Estimating the Costs and Benefits of Environmental, Health, and Safety Policies and Regulations

Committee for Developing a Long-Term Strategy for Low-Dose Radiation Research in the United States
National Academies of Sciences, Engineering, and Medicine

October 27, 2021

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Overview

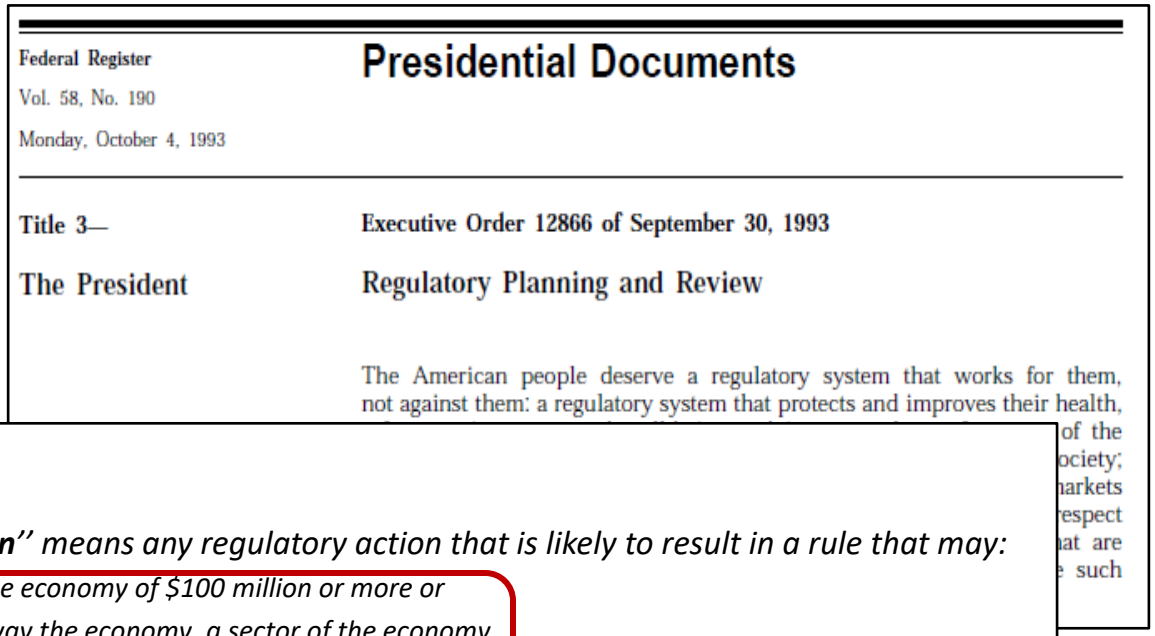
- Federal analytic requirements
- Components and major challenges
- Supplemental slides

Federal Requirements

Longstanding requirements

- Analysis of major U.S. regulations prior to promulgation has been required for over 40 years.
- Several presidential executive orders establish requirements for regulatory analysis and review.
  - Requirements apply to executive branch agencies (primarily cabinet agencies that report directly to the President).
  - Independent agencies (such as the Nuclear Regulatory Commission) typically also follow the analytic requirements voluntarily.
- Core is benefit-cost analysis; several supplemental analyses also required (e.g., small business impacts).
- Current requirements are in Executive Order 12866 (Clinton 1993) supplemented by Executive Order 13563 (Obama 2011).
- Focus on "economically significant" and "significant" regulations.
- Agencies often also assess less significant regulations.
  - Analysis frequently less comprehensive; e.g., focus on costs and do not estimate benefits.

Focus on significant regulations



Federal Register
Vol. 58, No. 190
Monday, October 4, 1993

Presidential Documents

Title 3—
The President

Executive Order 12866 of September 30, 1993

Regulatory Planning and Review

The American people deserve a regulatory system that works for them, not against them: a regulatory system that protects and improves their health,

of the
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such

Executive Order 12866

*(f) "**Significant regulatory action**" means any regulatory action that is likely to result in a rule that may:*

"Economically significant"

(1) Have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities;

(2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;

(3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or

(4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in this Executive order.

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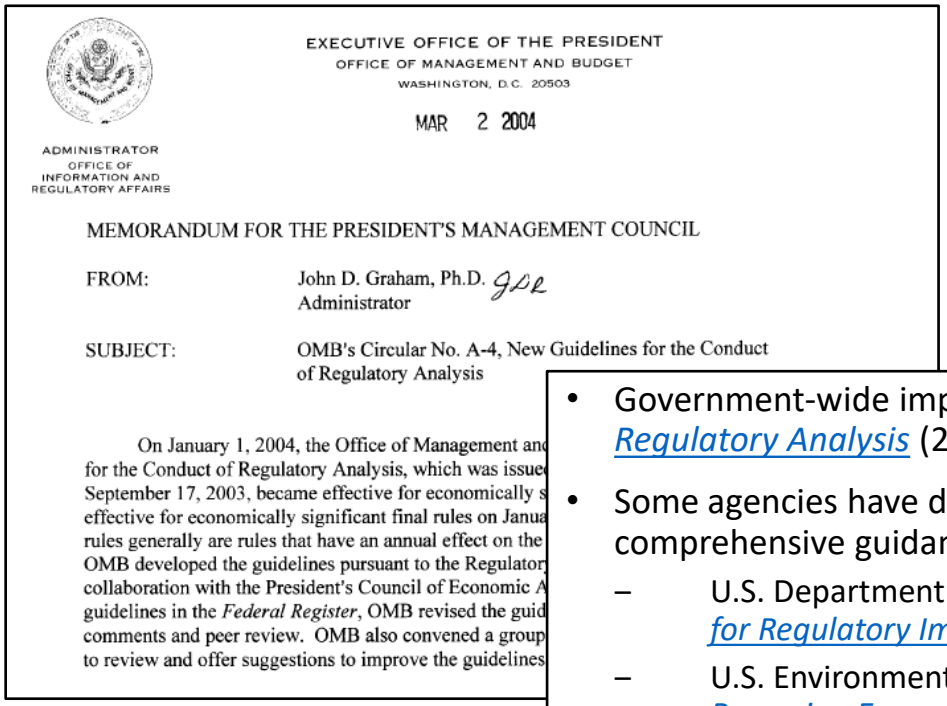
Substantial guidance available



EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET
WASHINGTON, D.C. 20503

MAR 2 2004

ADMINISTRATOR
OFFICE OF
INFORMATION AND
REGULATORY AFFAIRS

MEMORANDUM FOR THE PRESIDENT'S MANAGEMENT COUNCIL

FROM: John D. Graham, Ph.D.
Administrator

SUBJECT: OMB's Circular No. A-4, New Guidelines for the Conduct of Regulatory Analysis

On January 1, 2004, the Office of Management and
for the Conduct of Regulatory Analysis, which was issue
September 17, 2003, became effective for economically s
effective for economically significant final rules on Janua
rules generally are rules that have an annual effect on the
OMB developed the guidelines pursuant to the Regulator
collaboration with the President's Council of Economic A
guidelines in the *Federal Register*, OMB revised the guid
comments and peer review. OMB also convened a group
to review and offer suggestions to improve the guidelines

- Government-wide implementing guidance in *OMB Circular A-4: Regulatory Analysis* (2003).
- Some agencies have developed more detailed and comprehensive guidance.
  - U.S. Department of Health and Human Services. *Guidelines for Regulatory Impact Analysis*, 2016.
  - U.S. Environmental Protection Agency. *Guidelines for Preparing Economic Analyses*, 2010 (with updates; undergoing revision).
  - U.S. Nuclear Regulatory Commission. *NUREG/BR-0058 Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission*, 2017 (draft update).
  - U.S. Department of Transportation. Economic Values used in Analysis (2021).
    - Addresses values for fatal and nonfatal injuries and time savings only; updated annually.

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Comparative exercise

Aim is to:

- estimate net benefits (benefits minus costs) of alternative policies compared to no action,
- and describe the distribution of impacts across the advantaged and disadvantaged,
- with appropriate consideration of nonquantified effects and uncertainty.

Follows conventional benefit-cost analysis framework

- Focus on opportunity costs
- Value is derived from how much money an affected individual is willing to pay or accept for the outcome.
  - If we use resources (e.g., labor, materials) for one purpose, they will not be available for other uses.

- Assume individuals are the best (most legitimate) judge of their own welfare.
  - Respects individual preferences, not paternalistic.
- Focus on estimating reasonably thoughtful, well-informed preferences.*

* Robinson, L.A. and J.K. Hammitt. "Behavioral Economics and Regulatory Analysis," *Risk Analysis*, 31(9): 1408-1422, 2011; Robinson, L.A. and J.K. Hammitt. "Behavioral Economics and the Conduct of Benefit-Cost Analysis: Towards Principles and Standards," *Journal of Benefit-Cost Analysis*, 2(2): Art. 5, 2011.

Valuation approach depends on whether the outcome is traded in markets.

- Rely on *market data* where possible.
  - Presumably, if an individual chooses to buy a good or service, he or she values it more than the other things the money could buy.

- For nonmarketed goods, use stated or revealed preference methods.
  - *Stated preferences* – ask respondents what they would be willing to pay under hypothetical scenarios (contingent valuation, choice experiments).
  - *Revealed preferences* – use data on market transactions or observed behavior to estimate value, controlling statistically for other attributes.

Goal is to…

…describe extent to which individuals are willing, as members of a society, to reduce their consumption of other goods and services to achieve specific policy outcomes.

Informs, rather than determines, decision

A policy should not necessarily be implemented simply because its benefits exceed its costs.

- Comparison to other policies is necessary to identify the most efficient use of resources.
- Decision-makers also must consider issues such as legal, political, and budgetary constraints.

Process provides many additional insights

- Requirements motivate detailed examination of impacts, important discoveries regardless of end result.
  - Preferences of those affected,
  - Otherwise unanticipated consequences,
  - Key uncertainties,
  - Available technology, costs, effectiveness,
  - Who bears costs, who receives benefits,
  - Sources of support and opposition.

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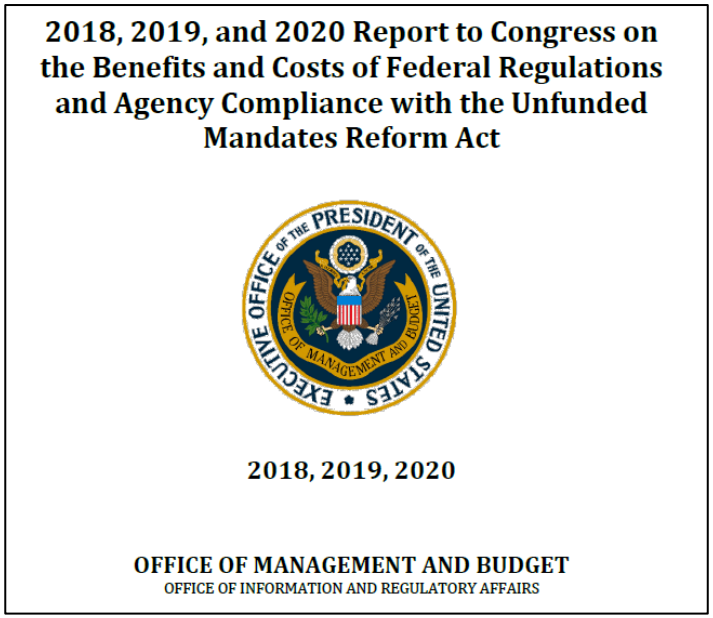
Some examples*

- U.S. Environmental Protection Agency
  - Drinking water, air emissions, waste management
- U.S. Department of Health and Human Services
  - Drugs, medical devices
- Nuclear Regulatory Commission
- Other agencies



2018, 2019, and 2020 Report to Congress on the Benefits and Costs of Federal Regulations and Agency Compliance with the Unfunded Mandates Reform Act

2018, 2019, 2020

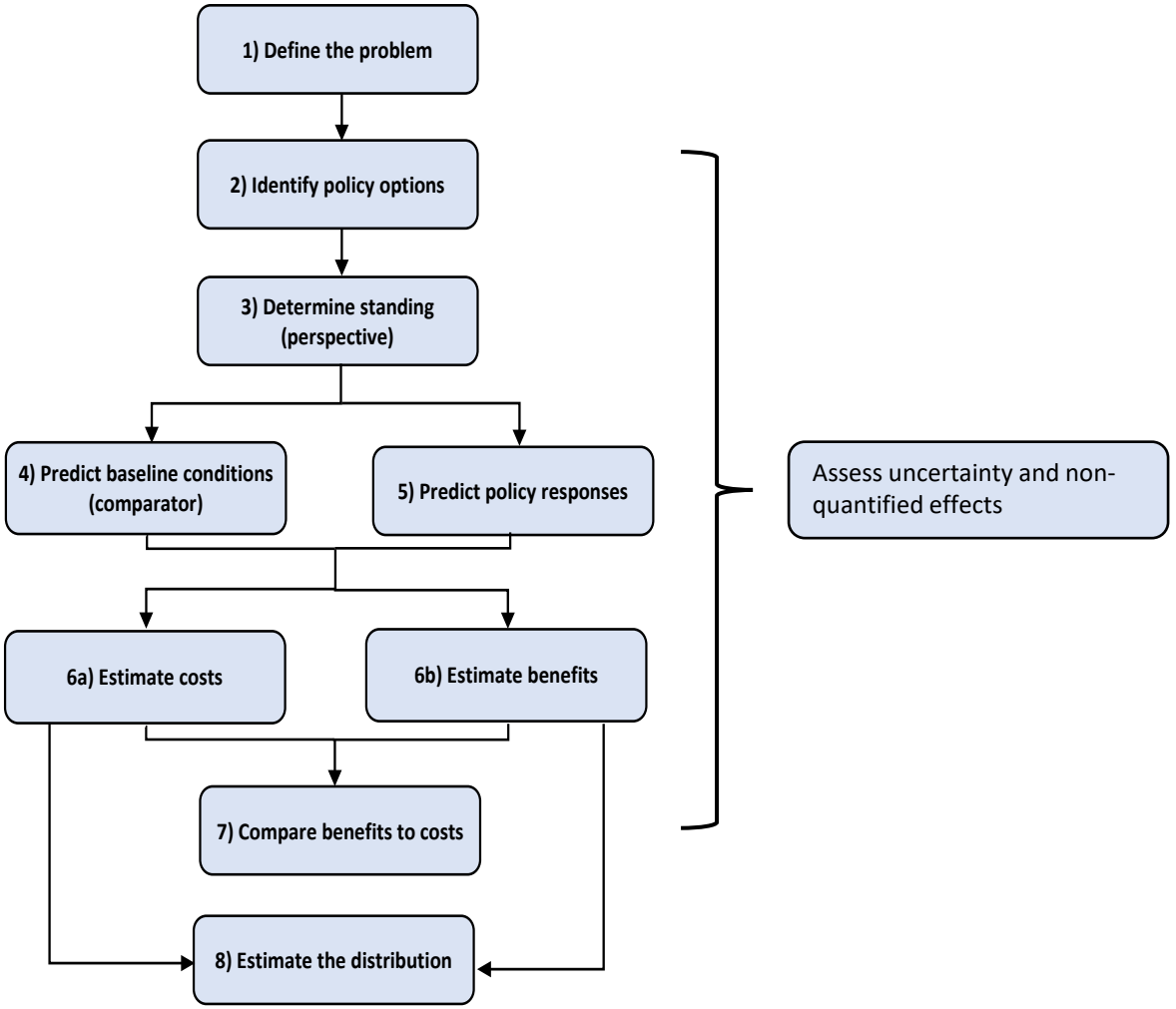
OFFICE OF MANAGEMENT AND BUDGET
OFFICE OF INFORMATION AND REGULATORY AFFAIRS

https://www.whitehouse.gov/omb/information-regulatory-affairs/reports/#ORC

* Links to several examples included with meeting agenda.

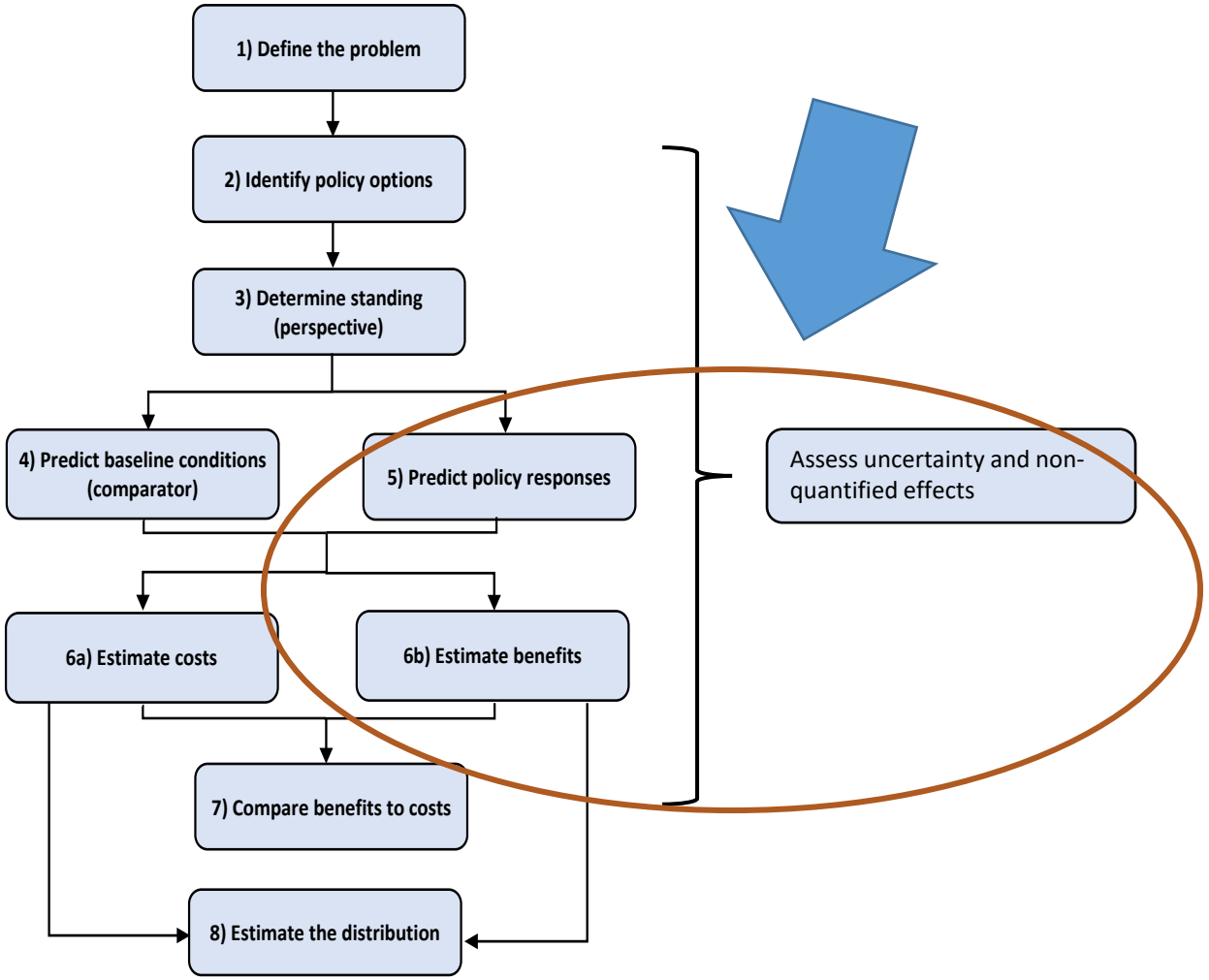
Components and Major Challenges

Analytic Components*



* For more detail, see supplemental slides, agency guidance documents, and chapter 2 of *Reference Case Guidelines for Benefit-Cost Analysis in Global Health and Development*.

Focus on health impacts



Two components

Estimate expected change in deaths, cases of nonfatal illnesses or injuries, over defined time period

Multiply by monetary value per expected death, nonfatal case averted, in each time period

Major challenge: Estimating regulatory impact

- Improve understanding of baseline exposures.
  - Changes over time due to changes in the economy, population, technology, etc.?
- Improve understanding of effect of risk management strategies on exposures.
  - Randomized control trials? Natural experiments? *Ex post* (retrospective) analysis?
  - Effects of technological innovation, monitoring and enforcement, detection limits?

Major challenges: Quantifying health impacts

- Requires dose-response functions for radionuclides of concern, at “without” and “with” regulation exposure levels.
  - Linear/nonlinear? thresholds? etc.
- To avoid biased results, estimates must be expected values (best, central tendency estimates) with appropriate characterization of uncertainty.
  - Not reasonably maximally exposed (RME) individual.
  - Must translate as low as reasonably achievable (ALARA) into risk estimates.
- For valuation, health impacts must be manifest, e.g., diagnosable diseases.
  - Understanding effects at cellular level is insufficient, requires estimating likelihood will lead to identifiable illness.

Major challenges: Valuing health impacts

- For changes in mortality risks, apply estimates of the value per statistical life (VSL).
  - Represents individual's willingness to exchange his or her own income for a small change in his or her own risk.
  - Not the value of saving an identifiable life with certainty.
- Should agency defaults be adjusted for differences in characteristics of individuals affected? Of risk attributes?
  - ***Would require funding more primary valuation research.***

Agency	Recommended VSL Estimates		Basis
	As reported (range)	***2019*** US dollars & income levels	
US Environmental Protection Agency (EPA 2010)	$7.4 million (standard deviation: $4.7 million) (2006 US dollars)	$11.1 million	21 wage-risk and 5 stated-preference studies (Viscusi 1992, 1993)
US Department of Health and Human Services (HHS 2016)	$9.3 million ($4.4 million to $14.6 million) (2014 US dollars)	$10.6 million	6 wage-risk studies plus 1 meta-analysis and 3 stated-preference studies (Robinson and Hammitt 2016)
US Department of Transportation (DOT 2020)	$9.4 million ($5.2 million – $13.0 million) (2014 US dollars)	$10.9 million	9 wage-risk studies (DOT 2016)

Major challenges: Valuing health impacts

- For changes in morbidity (nonfatal) risks, apply estimates of the value per statistical case (VSC).
  - Same conceptual approach as mortality.
  - Valuation research is lacking for many illnesses and injuries.
- How should agencies approximate these values?
  - EPA: Averted costs of illness (medical costs, lost productivity)
  - HHS, DOT: Monetized quality adjusted life years (QALYs) plus third party averted costs (insured medical costs, caregiving).
- More primary research needed:
  - Willingness to pay estimates.
  - Valuation functions for QALYs.

Quantitative analysis of uncertainty

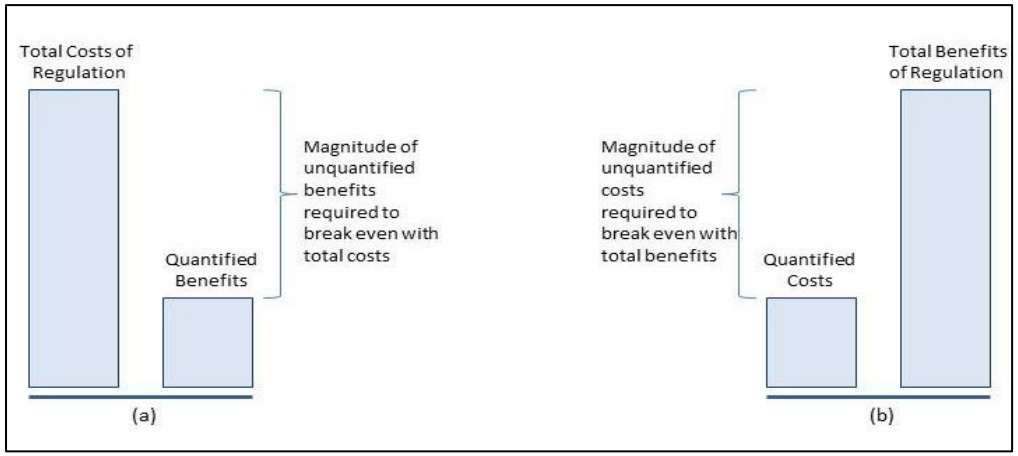
APPROACH	APPLICABILITY	CONDUCT
Qualitative Discussion	• For all analyses. • May suffice if: – the rule involves annual economic effects less than $1 billion; – the analyst is able to demonstrate that the results are robust to uncertainties; and, – the consequences of the rule are modest.	Disclose key assumptions and uncertainties and include information on the implications for decision-making.
Numerical Sensitivity Analysis	• For rules involving annual economic effects less than $1 billion, where: – the qualitative discussion raises questions about the robustness of the results; or, – the consequences of the rule are large.	Vary one or many parameters to calculate distinct sets of results for comparison.
Probabilistic Analysis	• For rules involving annual economic effects of $1 billion or more (required). • For rules with smaller impacts where numerical sensitivity analysis raises questions about the robustness of the results.	Develop distributions for the uncertain parameters and conduct Monte Carlo analysis to determine the distribution of the results.

* Replicates Table 6.1 from HHS Guidelines for Regulatory Impact Analysis.

Nonquantified effects

- Challenge is to ensure impacts are appropriately weighted; qualitative discussion necessary but insufficient.
- Options include bounding, breakeven, and cost-effectiveness analysis and/or structured expert elicitation.

Breakeven analysis



- All *require some information on potential magnitude* to apply or to interpret implications.

* Replicates Figure 6.1 from HHS Guidelines for Regulatory Impact Analysis.

Thank you!

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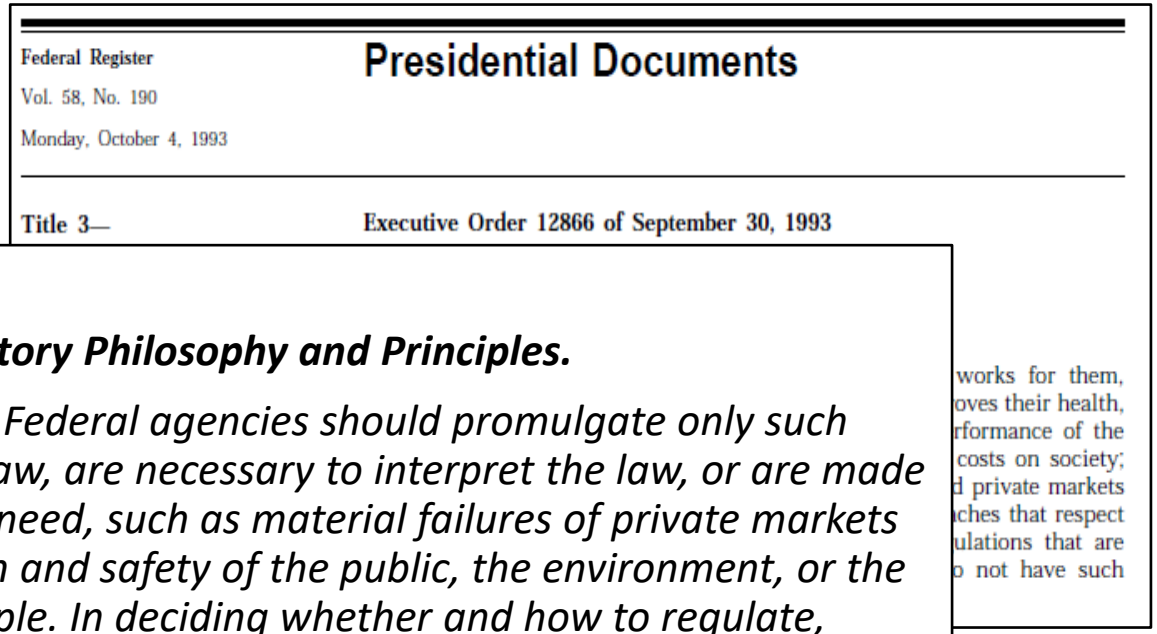
Supplemental Slides

Regulatory Development Process

- Congress authorizes agencies to develop regulations and other programs.
- Administrative Procedure Act governs the rulemaking process.
- Office of Information and Regulatory Affairs (OIRA) in the Office of Management and Budget (OMB), Executive Office of the President, reviews major rules from executive branch agencies prior to promulgation.
- Steps include:
  - Agency develops proposed regulation and supporting analysis; reviews internally.
  - OIRA reviews proposed regulation and supporting analysis, if applicable.
  - Agency publishes preamble and proposed rule in the Federal Register, placing supporting technical documents in the regulatory docket; requests public comments.
  - Agency develops, OMB reviews (if applicable), and agency publishes final rule and supporting documents.
  - Congress reviews rule under the Congressional Review Act.

Analytic Requirements



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Executive Order 12866

Section 1. Statement of Regulatory Philosophy and Principles.

*(a) **The Regulatory Philosophy**. Federal agencies should promulgate only such regulations as are required by law, are necessary to interpret the law, or are made necessary by compelling public need, such as material failures of private markets to protect or improve the health and safety of the public, the environment, or the well-being of the American people. In deciding whether and how to regulate, agencies should assess **all costs and benefits** of available **regulatory alternatives**, **including the alternative of not regulating**. Costs and benefits shall be understood to include **both quantifiable measures** (to the fullest extent that these can be usefully estimated) and **qualitative measures** of costs and benefits that are difficult to quantify, but nevertheless essential to consider. Further, in choosing among alternative regulatory approaches, agencies should select those approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; **distributive impacts; and equity**), unless a statute requires another regulatory approach.*

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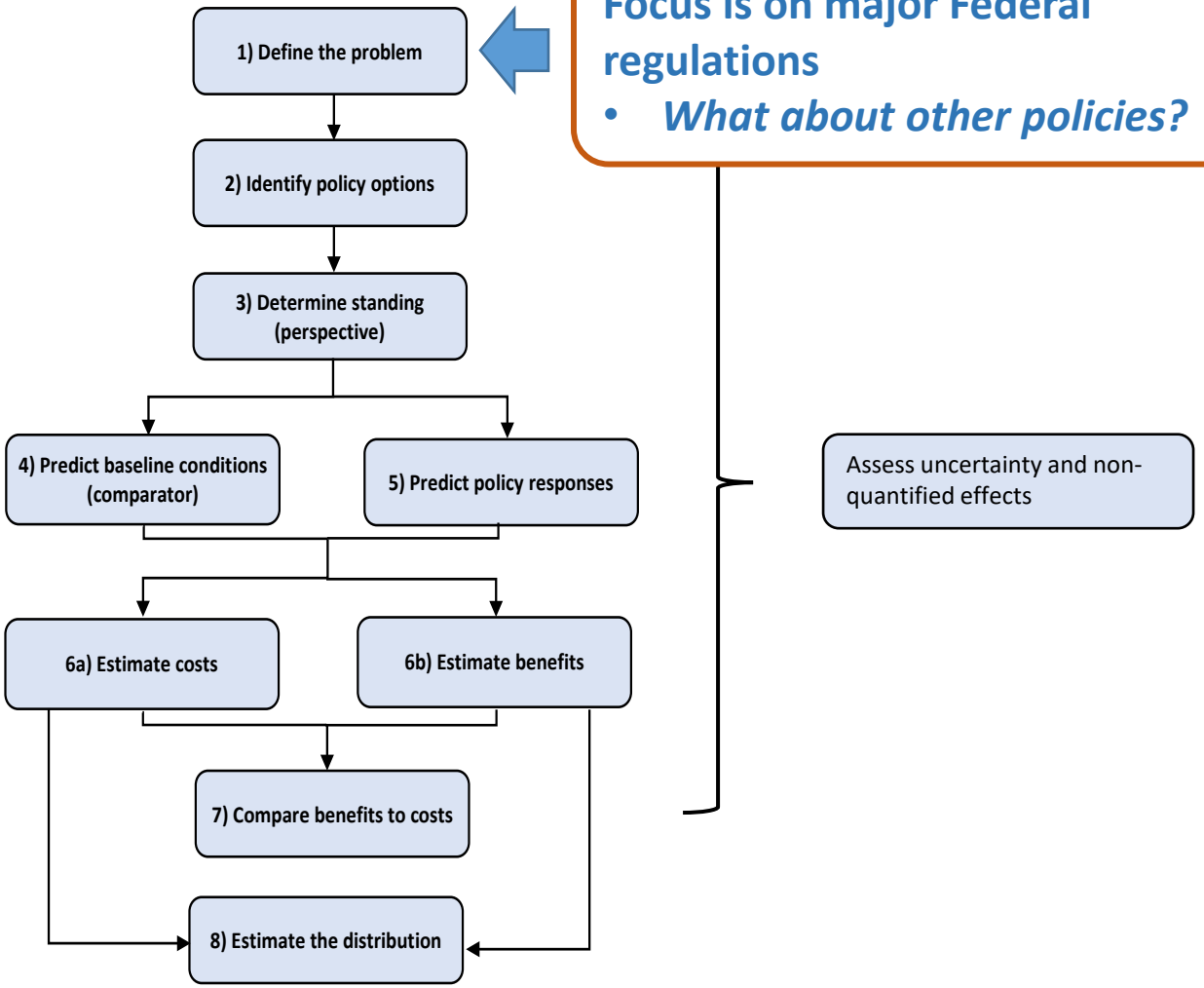
Major Components and Challenges



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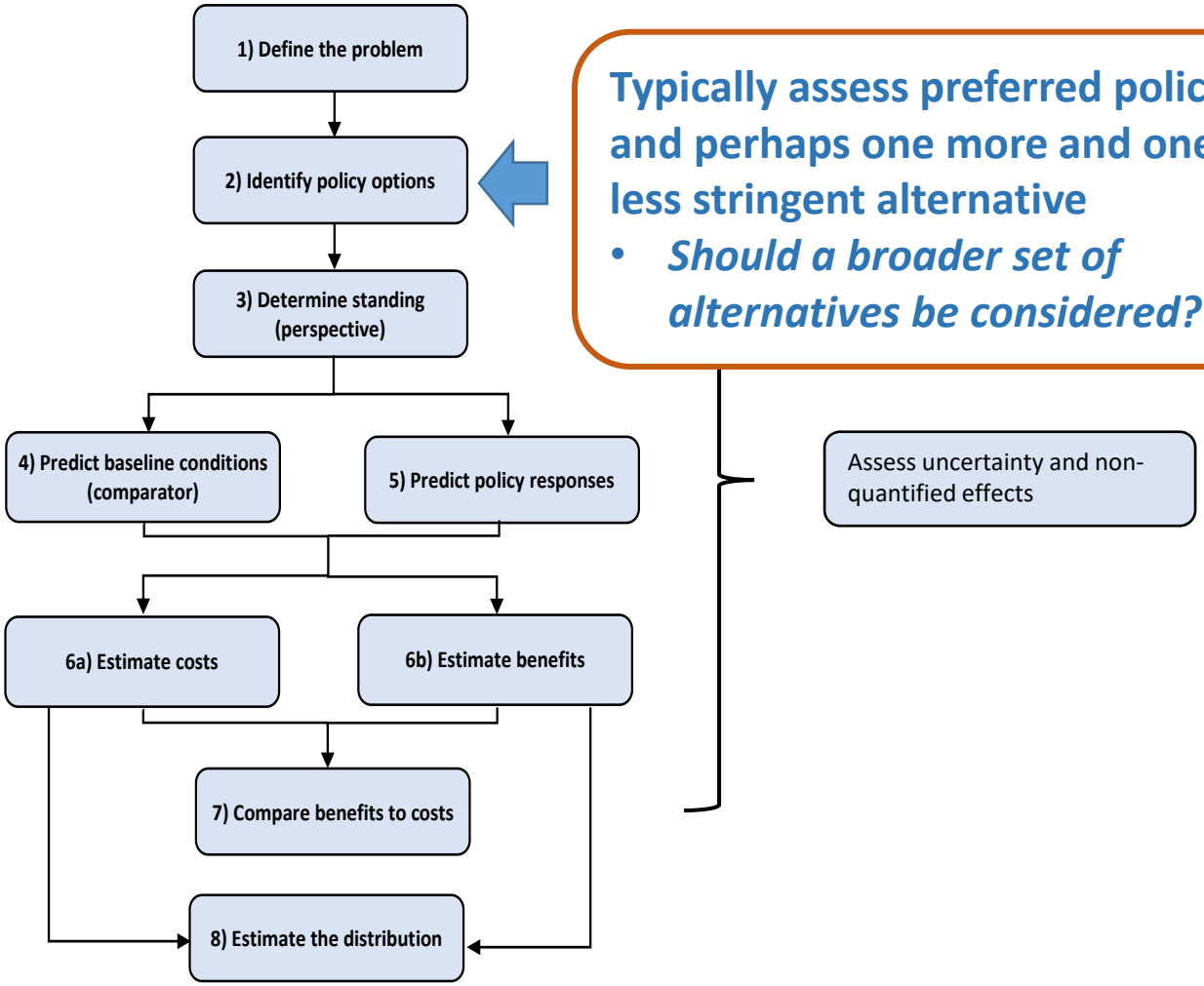

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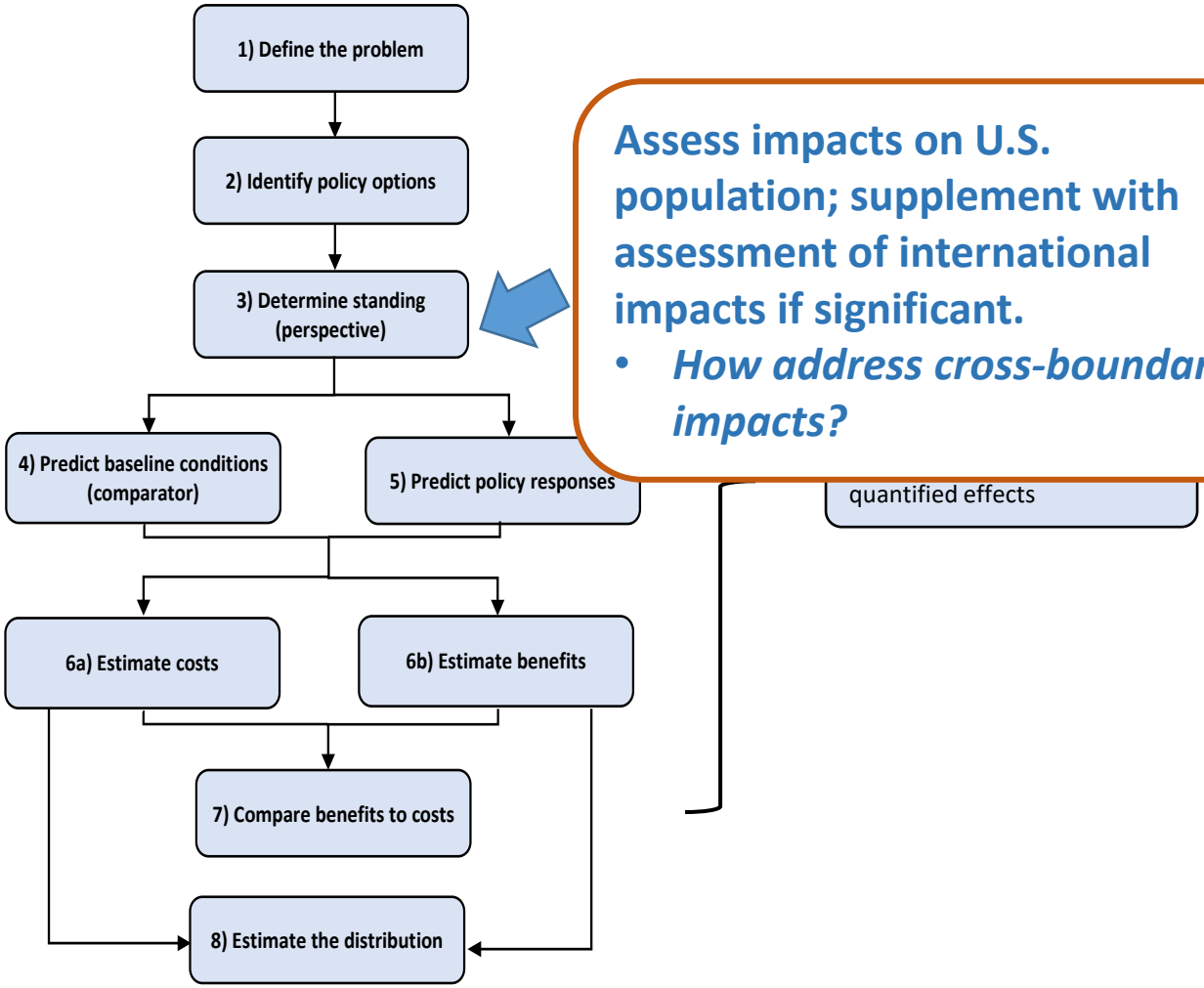

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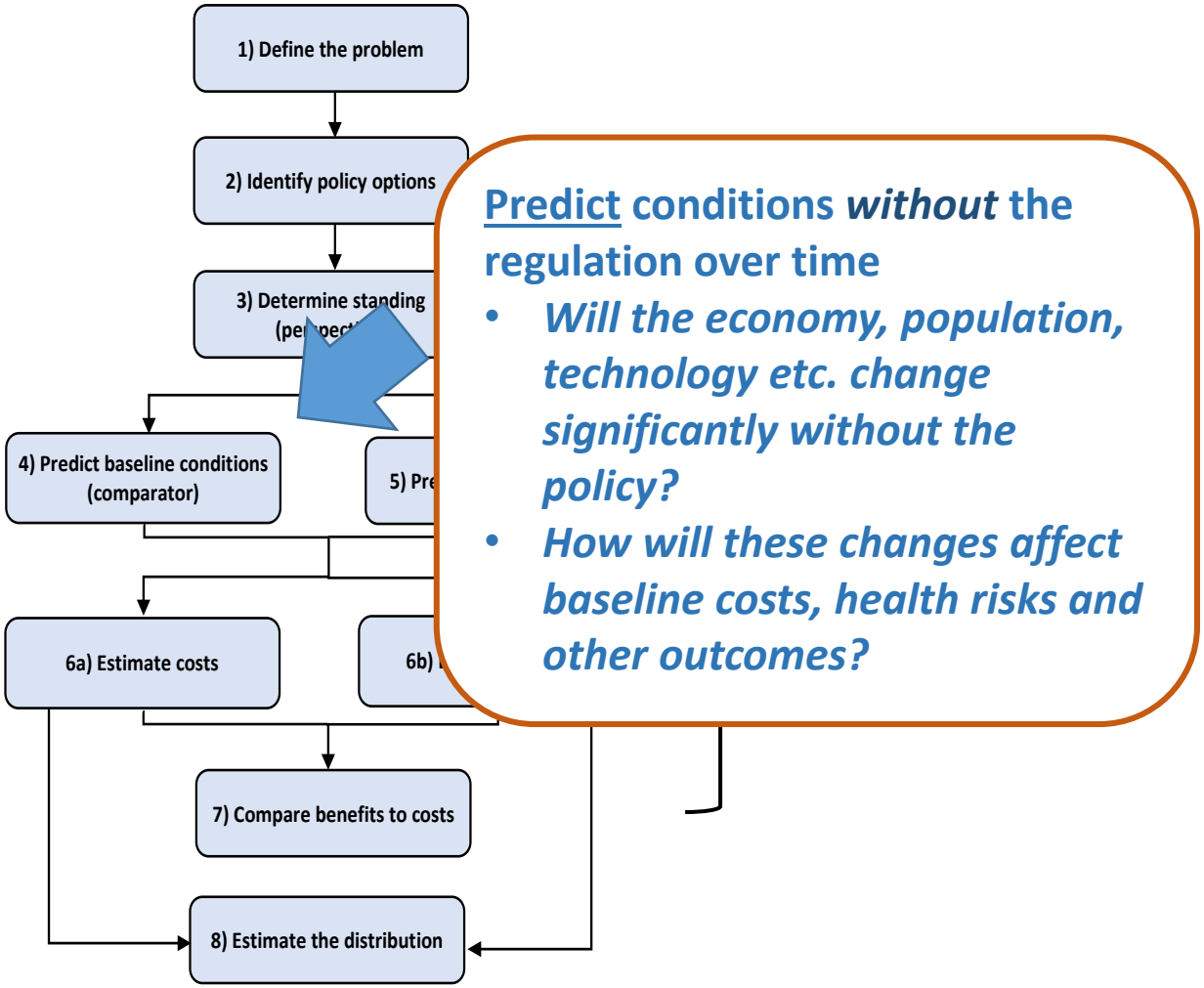

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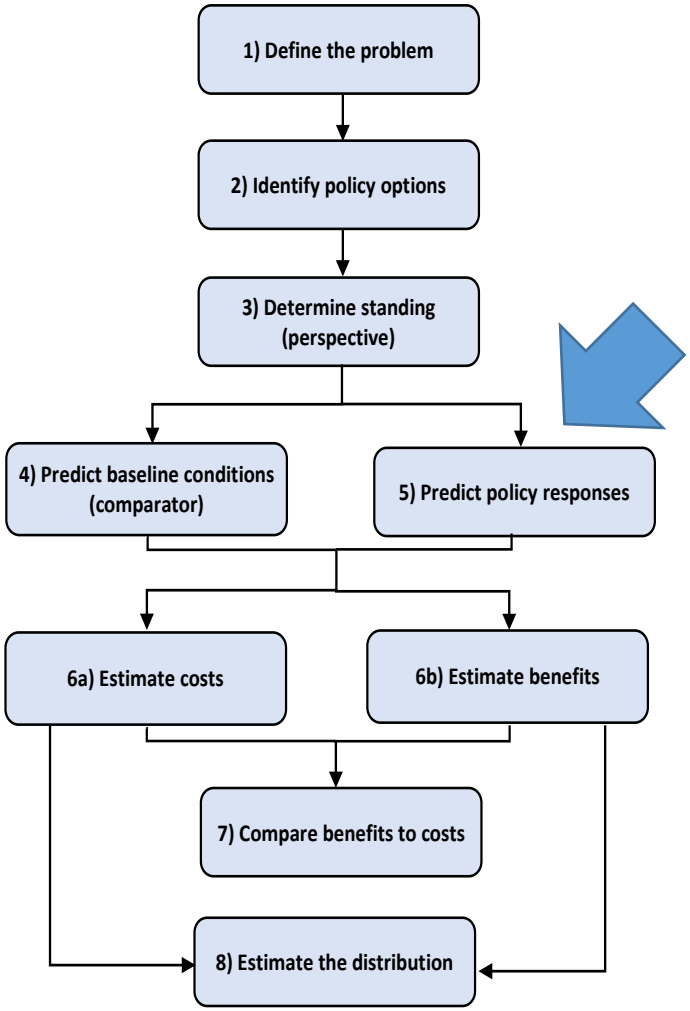
Major Components and Challenges



Predict conditions *with* the regulation over time

Often the most difficult step!

- ***How will regulated entities respond?***
- ***How will responses change over time?***
- ***What are the implications for costs, health risks, other impacts?***

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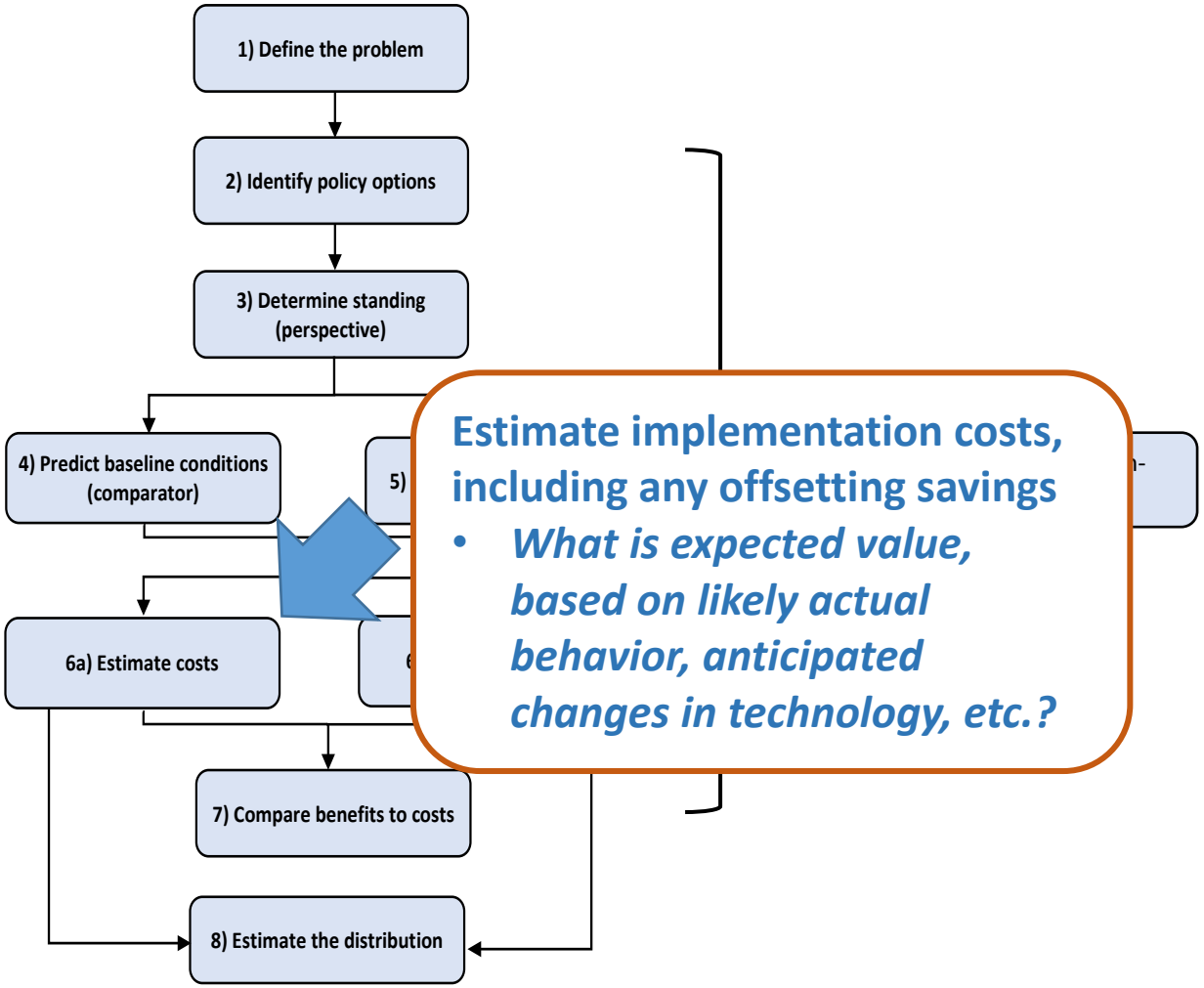
Major Components and Challenges



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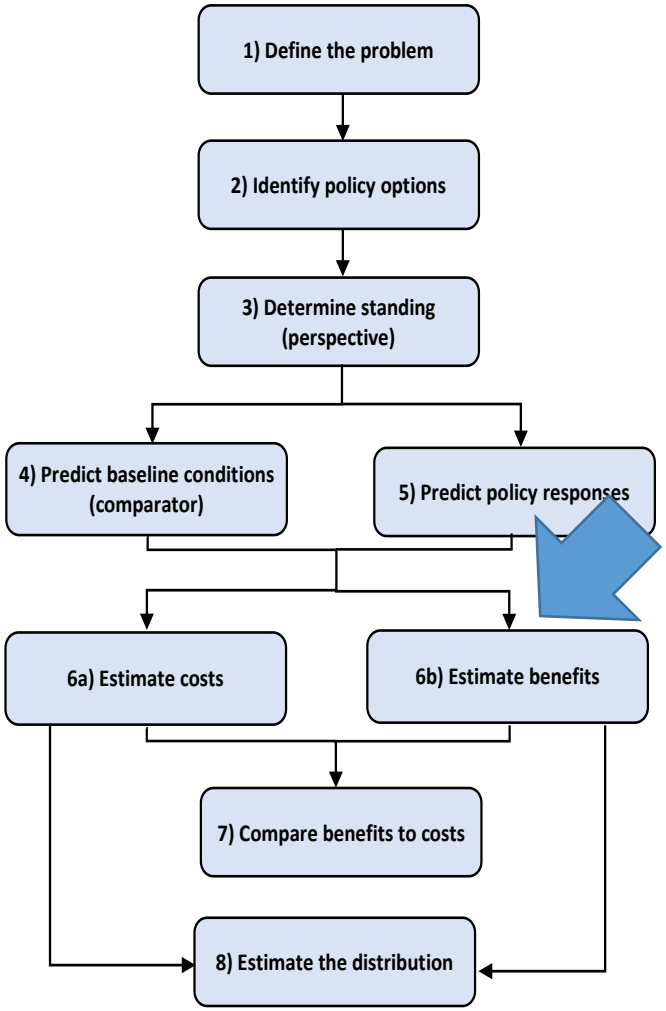
Major Components and Challenges



Estimate monetary value of changes in expected deaths, illnesses, injuries, and other outcomes including any countervailing risks

- ***How to address match between available valuation research and affected populations and risks?***

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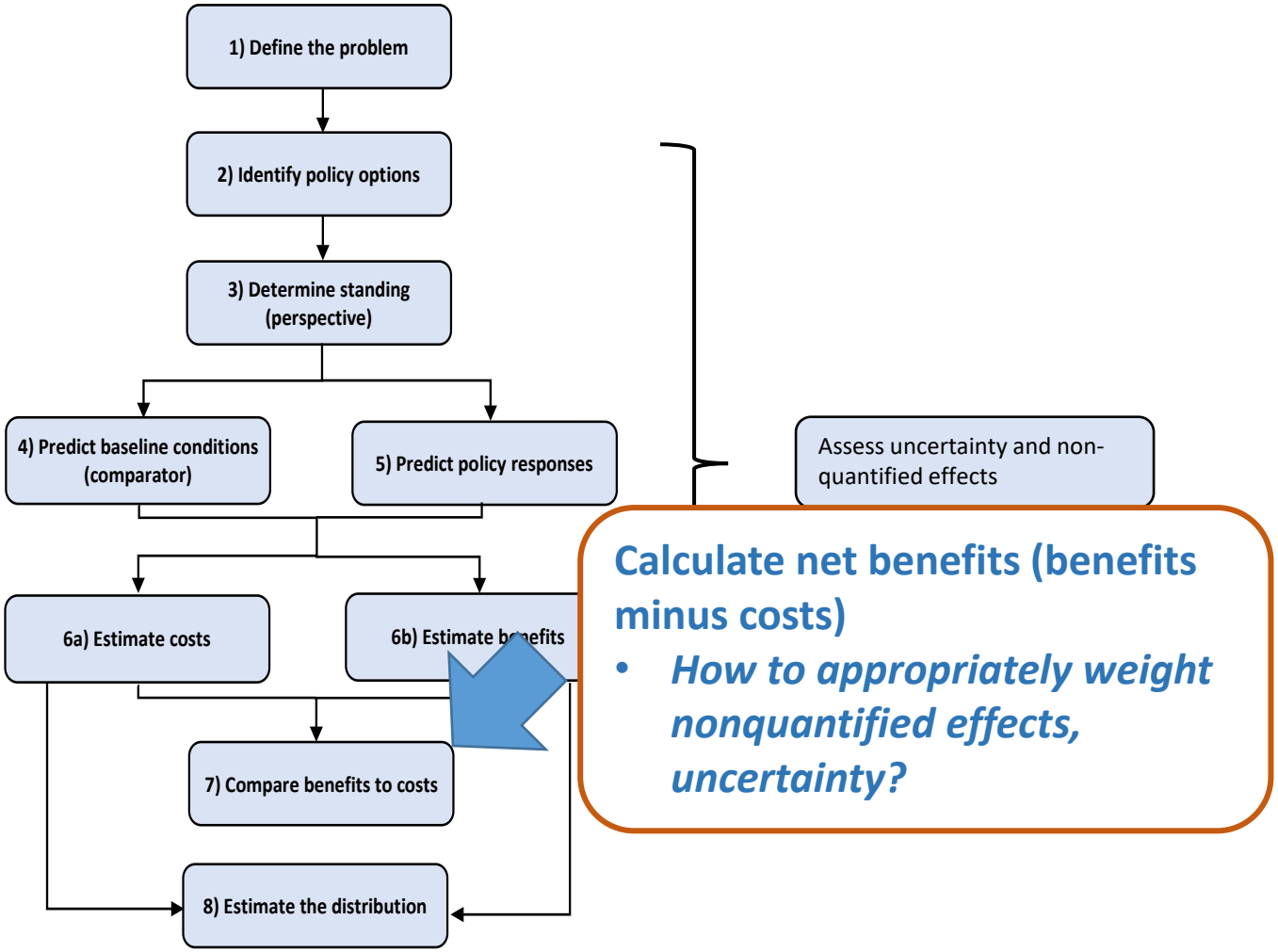
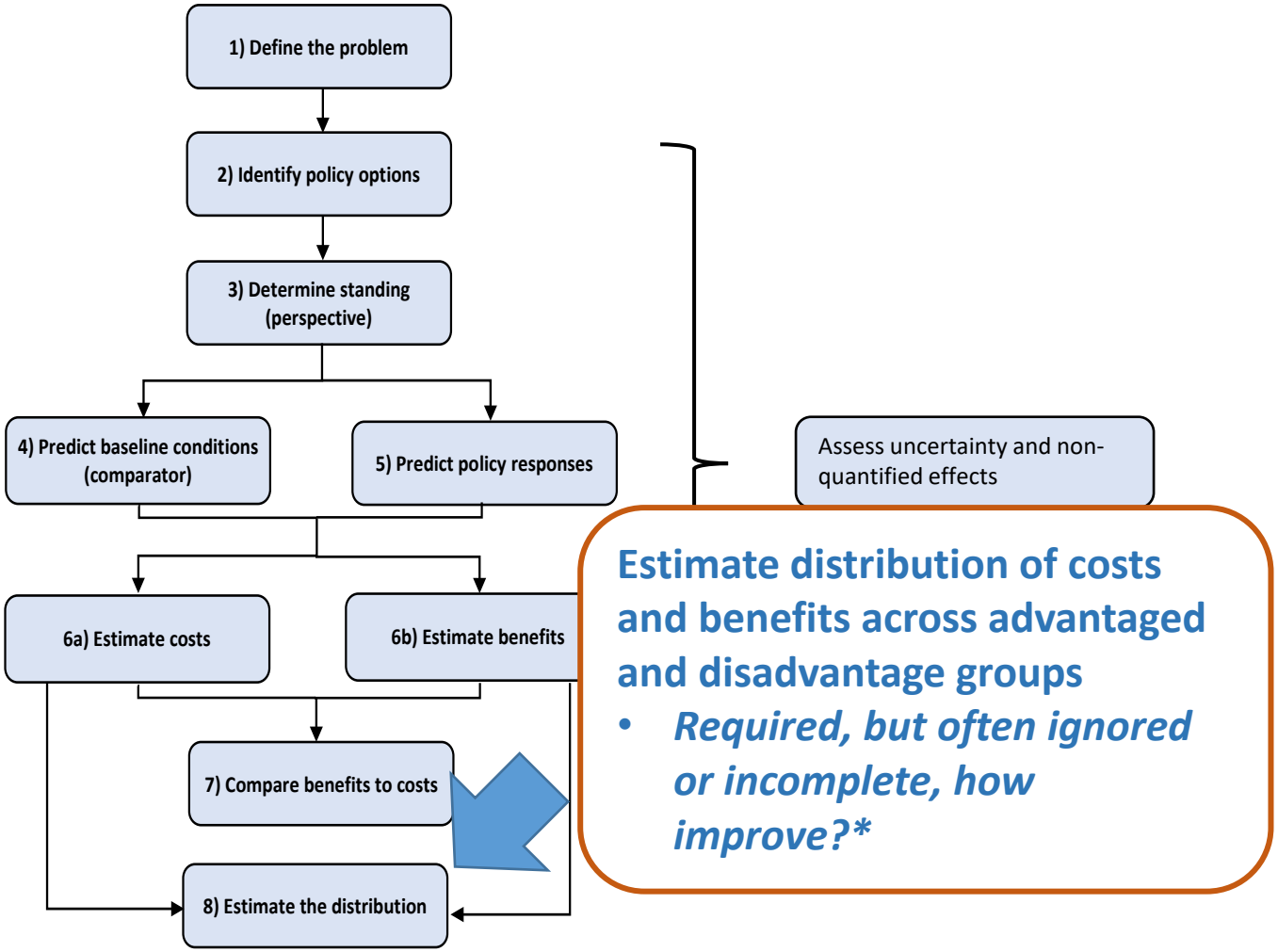
Major Components



Major Components and Challenges



See: Robinson, L.A., J.K. Hammitt, and R. Zeckhauser. "Attention to Distribution in U.S. Regulatory Analysis," *Review of Environmental Economics and Policy*, 10(2): 308-328, 2016.

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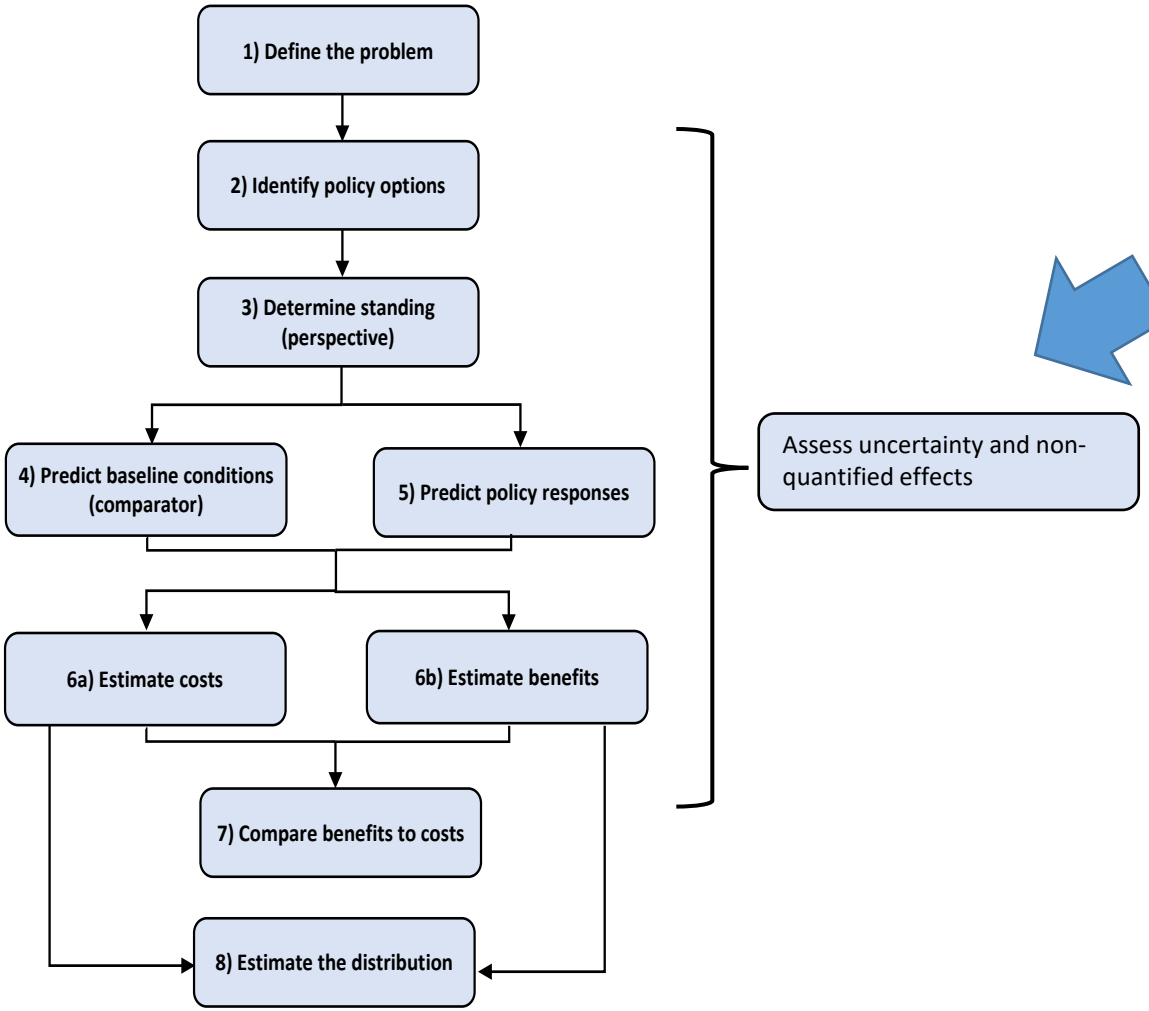
Major Components and Challenges



Characterize uncertainty, non-quantified effects

- ***How likely is it that the benefits will the exceed costs? that the relative ranking of policies will change? that the magnitude of the net benefits will change?***

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Example:
2000 Radionuclides in Drinking Water Rule*

**ECONOMIC ANALYSIS OF THE
RADIONUCLIDES
NATIONAL PRIMARY
DRINKING WATER REGULATIONS**

Prepared for:
Office of Ground Water and Drinking Water
U.S. Environmental Protection Agency

Prepared by:
Industrial Economics, Incorporated
2067 Massachusetts Avenue
Cambridge, MA 02140
(617) 354 - 0074

November 2000

* https://www.epa.gov/dwreginfo/radionuclides-rule

Exhibit ES-1

ALTERNATIVE REGULATORY LEVELS

Radionuclide	Current MCL	1991 Proposed MCLs	2000 Final MCLs
Combined radium-226 and radium-228	5 pCi/L	20 pCi/L for radium-226; 20 pCi/L for radium-228	No change from current.
Gross alpha	15 pCi/L, net of uranium and radon	15 pCi/L, net of radium-226, uranium, and radon	No change from current.
Gross beta	4 mrem	4 mrem, ede	No change from current.
Uranium	None	20 • g/L (30 pCi/L)	30 • g/L

Sources:
Current MCLs: U.S. Environmental Protection Agency, *National Primary Drinking Water Regulations*, 40 CFR 141.15.
1991 Proposed MCLs: U.S. Environmental Protection Agency, *National Primary Drinking Water Regulations; Radionuclides; Notice of Proposed Rulemaking;* 56 FR 33050, July 18, 1991.
Final MCLs: U.S. Environmental Protection Agency, *National Primary Drinking Water Regulations; Radionuclides; Final Rule*, forthcoming.

* Symbol for µg (micrograms) per liter displaying incorrectly as • g/L

Exhibit ES-2

NUMBER OF COMMUNITY WATER SYSTEMS EXCEEDING STANDARDS

Option	Number of Systems
Illegally out of compliance with existing MCLs	
Illegal noncompliance: gross alpha MCL of 15 pCi/L	400 systems
Illegal noncompliance: combined radium MCL of 5 pCI/L	420 systems
Total number of systems in illegal noncompliance (adjusts for overlap)	670 systems
Legally out of compliance with existing MCLs (due to monitoring loopholes)	
Legal noncompliance: gross alpha MCL of 15 pCi/L	230 systems (210 - 250 systems)
Legal noncompliance: combined radium MCL of 5 pCi/L	290 systems (270 - 320 systems)
Total number of systems in legal noncompliance (adjusts for overlap)	360 systems (310 - 400 systems)
Out of compliance with uranium options	
Uranium MCL at 20 • g/L	900 systems (830 - 970 systems)
Uranium MCL at 30 • g/L	500 systems (400 - 600 systems)
Uranium MCL at 40 • g/L	360 systems (300 - 430 systems)
Uranium MCL at 80 • g/L	110 systems (40 - 170 systems)

Source:
Industrial Economics, Incorporated analysis of data from the EPA's National Inorganics and Radionuclides Survey (NIRS).
Notes:
Ranges in parentheses are based on the directly proportional versus lognormal distribution approaches to estimating occurrence; the best estimate is the mean of these values (calculated prior to rounding).
Combined radium and gross alpha analyses include ground water systems only; uranium analysis includes both ground and surface water systems.
Illegal noncompliance estimates are based directly on the NIRS data; costs and risk reductions associated with full compliance with the existing requirements are not assessed because these impacts are not attributable to the regulatory changes under consideration.
Legal noncompliance is assessed after adjusting the occurrence data to eliminate illegal noncompliance.
Uranium results do not take into account the effects of the existing California standard, which may reduce the estimates as discussed later in the text.

Exhibit ES-3

SUMMARY OF QUANTIFIED ANNUAL COSTS AND BENEFITS: BEST ESTIMATES

	Statistical Cancer Cases Avoided (range)	Value of Avoided Cases (range)	Change in Compliance Costs (range)
Compliance with existing MCLs after closing monitoring loopholes (combined radium = 5 pCi/L, gross alpha = 15 pCi/L)			
Eliminate gross alpha monitoring loophole only	0.20 cases (0.04 - 0.35 cases)	$0.8 million ($0.2 - $1.3 million)	$14.6 million ($1.4 - $27.7 million)
Eliminate combined radium monitoring loophole only	0.43 cases (0.31 - 0.54 cases)	$1.7 million ($1.2 - $2.2 million)	$25.5 million ($16.0 - $34.9 million)
Eliminate both loopholes	0.59 cases (0.32 - 0.86 cases)	$2.4 million ($1.3 - $3.4 million)	$38.8 million ($16.3 - $61.3 million)
Compliance with new uranium MCL options			
Establish uranium MCL at 20 • g/L	1.03 cases (0.14 - 1.91 cases)	$4.0 million ($0.5 - $7.4 million)	$90.4 million ($25.5 - $155.4 million)
Establish uranium MCL at 30 • g/L	0.82 cases (0.06 - 1.58 cases)	$3.1 million ($0.2 - $6.1 million)	$49.7 million ($6.3 - $93.1 million)
Establish uranium MCL at 40 • g/L	0.71 cases (0.03 - 1.39 cases)	$2.8 million ($0.1 - $5.4 million)	$33.3 million ($2.2 - $64.3 million)
Establish uranium MCL at 80 • g/L	0.47 cases (0.01 - 0.92 cases)	$1.8 million ($<0.1 - $3.6 million)	$12.9 million ($0.2 - $25.5 million)

Notes:
Ranges in parentheses are based on the directly proportional versus lognormal distribution approach; the best estimate is the mean of these values (calculated prior to rounding).
Analysis does not fully quantify all risk reductions; uranium analysis addresses cancers but not kidney toxicity.
Cancer cases are total incidence (fatal and nonfatal cases combined).
Compliance costs include capital and operations and maintenance costs, but exclude monitoring costs.

* Risk coefficients from:

Eckerman, Keith F., Richard W. Leggett, Christopher B. Nelson, Jerome S. Pushkin, and Allan C.B. Richardson. *Cancer Risk Coefficients for Environmental Exposure to Radionuclides. Federal Guidance Report*, No. 13 (draft). September 1999.

Exhibit ES-4

RESULTS OF SENSITIVITY ANALYSES

Regulatory Option	Central Tendency Estimate		High Benefit / Low Cost Scenario		Low Benefit / High Cost Scenario	
	Benefits	Costs	Benefits	Costs	Benefits	Costs
Closing monitoring loopholes						
Eliminate gross alpha loophole only	$0.8 million	$14.6 million	$7.2 million	$8.7 million	$0.1 million	$19.0 million
Eliminate combined radium loophole only	$1.7 million	$25.5 million	$16.9 million	$15.1 million	$0.2 million	$33.2 million
Eliminate both loopholes[1]	$2.4 million	$38.8 million	$22.7 million	$22.9 million	$0.3 million	$50.6 million
Establishing a new uranium MCL						
Establish uranium MCL at 20• g/L	$4.0 million	$90.4 million	$31.8 million	$53.5 million	$0.5 million	$120.4 million
Establish uranium MCL at 40• g/L	$2.8 million	$33.3 million	$22.1 million	$19.6 million	$0.4 million	$44.5 million
Establish uranium MCL at 80• g/L	$1.8 million	$12.9 million	$14.5 million	$7.5 million	$0.3 million	$17.4 million

Notes:

These estimates are designed to illustrate the effects of alternative assumptions; the likelihood that these outcomes may occur is uncertain as described in the text.

This analysis does not address the impacts of a 30 • g/L uranium MCL, since these impacts were interpolated from the results for other options.

The central tendency estimates are derived from Exhibit ES-3 above.

The high benefits - low cost scenario compares the benefits resulting from the high end sensitivity analysis of the risk coefficients with the low end sensitivity analysis of the compliance costs.

The low benefits - high cost scenario compares the benefits resulting from the low end sensitivity analysis of the risk coefficients with the high end sensitivity analysis of the compliance costs.

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