and 2007 respectively) to alter some aspects of the review process and to expand the scope to cover guidance documents as well as regulations.

Executive Order 12866 sets out the basic principles for decision-making and establishes a process for ensuring adherence to these principles. It indicates that regulations should be implemented only when required by law or to address a “compelling public need.” It notes that agencies should assess the benefits and costs of alternative approaches for those regulations identified as economically significant; i.e., actions for which the resulting rule is likely to “[h]ave 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 governments or communities.” The Executive Order also indicates that regulations should be designed to meet their goals in a cost-effective manner. It supports the selection of the option with the largest net benefits, and defines benefits broadly to include nonquantified impacts and equity considerations.

To implement the Executive Order, the OMB has issued a series of guidance documents, the most recent of which was published in 2003 as Circular A-4, *Regulatory Analysis*. This Circular provides both requirements that the OMB expects agencies to follow and information on preferred practices. It indicates that professional judgment plays an important role, recognizing that the agencies’ ability to adhere to these practices may be hampered by the limited scientific research available or other constraints. The Circular is also intended to help standardize how agencies estimate the benefits and costs of regulations. It emphasizes the need for transparency; i.e., for clear communication of the policy options, analytic approach, and results, including related uncertainties. Ultimately, the details of the analytic approach for a particular rule are negotiated between OMB and agency staff, as part of the OMB’s review of the rulemaking.

General Framework

The initial sections of Circular A-4 focus on determining whether Federal regulation is needed and identifying the different types of policy options to be considered. In general, it

suggests that non-regulatory options, or regulations at the state or local level, are preferable to Federal regulation. It notes that government intervention may be appropriate to address market failure or other social problems. Market failure occurs, for example, when an action imposes uncompensated costs or externalities on third parties, such as the health risks associated with pollution. Another example is the need to protect common property or public goods (such as fisheries) that may be overused in the absence of government controls. Agencies must describe the particular market failure being addressed as part of their analysis.

Circular A-4 encourages agencies to consider a wide range of options to address these concerns, including those that vary, for example, in terms of stringency and/or the nature of the requirements (e.g., providing information, creating market-based approaches, or establishing performance standards). These options are then compared to a baseline (sometimes referred to as the no action alternative), which represents current and potential future conditions in the absence of the regulation or policy. When statutory language limits the consideration of desirable alternatives, the Circular requires that the agency discuss these constraints and estimate their impacts.

Measurement of Costs and Benefits

After describing the types of interventions that should be considered, Circular A-4 discusses the general analytic framework, which includes both longstanding requirements for benefit-cost analysis and new requirements for cost-effectiveness analysis. It covers a number of issues that affect the analysis of both costs and benefits. Two key issues are discounting and the assessment of uncertainty. Discounting is used to adjust for the timing of the impacts when costs and benefits accrue during different periods or are distributed unevenly over time. It reflects the general preference for receiving benefits sooner rather than later, and for deferring adverse impacts. Circular A-4 requires that agencies present costs and benefits discounted at both seven and three percent rates (representing investment and consumption rates of time preference, respectively) as well as undiscounted, and discusses circumstances where other approaches may be used.

The Circular frequently emphasizes the need to report the uncertainty associated with the estimates, noting that in this context the term refers to incomplete knowledge regarding likely outcomes. It indicates that analysts should, as relevant, qualitatively discuss the main uncertainties in the calculations, use sensitivity analysis to assess the effects of changes in the approach on the resulting estimates, and apply probabilistic approaches such as simulation models and/or expert judgment. Formal probabilistic analysis is now required for all rules with impacts that exceed \$1 billion annually. Circular A-4 also emphasizes the importance of providing information on impacts that cannot be quantified or that can be quantified in physical terms but not assigned a monetary value.

A relatively lengthy section of the Circular is devoted to describing the monetary valuation of benefits, including separate discussions of the valuation of morbidity and mortality impacts. In general, it notes that estimates of individual WTP are the appropriate measure of benefit values, because such estimates reflect what members of society would be willing to give up to gain the benefits provided by the regulation. For benefits that are not directly bought and

sold in the marketplace, such as health risk reductions and environmental improvements, stated preference studies (e.g., surveys) or revealed preference studies (based on related market goods or consumer behaviors) are typically used to estimate their value. Circular A-4 provides detailed information on the use of these methods, including criteria for evaluating individual studies, and references other guidelines on information quality.

The Circular indicates that the assessment of costs should follow the same general guidance as the assessment of benefits, but devotes relatively little attention to the cost side of the analysis. It also provides an accounting statement for agencies to use to report the results of their analyses in a consistent format.

Circular A-4 includes new requirements for conducting cost-effectiveness analysis along with benefit-cost analysis for major environmental, health, and safety regulations. It notes a number of issues related to developing appropriate effectiveness measures (such as QALYs) for regulations that address a range of different health impacts, suggesting that the Institute of Medicine (IOM) be asked to address related issues. The IOM published its report in 2006, but the OMB has not yet responded to its recommendations.

In addition to estimating the total national impacts of the policy options, Circular A-4 notes that agencies should consider how these impacts are distributed across different segments of the population, including across generations. If the distribution of impacts is important in the context of a particular regulation, it specifies that the analysis should report disaggregated results that indicate the effects on different subgroups of concern. In this distributional analysis, analysts should consider both the allocation of total social costs and benefits (included in the national benefit-cost analysis) and of impacts that represent transfers between different subgroups. The Circular also briefly summarizes the requirements of several statutes and Executive Orders that mandate analyses of certain types of impacts (e.g., on energy use), including distributional effects (e.g., on small businesses or children). It notes that it is important to present the analytic results without judging their fairness, because in most cases there will be no general agreement on what constitutes an equitable distribution. It is then up to decision-makers to weigh these distributional impacts along with other policy considerations; the economic analysis is only one of several inputs into the regulatory decision-making process.

Relatively few economically significant rules are finalized each year that are subject to these requirements, but their impact is large. For example, the OMB indicates that between 1996 and 2006 it reviewed 91 rules with impacts equal to or exceeding \$100 million annually, for which monetary estimates of costs and benefits were available (OMB 2008). In total, the costs of these rules exceed \$39 billion per year and their monetized benefits exceed \$98 billion (2001 dollars). Rules promulgated by the U.S. Environmental Protection Agency (USEPA) dominated these totals. Of the 91 rules, it promulgated 39 (43 percent), and its rules accounted for more than 60 percent of the costs and an even greater share of the benefits. Most of these major USEPA rules address air pollution; a few address drinking water contaminants or other environmental concerns.

U.S. Environmental Protection Agency Practices

In the U.S., Federal responsibility for environmental protection is spread across several agencies; however, the USEPA is the chief agency involved in developing related regulations. It was established in 1970 with the mission of protecting human health and the environment, focusing largely on the prevention and control of pollution. To achieve this mission, the USEPA develops and enforces regulations, sponsors voluntary efforts, conducts research, and supports education. Regulatory development is largely the responsibility of four program offices: the Office of Air and Radiation, the Office of Water, the Office of Solid Waste and Emergency Response, and the Office of Prevention, Pesticides, and Toxic Substances. In addition, several other offices have cross-program responsibilities for related activities such as legal counsel, research, and methods development.

Guidance for Economic Analysis

The USEPA published detailed guidelines for the conduct of regulatory analysis in September 2000, which it is now updating to reflect new research as well as the requirements of the OMB's more recent Circular A-4. Its *Guidelines for Preparing Economic Analyses* generally follow the same framework as those developed by OMB, but provide more detailed discussion of each topic. The USEPA places a similar emphasis on applying best practices consistent with the underlying economic theory, using informed professional judgment to appropriately design and implement the analysis, and ensuring that the analytic methods, results, and effects of uncertainty are clearly communicated. In general, given the limited resources available for regulatory analysis, EPA encourages analysts to focus their efforts on those impacts that are expected to be significant enough to affect regulatory decisions.

The USEPA guidelines begin by discussing how to determine whether Federal regulatory action is needed and identify policy options, and then describe the general analytic framework. The guidelines discuss several issues in detail, including the approach for discounting future effects, for valuing benefits and costs, for assessing the distribution of the impacts, and for using the results in decision-making.

For regulatory costs, the USEPA discusses the analytic options extensively. The options range from only assessing compliance costs to determining how these costs affect supply and demand throughout the economy. For regulated industries, direct compliance costs include those related to purchasing, installing, and operating pollution control equipment, implementing changes in production processes, and improving waste management. Regulations also impose costs on government agencies for program administration, monitoring, and enforcement. The USEPA notes that regulations may have transitional effects, resulting in firm closures or unemployment. The analysis of the effects of regulatory costs may be modeled, for example, by only focusing on those industries that are most affected (partial equilibrium models) or by considering effects throughout the economy (general equilibrium modeling), depending on the nature and the magnitude of the impacts.

For regulatory benefits, the USEPA guidance explores in detail the approaches used to value health risks and other impacts. It introduces the theoretical framework, describes the analytic process, and discusses the valuation of morbidity and mortality risks as well as effects on amenities or aesthetics, on ecological health, and on materials. In each case it describes the methods available for valuation as well as the steps involved in implementing them.

The contents of the USEPA's guidelines were influenced at least in part by research undertaken to support its studies of the costs and benefits of the Clean Air Act (e.g., USEPA 1999). While these studies address a complete statutory program rather than the selection of regulatory options, they have acted as a catalyst for the development of analytic methods that are useful in a number of other contexts.

Examples of Recent Analyses

In recent years, most of the economically significant environmental rules subject to the OMB and USEPA guidelines have addressed air pollution, with a few addressing drinking water contaminants. For example, in 2006, the USEPA published its *Regulatory Impact Analysis for the National Ambient Air Quality Standards for Particle Pollution*, which provides more than 700 pages of detailed information and is supplemented by several other technical documents. It focuses on the National Ambient Air Quality Standards (NAAQS) for fine particulate matter, comparing the costs and benefits of the final standards to both less and more stringent options. While the Clean Air Act prohibits the Agency from considering costs when setting the standard, it assesses both costs and benefits to comply with the OMB's requirements and to inform the implementation process.

Assessing this and other air pollution rules involves complex modeling of future emissions and their effects on air quality. This modeling addresses air quality under baseline conditions, taking into account national, regional, state, and local regulations that have been adopted but not yet fully implemented. This baseline is then compared to air quality under each regulatory option, considering the impacts of illustrative strategies for each geographic area that will need to implement additional controls to meet the revised standards.

The USEPA estimates that the total social costs of meeting its revised 24 hour standard for fine particles (a reduction from 65 micrograms per cubic meter to 35 micrograms per cubic meter) will be \$5.4 billion (1999 dollars, 3 percent discount rate) in once the new standards are fully attained in the year 2020. This estimate includes the costs of purchasing and installing controls as well as the predicted effects on the overall economy (e.g., on national productivity). In addition to this national estimate, the USEPA reports the results broken out by emissions source (electrical power generation, mobile sources, and industrial or stationary sources) and by geographic region.

The benefit estimates cover a wide range, from \$9 billion to \$76 billion for the same time period, reflecting recent efforts to more fully account for the uncertainty in the relationship between exposure to fine particles and premature mortality. Based on a key epidemiological study, the USEPA's best estimate is that the rule will avert 2,500 premature deaths per year. If the assessment instead relies on concentration-response functions elicited from 12 experts, the

mean estimates range from 1,200 to 13,000 deaths per year. This range masks significant clustering of the experts' estimates, however. Elimination of the estimates from the two experts who report the highest and lowest mean values narrows the range, to 4,500 to 10,000 deaths annually.

Other quantified benefits include reductions in a variety of nonfatal health effects, consisting of 2,600 cases of chronic bronchitis, 5,000 nonfatal heart attacks, 1,630 hospital admissions for cardiovascular or respiratory symptoms, 1,200 emergency room visits for asthma, 7,300 cases of acute bronchitis, 97,000 cases of upper or lower respiratory symptoms, 51,000 cases of aggravated asthma, 350,000 days when individuals miss work or school, and 2 million days when people must restrict their activities because of particle pollution-related symptoms. The analysis also includes the value of improving visibility at selected national parks and wilderness areas. However, the value of averted premature mortality dominates the monetized benefit estimates. In total, monetized benefits exceed costs by an estimated \$3.6 billion to \$70.6 billion, reflecting the effects of the range of estimates for averted premature mortality from the expert elicitation. The USEPA also provides a detailed list of beneficial effects that could not be quantified (which would further increase the net benefits of the regulations); assesses uncertainty in both its cost and benefit estimates; and provides an illustrative cost-effectiveness analysis.

A second example is the USEPA's *Economic Analysis for the Final Stage 2 Disinfectants and Disinfection Byproducts Rule*, related to the disinfection of public drinking water supplies. The USEPA assessed alternative Maximum Contaminant Levels (MCLs) for total trihalomethanes, haloacetic acids, and bromate, as well as different options for compliance monitoring. This regulation involves considering off-setting risks, because some of the chemicals used for disinfection also pose risks to human health. The economic analysis is again a detailed document (over 1,200 pages in length), accompanied by several other technical reports. Under the Safe Drinking Water Act, the USEPA is allowed to take both costs and benefits into account, considering whether the MCL "maximizes health risk reduction benefits at a cost that is justified by the benefits."

The analysis, published in 2005, involves identifying the water systems of different types that will be affected by the regulatory options, and assessing the costs associated with implementing each option and with installing, operating, and monitoring new treatments. It also addresses the affordability of the costs across different sized systems as well as their impact per household. The quantified benefits include prevention of fatal and nonfatal cases of bladder cancer.

The USEPA estimates that the total cost of complying with the new MCLs is about \$79 million per year (2003 dollars, annualized using a 3 percent discount rate). The annualized quantifiable benefits range from \$763 million to \$1,531 million depending on the approach used to value nonfatal cases of bladder cancer. The annualized number of bladder cancer cases averted total 279, of which 26 percent are expected to be fatal. The USEPA notes that the rule is likely to affect the incidence of other cancers and of reproductive and developmental effects, but assesses these separately in illustrative analyses (rather than including them in the main benefits estimates) due to the limited research available. It also includes an illustrative analysis of the

cost-effectiveness of the regulations. Additional effects that could not be quantified are discussed in the text.

Canadian and European Practices

An increasing number of other countries have developed requirements for regulatory analysis. For example, a 2005 survey by the Organization for Economic Co-operation and Development (OECD) indicated that, of its 30 member countries, 25 required regulatory impact analysis and 15 required demonstration that the benefits of interventions justify their costs (OECD 2007). The OECD provides reports on the practices of different countries on its Regulatory Reform Programme website (<http://www.oecd.org/>). This section briefly summarizes the analytic requirements of selected countries in comparison to the U.S. practices discussed earlier, focusing on their formal guidance.

The Canadian government issued a new Cabinet Directive on Streamlining Regulation in 2007, establishing an updated framework for developing, implementing, evaluating, and reviewing regulations. The Directive references a number of guidance documents that address different aspects of this process, such as designing interventions, consulting with stakeholders, and assessing environment impacts. The specific requirements for regulatory impact analysis are described in detail in the interim *Canadian Cost-Benefit Analysis Guide: Regulatory Proposals* (2007). This document notes the importance of proportionality; i.e., of ensuring that the level of analysis is commensurate with the level of expected impacts. It refers to separate guidance on the triage of regulatory submissions, which provides a series of 13 questions that allow agencies to identify whether their actions are of low, medium, or high significance. These questions address impacts on health, safety, the environment, the economy, and other areas in both quantitative and qualitative terms. Generally, regulatory proposals of low significance (e.g., annual gross costs or savings of less than \$1 million Canadian) may be accompanied by only a brief analysis; proposals of medium significance (e.g., annual costs or savings between \$1 million and \$10 million Canadian) require a qualitative analysis accompanied by any readily available quantitative data; and, proposals of high significance (\$10 million and above) require a full regulatory analysis with impacts quantified to the extent possible.

The *Canadian Cost-Benefit Analysis Guide: Regulatory Proposals* parallels the U.S. guidance in several respects, discussing issues related to determining the need for government intervention, identifying alternative approaches, and assessing related impacts. It describes a five step process: (1) identify the issues and define the baseline scenario; (2) determine the policy objectives; (3) develop regulatory and non-regulatory options and determine their effects on the baseline; (4) assess the impacts, including both benefits and costs and an analysis of stakeholder and distributional effects; and, (5) prepare an accounting statement that summarizes the results. Similar to the U.S. guidance (and consistent with the theoretical framework underlying benefit-cost analysis), the guidance suggests that nonmarket benefits should be valued based on estimates of WTP, and that costs should reflect the real resources used for government administration and private sector compliance, including spillover or indirect costs on other sectors if significant.

In the United Kingdom (U.K.), the Better Regulation group, within the newly formed Department for Business Enterprise and Regulatory Reform, issued updated *Impact Assessment Guidance* in 2007. This guidance notes that impact assessment is a process, which starts with the initial identification of a policy problem and proceeds through determining the effects of interventions after they are implemented. It applies to a wide range of proposals that increase or decrease the costs imposed on the business, nonprofit, or public sector, that have redistributive effects, or that relate to legislation or international agreements. It emphasizes the need for the analysis to be proportionate to the problem being addressed.

The U.K. *Impact Assessment Guidance* primarily provides an overview of the general process and contents of the analysis, noting that it should address economic, social, and environmental impacts, expressed in monetary terms to the extent possible. More detailed guidance is provided via the *Impact Assessment Toolkit*, which is an on-line resource that leads analysts and others through the assessment process and provides links to a number of other relevant guidance documents. In particular, the 2003 *Green Book: Appraisal and Evaluation in Central Government*, provides detailed guidance on assessing costs and benefits for all types of policies and projects, while the 2005 report, *Managing Risks to the Public: Appraisal Guidance* focuses on the assessment of proposals that address the risks of fatality, injury, or other harm. These documents cover a number of different analytic approaches, including structured methods for developing qualitative information as well as quantitative approaches (i.e., cost-effectiveness and benefit-cost analysis). Within this broad scope, the U.K. guidance discusses many of the same issues as the U.S. and Canadian guidance, addressing the need for careful assessment of whether government intervention is needed and of a wide range of policy options, and discussing the advantages and limitations of different approaches to estimating costs, benefits, and other impacts.

The European Union (E.U.), of which the U.K. is a member, has also implemented a number of reforms to its regulatory review process in recent years. As the result of studies completed in 2001, it adopted requirements for regulatory analysis in 2002, which were revised in 2005 then updated in 2006. Under the E.U. structure, these requirements apply to legislation, not solely to regulations designed to implement statutory requirements. As a result, they are typically initiated early in the policy development process. Since 2006, the resulting analyses have been subject to review by the European Commission's Impact Assessment Board.

The E.U. *Impact Assessment Guidelines* are similar to the U.K. guidance in that they require assessment of economic, social, and environmental impacts, regardless of whether monetization is possible. The E.U. guidance also discusses the need for proportionate analysis, so that more detailed assessment is undertaken for more significant initiatives. It identifies six analytic steps: (1) defining the problem; (2) setting objectives; (3) identifying policy options; (4) assessing economic, social, and environmental impacts; (5) comparing the options; and (6) considering future monitoring and evaluation. It covers a number of different approaches for assessing costs, benefits and other impacts both qualitatively and quantitatively, allowing analysts to choose the approach most appropriate in a given context.

Although each of these guidance documents differs in details and emphasis, all share some common themes, as summarized in Table 1. In addition to the concerns listed, each

document also discusses the need for involving stakeholders and requires various types of formal review. Although the table focuses on regulatory analysis, the European guidelines also address other types of policy decisions, as noted above.

<< Insert here, Box 1, “Common themes...” >>

In general, the goal of these analyses is to promote thoughtful consideration of the likely impacts of different policy options before they are implemented. Such consideration requires both careful data collection and analysis and clear communication of the results and associated uncertainties. While governments vary in how they document related requirements and in the extent to which they mandate specific approaches, their guidance documents focus on ensuring that appropriate analytic tools are used to estimate the costs and benefits of alternative approaches and the distribution of the impacts throughout the affected population.

See Also:

221, 224, 290, 301-310, 414, 441-444, 621

Further Reading

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Web-based Resources

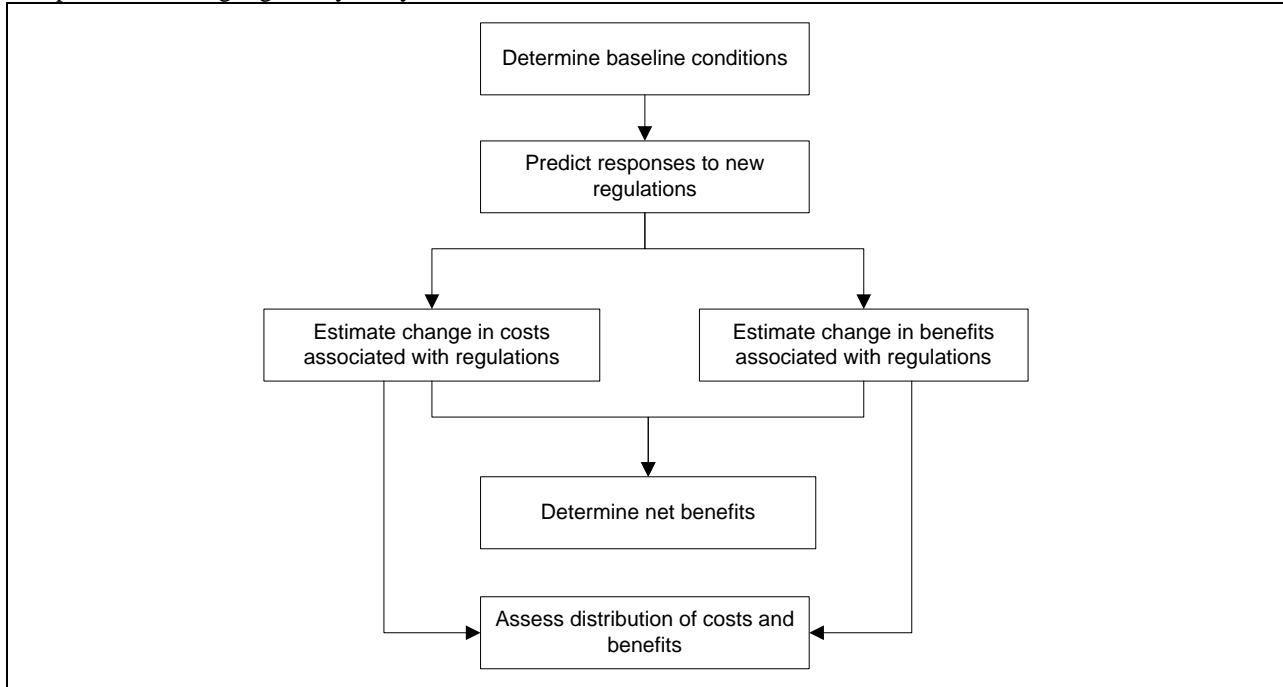
Center for Regulatory and Market Studies, American Enterprise Institute, 1150 Seventeenth St., N.W., Suite 1100, Washington, D.C. 20036, USA. Web: <http://www.reg-markets.org/>.
Department for Business, Enterprise and Regulatory Reform, United Kingdom, 1 Victoria Street, London SW1H0ET, England. Web: <http://www.berr.gov.uk/>
Impact Assessment Board, European Commission, Secretariat-General, B-1049 Brussels, Belgium. Web: http://ec.europa.eu/governance/impact/iab_en.htm.
Regulatory Affairs Directorate, Government Canada, 155 Queen Street, Ottawa, ON, K1A 0R5, Canada. Web: <http://www.regulation.gc.ca/>.
Regulatory Reform Programme, Organization for Economic Co-operation and Development, 2, rue André Pascal, F-75775 Paris Cedex 16, France. Web: <http://www.oecd.org/>.
Resources for the Future, 1616 P Street NW, Washington, DC 20036, USA. Web: <http://www.rff.org/>.
U.S. Environmental Protection Agency, Washington, DC, 20460, USA. Web: <http://www.epa.gov/>.
U.S. Office of Management and Budget, 725 17th Street, NW, Washington, DC 20503, USA. Web: <http://www.whitehouse.gov/omb/>.

Abbreviations

IOM:	Institute of Medicine
MCL:	Maximum Contaminant Level
NAAQS:	National Ambient Air Quality Standards
OECD:	Organization for Economic Co-operation and Development
OMB:	Office of Management and Budget (U.S.)
QALY:	Quality Adjusted Life Year
USEPA:	U.S. Environmental Protection Agency
WTP:	willingness to pay

Figure 1

Steps in conducting regulatory analysis.



Box 1

Common themes in U.S., Canadian, and European guidance for regulatory analysis

1. The government should intervene only when necessary to address compelling problems that cannot be otherwise resolved.
2. Agencies should consider a range of regulatory and non-regulatory options, including the “no action” alternative.
3. The costs, benefits, and other impacts of each option should be assessed in comparison to current and likely future conditions in the absence of the intervention.
4. Costs and benefits should include both the direct impacts of the policy and any significant secondary or indirect impacts.
5. The analysis should identify the option most likely to lead to the largest net benefits, and also address non-quantifiable effects, uncertainty, cost-effectiveness, and the distribution of the impacts.
6. The analysis, its results, and its limitations should be clearly communicated; a summary should be provided using a standardized format.
7. The results of the analysis should inform rather than dictate the policy decision, which must take into account a number of other factors.