

Regulatory Impact Analysis: A Primer

With this document, the Office of Information and Regulatory Affairs is providing a primer to assist agencies in developing regulatory impact analyses (RIAs), as required for economically significant rules by Executive Order 13563, Executive Order 12866, and OMB Circular A-4.¹

In accordance with those requirements, agencies should include the information described below in their RIAs. This primer is limited to the requirements of Executive Order 13563,² Executive Order 12866,³ and Circular A-4⁴; it does not address requirements imposed by other authorities, such as the National Environmental Policy Act, the Regulatory Flexibility Act, the Unfunded Mandates Reform Act, the Paperwork Reduction Act, and various Executive Orders that require analysis. Executive Order 13563, Executive Order 12866, and Circular A-4, as well as those other authorities, should be consulted for further information.

The purpose of this primer is to offer a summary of the requirements of OMB Circular A-4. The primer is not meant to be a substitute for the more detailed description in that Circular. Nothing in this primer is intended to alter existing requirements or policy.

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¹ Agencies may also find “Regulatory Impact Analysis: Frequently Asked Questions” (http://www.whitehouse.gov/sites/default/files/omb/circulars/a004/a-4_FAQ.pdf) and “Agency Checklist: Regulatory Impact Analysis” (http://www.whitehouse.gov/sites/default/files/omb/inforeg/regpol/RIA_Checklist.pdf), helpful as well.

² Available at: http://www.reginfo.gov/public/jsp/Utilities/EO_13563.pdf

³ Available at: http://www.reginfo.gov/public/jsp/Utilities/EO_12866.pdf

⁴ Available at: <http://www.whitehouse.gov/sites/default/files/omb/assets/omb/circulars/a004/a-4.pdf>

A. Introduction

Executive Orders 13563 and 12866 require agencies to provide to the public and to OMB a careful and transparent analysis of the anticipated consequences of economically significant regulatory actions. This analysis includes an assessment and (to the extent feasible) a quantification and monetization of benefits and costs anticipated to result from the proposed action and from alternative regulatory actions. Executive Order 13563 specifically requires agencies “to use the best available techniques to quantify anticipated present and future benefits and costs as accurately as possible.”

The purpose of the RIA is to inform agency decisions in advance of regulatory actions and to ensure that regulatory choices are made after appropriate consideration of the likely consequences. To the extent permitted by law, agencies should proceed only on the basis of a reasoned determination that the benefits justify the costs (recognizing that some benefits and costs are difficult to quantify). Regulatory analysis also has an important democratic function; it promotes accountability and transparency and is a central part of open government.

Important goals of regulatory analysis are (1) to establish whether federal regulation is necessary and justified to achieve a social goal and (2) to clarify how to design regulations in the most efficient, least burdensome, and most cost-effective manner. To that end, Executive Orders 13563 and 12866 require agencies to consider a range of regulatory alternatives, including the option of not regulating, and to design their regulations in the most cost-effective manner to achieve the regulatory objective. Agencies should select the alternative that maximizes net benefits, while also taking into consideration distributive impacts and qualitative benefits and costs, unless a statute requires another approach.

B. Key Elements of a Regulatory Impact Analysis

An RIA should include the following three basic elements:

A statement of the need for the regulatory action: An analysis should begin with a clear explanation of the need for the regulatory action, including a description of the problem that the agency seeks to address. Agencies should explain whether the action is intended to address a market failure or to promote some other goal, such as improving governmental processes, protecting privacy, or combating discrimination. If the action is compelled by statute or judicial directive, agencies should describe the specific authority and the extent of discretion permitted.

A clear identification of a range of regulatory approaches: If an agency has decided that Federal regulation is appropriate, it should identify and include in its RIA a range of alternative regulatory approaches, including the option of not regulating. Alternatives to Federal regulation include State or local regulation, voluntary action on the part of the private sector, antitrust enforcement, consumer-initiated litigation in the product liability system, and administrative compensation systems. Where relevant, agencies should consider flexible approaches that reduce burdens and maintain freedom of choice, such as warnings, appropriate default rules, and

disclosure requirements. To the extent feasible, agencies should specify performance objectives, rather than specifying the behavior or manner of compliance that regulated entities must adopt.

An estimate of the benefits and costs—both quantitative and qualitative—of the proposed regulatory action and its alternatives: After identifying a set of potential regulatory approaches, the agency should conduct a benefit-cost analysis that estimates the benefits and costs associated with each alternative approach. The benefits and costs should be quantified and monetized to the extent possible, and presented in both physical units (e.g., number of illnesses avoided) and monetary terms. When quantification of a particular benefit or cost is not possible, it should be described qualitatively. The analysis of these alternatives may also consider, where relevant and appropriate, values such as equity, human dignity, fairness, potential distributive impacts, privacy, and personal freedom.

The agency's analysis should be based on the best available scientific, technical, and economic information. To achieve this goal, the agency should generally rely on peer-reviewed literature, where available, and provide the source for all original information. In cases of particular complexity or novelty, the agency should consider subjecting its analytic models to peer review.⁵ In cases in which there is no reliable data or research on relevant issues, the agency should consider developing the necessary data and research. In addition, the agency should comply with the Information Quality Guidelines for the agency and with OMB's "Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies."⁶ Executive Order 13563 also provides that "[c]onsistent with the President's Memorandum for the Heads of Executive Departments and Agencies, 'Scientific Integrity' (March 9, 2009), and its implementing guidance, each agency shall ensure the objectivity of any scientific and technological information and processes used to support the agency's regulatory actions."

The agency should clearly document all of the assumptions and methods used in the analysis, discuss the uncertainties associated with estimates, and publicly provide the supporting data and underlying analysis (if possible on the Internet; see Executive Order 13563, section 2 (b)), so that a qualified third party reading the analysis could understand and reproduce the analysis. Regulatory analysis should also include a clear, plain language executive summary, including a table, that summarizes the benefit and cost estimates for each regulatory action and alternative under consideration, including the qualitative and non-monetized benefits and costs.⁷

C. Preparing a Regulatory Impact Analysis

This section provides a step-by-step guide to preparing an RIA. The three key elements discussed in the previous section are important; this section focuses primarily on the benefit and

⁵ For additional discussion, see OMB's "Final Information Quality Bulletin for Peer Review", available at: http://www.whitehouse.gov/sites/default/files/omb/assets/omb/fedreg/2005/011405_peer.pdf

⁶ Available at http://www.whitehouse.gov/omb/fedreg_reproducible/

⁷ For additional discussion, see 2010 Report to Congress on the Benefits and Costs of Federal Regulations and Unfunded Mandates on State, Local, and Tribal Entities, page 51. Available at: http://www.whitehouse.gov/sites/default/files/omb/legislative/reports/2010_Benefit_Cost_Report.pdf

cost assessment of regulatory alternatives required by Executive Order 13563, Executive Order 12866, and Circular A-4.

Benefit-cost analysis (BCA) provides a systematic framework for evaluating the likely outcomes of alternative regulatory choices. It allows agencies to evaluate different regulatory options with a variety of attributes using a common measure – a monetary unit. When important benefits and costs cannot be expressed in monetary units or quantified in any manner, the BCA can provide useful information about the relative merits of regulatory alternatives, but the “net benefits” estimate, viewed in isolation, may be incomplete and misleading.

To provide a complete RIA, agencies should follow these steps:

- Describe the need for the regulatory action
- Define the baseline
- Set the timeframe of analysis
- Identify a range of regulatory alternatives
- Identify the consequences of regulatory alternatives
- Quantify and monetize the benefits and costs
- Discount future benefits and costs
- Evaluate non-quantified and non-monetized benefits and costs
- Characterize uncertainty in benefits, costs, and net benefits

Below we provide additional information for each of these steps.

Step 1: Describe the need for the regulatory action

As discussed in the previous section, an analysis should begin with a reasonably detailed description of the need for the regulatory action and should include an explanation of how the regulatory action will meet that need. The RIA should explain whether the action is intended to address a significant market failure (e.g., externality, market power, and inadequate or asymmetric information) or to meet some other compelling public need such as improving governmental processes or promoting values such as privacy or human dignity. If the regulation is designed to correct a significant market failure, the RIA should describe the failure both qualitatively and (where feasible) quantitatively. If a regulation is required by statute or judicial directive, the RIA should clearly explain the specific authority, extent of agency discretion, and permissible regulatory instruments.

Step 2: Define the Baseline

The baseline represents the agency’s best assessment of what the world would be like absent the action. To specify the baseline, the agency may need to consider a wide range of factors and should incorporate the agency’s best forecast of how the world will change in the future, with particular attention to factors that affect the expected benefits and costs of the rule. For example, population growth, economic growth, and the evolution of the relevant markets should all be taken into account. For regulations that largely restate statutory requirements, the analysis

should use a pre-statutory baseline. For analyses supporting modifications to an existing regulation, a baseline assuming no change in the regulatory program generally provides an appropriate basis for evaluating regulatory alternatives.

The analysis should focus on benefits and costs that accrue to citizens and residents of the United States. Where the agency chooses to evaluate a regulation that is likely to have effects beyond the borders of the United States, these effects should be reported separately.

Step 3: Set the Time Horizon of Analysis

When choosing the appropriate time horizon for estimating benefits and costs, agencies should consider how long the regulation being analyzed is likely to have economic effects. The time frame for the analysis should cover a period long enough to encompass all the important benefits and costs likely to result from the rule. However, the agency should also consider for how long it can reasonably predict the future and should limit its analysis to that time period. Thus, if a regulation has no predetermined sunset provision, the agency will need to choose the endpoint of its analysis based on the foreseeable future or the agency's ability to forecast reliably. For rules that require large up-front capital investments, the life of the capital is also an option.

Step 4: Identify a Range of Regulatory Alternatives

The agency should consider a range of potentially effective and reasonably feasible regulatory alternatives. The relevant alternatives might involve different approaches, with distinct advantages and disadvantages. In considering which alternatives to discuss, an agency should reasonably explore which approaches are feasible and plausible ways of meeting the regulatory objective. An agency should give particular attention to identifying and assessing flexible regulatory approaches, 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.

Consistent with Executive Order 13563, section 4, an agency might consider flexible approaches that maintain freedom of choice. If, for example, an agency is considering banning the sale of a potentially unsafe product, it might consider instead requiring disclosure of health risks to the public. Once an agency identifies the least burdensome tool for achieving its regulatory objective, measuring the incremental benefits and costs of successively more stringent regulatory alternatives will allow an agency to identify the alternative that maximizes net benefits.

Agencies should consider any of the following, alone or in combination, to develop regulatory alternatives:

- *Deferral to state or local regulation.* Agencies should consider the option of deferring to regulation at the State or local level. To be sure, problems that affect interstate commerce or spill across State lines may best be addressed by Federal regulation. But more localized problems may be more efficiently addressed locally. In such situations,

deferring to state and local regulation can encourage regulatory experimentation and innovation while also fostering learning and competition to establish the best regulatory policies.

- *Market-oriented approaches rather than direct controls.* Agencies should consider market-oriented regulatory approaches that use economic incentives to achieve regulatory goals and that afford entities greater flexibility in compliance. Such approaches include fees, penalties, subsidies, marketable permits or offsets, changes in liability rules or property rights, and required bonds, insurance, or warranties. In the domain of environmental protection, for example, emissions trading may deserve careful consideration as an approach that might achieve the same gain at a significantly lower cost.
- *Performance standards rather than design standards.* Performance standards express requirements in terms of outcomes, for example requiring achievement of a particular emissions level. By contrast, design standards specify the means to achieve those outcomes, for example requiring installation of a particular emissions control technology. Because they allow firms to have the flexibility to choose the most cost-effective methods for achieving the regulatory goal, and create an incentive for innovative solutions, performance standards are generally preferred to design standards.
- *Informational Measures.* If intervention is contemplated to address a market failure that arises from inadequate or asymmetric information or poor information processing, informational remedies will often be preferred. To the extent feasible, specific informational measures should be evaluated with reference to their benefits and costs.
- *Default rules rather than mandates.* Agencies should consider whether default rules are a better instrument than mandates for achieving regulatory objectives. If, for example, there is significant heterogeneity in the relevant population, a default rule may be preferable to a mandate because it allows people to act in ways that are suited to their own situations.
- *Enforcement Methods.* Alternative monitoring (e.g., Federal, State, or local authorities) and reporting methods (e.g., on-site inspections, periodic reporting, and noncompliance penalties) may vary in their benefits and costs.
- *Stringency.* Typically both the benefits and costs associated with a regulation will increase with the level of stringency. Agencies should study alternative levels of stringency to determine the level that maximizes net benefits.
- *Compliance dates.* The timing of a regulation can have an important effect on its net benefits. Agencies should consider various possible compliance dates, because (for example) a later date might, in some circumstances, promote predictability and significantly reduce compliance costs without greatly reducing benefits.
- *Requirements based on firm size.* If the expected costs or the expected benefits of compliance vary based on firm size, different requirements for large and small firms, based on these estimated differences, may be appropriate. Greater flexibility for small business, in the form of delayed compliance dates or partial or total exemptions, is worth careful consideration. At the same time, agencies should consider whether such differences in regulatory treatment provide one group of firms with a competitive advantage over others, create artificial incentives to keep firm sizes small (and thus deter hiring), or lead to foregone benefits that exceed the cost savings to exempted firms.

- *Requirements based on geographic regions.* Where there are significant regional variations in benefits and/or costs, agencies should consider setting different requirements for different regions to maximize net benefits.

At a minimum, agencies should compare, with their preferred option, a more stringent and less stringent alternative, and assess the benefits and costs of the three possibilities, with careful consideration of which achieves the greatest net benefits. And when the preferred option includes a number of distinct provisions, the benefits and costs of different regulatory provisions should be analyzed separately in order to facilitate consideration of the full range of potential alternatives.

Step 5: Identify the Consequences of Regulatory Alternatives

Benefits and costs. Agencies should identify the potential benefits and costs for each alternative and its timing. It may be useful to identify the benefits and costs in the following manner:

- Benefits and costs that can be monetized, and their timing;
- Benefits and costs that can be quantified, but not monetized, and their timing;
- Benefits and costs that cannot be quantified.

In addition to the direct benefits and costs of each alternative, the list should include any important ancillary benefits and countervailing risks. An ancillary benefit is a favorable impact of the alternative under consideration that is typically unrelated or secondary to the purpose of the action (e.g., reduced refinery emissions due to more stringent fuel economy standards for light trucks). A countervailing risk is an adverse economic, health, safety, or environmental consequence that results from a regulatory action and is not already accounted for in the direct cost of the action (e.g., adverse safety impacts from more stringent fuel-economy standards for light trucks). As with other benefits and costs, an effort should be made to quantify and monetize both ancillary benefits and countervailing risks.

Distributional effects. Those who bear the costs of a regulation and those who enjoy its benefits often are not the same people. The term "distributional effect" refers to the impact of a regulatory action across the population and economy, divided up in various ways (e.g., income groups, race, sex, industrial sector, geography).

The regulatory analysis should provide a separate description of distributional effects (i.e., how both benefits and costs are distributed among sub-populations of particular concern) so that decision makers can properly consider them along with the effects on economic efficiency (i.e., net benefits). Executive Order 13563 and Executive 12866 authorize this approach. Where distributive effects are thought to be important, the effects of various regulatory alternatives should be described quantitatively to the extent possible, including the magnitude, likelihood, and severity of impacts on particular groups.

Examples of distributional effects that could potentially be quantified include:

- Health benefits that accrue principally to low-income groups
- Regulatory costs that are imposed principally on low-income groups
- Reductions in sales by one business that are matched by increases in sales by another (transfer in economic activity from one business to another)
- Reductions in well-being for some consumers that are matched by increases for others (transfer of well-being among consumers)

Transfer payments. Distributional effects may arise through "transfer payments" that stem from a regulatory action as well. Transfer payments are monetary payments from one group to another that do not affect total resources available to society. For example, transfers payments include revenue collected through a fee, a surcharge in excess of the cost of services provided, and a tax.

Distinguishing between real costs and transfer payments is an important, but sometimes difficult, problem in cost estimation. A stylized example may help to clarify. Consider a regulation that taxes an air pollutant that is harmful to human health and is a by-product of some manufacturing process. In response to the tax, firms modify their manufacturing process to reduce (but not eliminate) the pollutant. The benefits of the regulation are reductions in premature death, illness, and disability resulting from the decreased emission of the regulated pollutant, as well as benefits to ecosystems, improvements in visibility, and so on. The cost of the regulation is equal to the cost to firms of modifying their production process (e.g., purchasing abatement technology). The taxes paid on the pollutant by the firm to the government are a transfer and have no effect on the net benefits of the regulation.

Examples of costs include:

- Goods and services required to comply with the regulation
- Reductions in consumer and producer well-being due to regulation-induced price or quantity changes
- Increases in premature death, illness, or disability (e.g., in the case where a regulatory proposal that would reduce certain safety and/or health risks would also have the consequence of increasing other safety and/or health risks).

Examples of transfer payments include:

- Changes in sales tax revenue due to changes in sales (monetary transfers from consumers to government)
- Payment by the Federal government for goods or services provided by the private sector (monetary transfers to the government to service providers, such as reimbursements by the Medicare program)
- Fees to government agencies for goods or services provided by the agency (monetary transfers from fee payers to the government—the goods and services are already counted as government costs and including them as private costs would entail double counting)

Step 6: Quantify and Monetize the Benefits and Costs

The agency should use the best reasonably obtainable scientific, technical, economic, and other information to quantify the likely benefits and costs of each regulatory alternative. Presenting benefits and costs in physical units in addition to monetary units will improve the transparency of the analysis. For example, the benefits of a regulation that reduces emissions of air pollution might be quantified in terms of the number of premature deaths avoided each year; the number of prevented nonfatal illnesses and hospitalizations; the number of prevented lost work or school days; improvements in visibility in specific regions; and improvements in ecosystem health as measured by specific indicators (e.g. lake acidification). Some costs – such as countervailing risks – may also be quantified in similar terms before they are turned into monetary equivalents.

As discussed in greater detail below, the agency should, to the extent feasible, estimate the monetary value of the benefits and costs of each regulatory alternative considered. Both benefits and costs are measured by the value that individuals place on the change resulting from a particular regulatory alternative. This value is typically and most easily measured in terms of the amount of money the individual would pay (“willingness to pay” (WTP)) or require as compensation (“willingness to accept” (WTA)), so that the individual is indifferent between the current state of the world (baseline), on the one hand, and the consequences of the regulatory alternative along with the monetary payment, on the other hand.

To the extent possible, agencies should estimate people’s valuations of benefits and costs using revealed preference studies based on actual behavior. Revealed preference methods develop estimates of the value of goods and services — or attributes of those goods and services — based on actual market decisions by consumers, workers, and other market participants. If the market participant is well-informed and confronted with a real choice, and properly processes information, it may be feasible to determine accurately and precisely the monetary value of the changes associated with an alternative.

If the goods or attributes of goods that are affected by regulation — such as preserving environmental or cultural amenities — are not traded in markets, it may be difficult to use revealed preference methods. In such cases, the value of the goods or attributes may arise both from use and non-use. “Use values” arise where an individual derives satisfaction from using the resource, either now or in the future, for example by living in or moving to a neighborhood with clean air or water. “Non-use values” arise where an individual places value on a resource, good, or service even though the individual will not use the resource, now or in the future, for example by valuing wildlife in remote areas.

In the absence of an organized market, it is difficult to estimate use and non-use values. When studies are designed to elicit such values either through indirect market studies or stated preference methods, agencies should pay careful attention to characterization of the uncertainties. However, overlooking or ignoring these values may significantly understate the benefits and/or costs of regulatory action.

Agencies should include the following effects, where relevant, in their analysis and provide estimates of their monetary values:

- Private-sector compliance costs and savings;
- Government administrative costs and savings;
- Gains or losses in consumers' or producers' surpluses;
- Discomfort or inconvenience benefits and costs; and
- Gains or losses of time in work, leisure, and/or commuting/travel settings.

To improve the transparency of the analysis, monetary values of distinct benefits and costs should be presented separately, in addition to being summed and presented as total benefits and total costs.

Considerations in monetizing health and safety effects

In monetizing health and safety benefits, the agency should use the WTP measure (or, if appropriate, the WTA measure), rather than other alternatives (e.g., avoided cost of illness or avoided lost earnings). This is because WTP/WTA attempts to capture pain and suffering and other quality-of-life effects.

When monetizing nonfatal health effects, the agency should consider two factors: (1) the private demand for prevention of the nonfatal health effect, to be represented by the preferences of the target population at risk and (2) the net financial externalities associated with poor health, such as net changes in public medical costs and any net changes in economic production that are not experienced by the target population. Revealed-preference or stated-preference studies are necessary to estimate the private demand; health economics data from published sources can typically be used to estimate the financial externalities caused by changes in health status. If an agency uses literature values to monetize nonfatal health and safety risks, it is important to make sure that the values selected are appropriate for the severity and duration of health effects to be addressed by the alternative under consideration.

Since agencies often design health and safety regulation to reduce risks to life, evaluation of the benefits of reducing fatality risks can be the key part of the analysis. The goal of this analysis is to monetize the value of small changes in fatality risk – a measurement of WTP for reductions in only small risks of premature death. This concept is commonly referred to as the "value of statistical life" (VSL).⁸ A considerable body of academic literature is available on this subject. Current agency practice provides a VSL ranging from roughly \$5 million to \$9 million per statistical life.

Another approach to express reductions in fatality risks is to use the life expectancy method, the "value of statistical life-years (VSLY) extended." If a regulation protects individuals whose average remaining life expectancy is 40 years, a risk reduction of one fatality is expressed as "40

⁸ The term "value of life" is sometimes used to describe this concept. However, this term can be misleading because it suggests, erroneously, that the monetization exercise tries to place a "value" on individual lives. Use of VSL should not suggest that the value of any individual's life can be expressed in monetary terms. The sole purpose is to help estimate the likely benefits of a regulatory action that reduces the risks that people face.

life-years extended." Those who favor this alternative approach emphasize that the value of a statistical life is not a single number relevant for all situations. In particular, when there are significant differences between the effect on life expectancy for the population affected by a particular health risk and the populations studied in the labor market studies, they prefer to adopt a VSLY approach to reflect those differences. It is appropriate to consider providing estimates of both VSL and VSLY, while recognizing the developing state of knowledge in this area.

Step 7: Discount Future Benefits and Costs

The benefits and costs of a regulatory action typically take place in the future. Moreover, benefits and costs may not be distributed across time in the same manner. For example, a common challenge in evaluating alternatives that have health-related consequences is to quantify the time lag between when an action would take effect and when the resulting change in health status will be observed.

To provide an accurate assessment of benefits and costs that occur at different points in time or over different time horizons, an agency should use discounting. Agencies should provide benefit and cost estimates using both 3 percent and 7 percent annual discount rates expressed as a present value as well as annualized. These are "real" interest rates that should be used to discount benefits and costs measured in constant dollars. Unlike typical market interest rates, real rates exclude the expected rate of future price inflation.

The 7 percent rate is an estimate of the average before-tax rate of return to private capital in the U.S. economy, based on historical data. It is a broad measure that reflects the returns to real estate and small business capital as well as corporate capital. It approximates the opportunity cost of capital, and it is the appropriate discount rate whenever the main effect of a regulation is to displace or alter the use of capital in the private sector.

The 3 percent discount rate is based on a recognition that the effects of regulation do not always fall exclusively or primarily on the allocation of capital. When regulation primarily and directly affects private consumption, a lower discount rate is appropriate. The alternative most often used is sometimes called the "social rate of time preference." This term simply means the rate at which "society" discounts future consumption flows to their present value. If one assumes the rate that the average saver uses to discount future consumption is a measure of the social rate of time preference, the real rate of return on long-term government debt may provide a fair approximation. Over the last thirty years, this rate has averaged around 3 percent in real annual terms on a pre-tax basis.

Special considerations arise when comparing benefits and costs across generations. Although most people demonstrate time preference in their own consumption behavior, it may not be appropriate for society to demonstrate a similar preference when deciding between the well-being of current and future generations. Future citizens who are affected by such choices cannot take part in making them, and today's society must act with due consideration of their interests. Many people have argued for a principle of intergenerational neutrality, which would mean that those in the present generation would not treat those in later generations as worthy of less

concern. Discounting the welfare of future generations at 7 percent or even 3 percent could create serious ethical problems.

An additional reason for discounting the benefits and costs accruing to future generations at a lower rate is the longer the horizon for the analysis, the greater the uncertainty about the appropriate value of the discount rate. Private market rates provide a reliable reference for determining how society values time within a generation, but for extremely long time periods no comparable private rates exist. As several economists (including Martin Weitzman⁹) have explained, for the very distant future, the properly averaged discount factor corresponds to the minimum discount rate having any substantial positive probability.

At the same time, some economists have cautioned that using a zero discount rate could raise intractable analytical problems. They have argued that with zero discounting, even a small improvement in welfare, if permanent, would justify imposing any cost on current generations since the benefits would be infinite.

If the regulatory action will have important intergenerational benefits or costs, the agency might consider a sensitivity analysis using a lower but positive discount rate, ranging from 1 to 3 percent, in addition to calculating net benefits using discount rates of 3 percent and 7 percent.

Step 8: Evaluate Non-quantified and Non-monetized Benefits and Costs

Sound quantitative estimates of benefits and costs, where feasible, are preferable to qualitative descriptions of benefits and costs because they help decision-makers to understand the magnitudes of the effects of alternative actions and compare across different types of consequences. However, some important benefits and costs (e.g., protection of human dignity, equity, or privacy, see Executive Order 13563, section 1(c)) may be difficult or impossible to quantify or monetize given current data and methods. Agencies should carry out a careful evaluation of non-quantifiable and non-monetized benefits and costs.

Benefits and costs that are difficult to monetize. If monetization is not possible, the agency should explain why and present all available quantitative information. For example, an agency may not be able to monetize a benefit in terms of privacy or dignity, but it may be able to quantify the number of beneficiaries. Alternatively, an agency may be able to quantify, but not to monetize, increases in water quality and fish populations resulting from water quality regulation. If so, the agency should attempt to describe benefits in terms of (for example) stream miles of improved water quality for boaters and increases in game fish populations for anglers. When estimates of monetized effects and quantified physical effects are mixed in the same analysis, the agency should describe the timing and likelihood of such effects, and should avoid double-counting of effects.

⁹ Weitzman ML In Portney PR and Weyant JP, eds. (1999), *Discounting and Intergenerational Equity*, Resources for the Future, Washington, DC.

Benefits and costs that are difficult to quantify. If the agency cannot quantify a benefit or cost, the agency should explain why and present any available quantitative information. For example, the agency may not be able to quantify the number of individuals exposed to a risk but may be able to quantify the magnitude of the risk to those who are exposed. The agency should also provide a detailed qualitative description of any unquantified effects, such as ecological gains, improvements in quality of life, and aesthetic beauty. The agency should provide a discussion of the strengths and limitations of the qualitative information.

When the unquantified benefits or costs affect a policy choice, the agency should provide a clear explanation of the rationale behind the choice. Such an explanation could include detailed information on the nature, timing, likelihood, location, and distribution of the unquantified benefits and costs. The agency should include a summary table that lists all significant unquantified benefits and costs, highlighting (e.g., with categories or rank ordering) those that the agency believes are most important (e.g., by considering factors such as the degree of certainty, expected magnitude, and reversibility of effects).

Breakeven analysis. When quantification and monetization are not possible, many agencies have found it both useful and informative to engage in threshold or “breakeven” analysis. This approach answers the question, “How large would the value of the non-quantified benefits have to be for the rule to yield positive net benefits?” Suppose, for example, that a regulation that protects water quality costs \$105 million annually, and that it also has significant effects in reducing pollution in rivers and streams. It is clear that the benefits of the regulation would exceed its costs if and only if those effects could reasonably be valued at \$105 million or more. Once the nature and extent of the water quality benefits are understood, it might well be easy to see whether or not the benefits plausibly exceed the costs – and if the question is difficult, at least it would be clear why it is difficult. Breakeven analysis is an important tool, and it can provide insights when quantification is speculative or impossible.¹⁰

Cost-effectiveness analysis. Cost-effectiveness analysis (CEA) can provide a helpful way to identify options that achieve the most effective use of the available resources (without requiring monetization of all of the relevant benefits and costs). Generally, cost-effectiveness analysis is designed to compare a set of regulatory actions with the same primary outcome (e.g., an increase in the acres of wetlands protected) or multiple outcomes that can be integrated into a single numerical index (e.g., units of health improvement). This approach provides useful information about relative performance of regulatory alternatives (i.e., best ‘bang for the buck’). At the same time, a comparison of monetized benefits and costs is necessary to determine which alternative maximizes net benefits.

When CEA is applied to public health and safety rulemakings, a measure of effectiveness must be selected that permits comparison of regulatory alternatives. Agencies currently use a variety of effectiveness measures. There are relatively simple measures such as the number of lives saved, cases of cancer reduced, or cases of paraplegia prevented. Sometimes these measures

¹⁰ For additional discussion, see *2011 Report to Congress on the Benefits and Costs of Federal Regulations and Unfunded Mandates on State, Local, and Tribal Entities*, page 66-67. Available at: http://www.whitehouse.gov/sites/default/files/omb/inforeg/2011_cb/2011_cba_report.pdf

account only for mortality information, such as the number of lives saved and the number of years of life saved. There are also more comprehensive, integrated measures of effectiveness such as the number of "equivalent lives" (ELs) saved and the number of "quality-adjusted life years" (QALYs) saved. While OMB does not require agencies to use any specific measure of effectiveness, an Institute of Medicine report recommends that agencies use QALYs for all health and safety issues.¹¹ In any event, the regulatory analysis should explain why a measure was selected and how it was implemented.

Step 9: Characterize uncertainty in benefits, costs, and net benefits

Regulatory analysis requires forecasts about the future. What the future holds, both in the baseline and under the regulatory alternative under consideration, is typically not known for certain. The important uncertainties connected with the regulatory decision should be analyzed and presented as part of the overall regulatory analysis. The goal of the agency's uncertainty analysis is to present both a central "best estimate," which reflects the expected value of the benefits and costs of the rule, as well as a description of the ranges of plausible values for benefits, costs, and net benefits, which informs decision-makers and the public of the degree of uncertainty associated with the regulatory decision.

In developing an uncertainty analysis, agencies should follow these steps:

Specify potential scenarios. As a first step, the agency should specify a set of plausible, mutually exclusive *scenarios* for both the baseline and for each regulatory alternative. Each scenario represents a complete description of a state of the world, including its evolution through time, that could arise. The goal is to specify scenarios that cover the full range of how the benefits and costs of the rule might vary. Typically this is done by specifying the set of factors that affect the benefits and costs of the regulatory alternatives.

Calculate the benefits and costs associated with each scenario. Once the set of plausible scenarios has been specified, the agency can calculate the benefits and costs associated with each scenario. At this stage, the agency has all of the information it needs to conduct a *sensitivity analysis*. A sensitivity analysis examines how the benefits and costs of the rule change with key uncertain variables.

Construct a range of values. When the agency cannot specify probabilities for the relevant scenarios, the agency should develop a central scenario for the baseline and for each regulatory alternative that reflects the agency's *best estimate* of the likely consequences of each regulatory alternative. The agency should use the benefits and costs of these best estimates to approximate the expected value of the benefits and costs of each regulatory alternative to use in its regulatory decision-making. The agency should also characterize ranges of *plausible* benefits, costs, and net benefits of each regulatory alternative. The goal is not to characterize the full range of *possible* outcomes, which

¹¹ IOM (2006). Valuing Health for Regulatory Cost-Effectiveness Analysis. The National Academies Press, Washington, DC.

may turn out to be extremely large, but rather the range of *plausible* outcomes as in a confidence interval. The agency must use its judgment on the range of scenarios that such ranges should reflect. At a minimum, the range should include a “high” and a “low” scenario that provide plausible upper and lower bounds.

The approach to constructing a range outlined above should be thought of as the minimal analysis that agencies should conduct. When feasible, agencies should also:

Assign probabilities and calculate expected values. Having specified the set of plausible scenarios, the benefits and costs associated with each scenario, and the probabilities of each scenario, the agency should calculate expected values of the benefits and costs for each regulatory alternative. In these cases, where probability distributions can be assigned to each scenario, the agency should conduct a formal uncertainty analysis in which it characterizes the distributions of benefits, costs, and net benefits.

Circular A-4 requires formal quantitative analysis of uncertainty for rules that exceed the \$1 billion annual threshold in benefits or costs.

D. Summarizing the Regulatory Analysis

Regulatory analysis should include a clear, plain language executive summary. The summary should include one or more tables that summarize the benefit and cost estimates for each regulatory action and alternative under consideration as well as the qualitative and non-monetized benefits and costs.¹² The summary should include:

- *Alternative regulatory approaches.* At a minimum, one or more tables should generally be used to report the benefits and costs of both the agency’s preferred option and at least one alternative that is less stringent (i.e., lower cost) and one alternative that is more stringent (i.e., higher cost). For each of the regulatory alternatives, the agency should calculate benefits and costs relative to a common baseline.
- *Categories of benefits and costs.* The agency should categorize the benefits and costs into three mutually exclusive and exhaustive categories: (1) quantified and monetized; (2) quantified but not monetized; and (3) neither quantified nor monetized. The agency should not include any benefit or cost in more than one of these categories. For example, if the agency has monetized fatalities averted by an alternative, it should report the dollar value as part of the quantified and monetized benefits, and should avoid double-counting the number of “lives saved” in the quantified but not monetized benefits category. (Of

¹² Circular A-4 states: “...you should present a summary of the benefit and cost estimates for each alternative, including the qualitative and non-monetized factors affected by the rule, so that readers can evaluate them.” (P.3) In addition, it states: “Your analysis should also have an executive summary, including a standardized accounting statement.” (P. 3). It further states, “You need to provide an accounting statement with tables reporting benefit and cost estimates for each major final rule for your agency.” (P. 44). Circular A-4 includes an example of a format for agency consideration.

course, the agency may also choose to report the monetized benefits in physical units, but should do so in a way that clearly avoids double-counting).

- *Separate reporting of distributional effects, including transfers.* The agency should report distributional effects, including transfers, separately and avoid the misclassification of transfer payments as benefits or costs.
- *Rank qualitative impacts.* The agency should categorize or rank the qualitative effects in terms of their importance (e.g., certainty, likely magnitude, and reversibility). The agency should distinguish the effects that are likely to be significant enough to warrant serious consideration by decision-makers from those that are likely to be minor.
- *Transparency.* The agency should add notes to the bottom of the tables that enable readers to interpret the information in the tables correctly. For example, when there is significant uncertainty to estimates, a caveat describing the nature of the uncertainty should be provided in the notes.