Informing Regulatory Decisions:

2003 Report to Congress on the Costs and Benefits of Federal Regulations and Unfunded Mandates on State, Local, and Tribal Entities

2003

Office of Management and Budget

Office of Information and Regulatory Affairs

Table of Contents

Informing Regulatory Decisions:

Report to Congress on the Costs and Benefits of Federal Regulations and Unfunded Mandates on State, Local, and Tribal Entities

EXECUTIVE SUMMARY

This final report to Congress on regulatory policy was prepared pursuant to the Regulatory Right-to-Know Act and the Unfunded Mandates Reform Act. The major features and findings of the Report include the following:

- OMB reviewed 107 major Federal rulemakings finalized over the previous ten years (October 1, 1992 to September 30, 2002). The estimated total annual quantified benefits of these rules range from $146 billion to $230 billion, while the estimated total annual quantified costs range from $36 billion to $42 billion. The majority of the quantified benefits are attributable to a handful of clean-air rules issued by EPA pursuant to the 1990 amendments to the Clean Air Act. (Chapter I)

- In order to achieve better regulations, OMB invited public nominations of specific regulatory reforms: additions, modifications or rescissions. Over 1,700 public commenters nominated 316 distinct rules, guidance documents, and paperwork requirements for reform. With the assistance of the Advocacy Office of the US Small Business Administration, OMB worked with agencies during the last year to evaluate these reform nominations. The agencies and OMB determined that (1) 109 of these reform nominations were recently addressed by agencies or were currently under review, (2) 51 of the reform nominations were directed at independent agencies, and (3) 156 of the reform nominations were ripe for consideration by Cabinet-level agencies and EPA. Of these 156 reform nominations, agencies have decided to pursue 34 rules and 11 guidance documents for reform, are undecided about 26 rules and 4 guidance documents, and have decided not to pursue reform of 62 rules and 19 guidance documents at this time. (Chapter II)

- In order to make continued improvements in regulatory analysis, OMB and the Council of Economic Advisors have finalized new guidance for agencies on regulatory analysis. Key features of the revised guidance include: (1) more emphasis on cost-effectiveness analysis as well as benefit-cost analysis; (2) formal probability analysis of future rulemakings with more than a billion-dollar impact on the economy; and (3) more systematic evaluation of qualitative as well as quantified benefits and costs. Appendix D contains the final regulatory analysis guidelines, which have been formally issued as "OMB Circular A-4, Regulatory Analysis". Appendix E includes a summary of the public comments on the draft revised guidance and OMB's response to those comments. Appendix F presents evidence supporting the discount rate recommended in Circular A-4.

- With regard to emerging risks to public health, safety and the environment, an Interagency Work Group on Risk Management has described current U.S. approaches to risk assessment and management. The concept of precaution plays an important role in these approaches, but precaution, coupled with objective scientific analysis, needs to be applied wisely on a case-by-case basis. The Work Group was co-chaired by OMB and CEQ and used public comments to assist in the development of the risk management report in Chapter III.

- In light of the significant interest in homeland security regulation, OMB sought public comment on how to effectively evaluate the benefits and costs of homeland security proposals. The challenges in measuring anti-terrorism benefits and the direct and indirect costs of anti-terrorism rules are discussed. Special concerns are raised about costs related to time, convenience, privacy and civil rights and liberties, and economic productivity. An updated listing of proposed and final rules related to homeland security is provided as well as a summary of recent legislative activity. (Chapter IV)

- OMB surveyed agency consultation with State and local governments, a process critical to the development of sound regulatory policy. Federal departments such as Education, Health and Human Services and Agriculture are engaged in a wide range of intergovernmental consultation activities. For example, Education has undertaken extensive dialogue with State, local and tribal governments in support of implementation of the No Child Left Behind Act (NCLBA). The result was the development of rules implementing the NCLBA's provisions on academic standards and accountability. During the last year, Federal agencies issued five proposed or final rules that were subject to the reporting requirements of the Unfunded Mandates Reform Act. Although these rules imposed significant expenditures on the private sector, none of them involved rules where expected costs to State, local, or tribal governments were expected to exceed $100 million. (Part II).

This final report was issued in draft form in February of this year and was revised in response to public comment, external peer review, and interagency review. OMB has already begun to prepare the 2004 Report to Congress on the Costs and Benefits of Federal Regulations. OMB's objective is to publish the draft 2004 report as part of the President's FY 2005 budget submission to Congress, which will be released in February 2004.

PART 1: Report to Congress on the Costs and Benefits of Federal Regulations

CHAPTER I: THE COSTS AND BENEFITS OF FEDERAL REGULATIONS

The "Regulatory Right-to-Know Act,"[1] requires OMB to submit "an accounting statement and associated report" including:

> (1) an estimate of the total annual costs and benefits (including quantifiable and nonquantifiable effects) of Federal rules and paperwork, to the extent feasible:
>
> (A) in the aggregate;
>
> (B) by agency and agency program; and
>
> (C) by major rule;
>
> (2) an analysis of impacts of Federal regulation on State, local, and tribal government, small business, wages, and economic growth; and
>
> (3) recommendations for reform.[2]

This chapter presents the accounting statement. Our new estimates are based on the major regulations reviewed by OMB over the last ten years. We revised the benefit-cost estimates in last year's report by updating the estimates to the end of fiscal year 2002 (September 30, 2002) and including new estimates from October 1, 1992 to March 31, 1995.

All of the estimates presented in this chapter are based on agency information or transparent modifications of agency information performed by OMB. We have not provided new information on the impacts of Federal regulation on State, local, and tribal government, small businesses, wages, and economic growth in this report, because little new information has become available since last year's report. The 2002 report includes discussions of these issues (see pages 41 to 46).

This chapter also includes a discussion of major rules issued by independent regulatory agencies, although OMB does not review these rules under Executive Order 12866. This discussion is based on data provided by these agencies to the General Accounting Office (GAO) under the Congressional Review Act.

---

[1] 31 U.S.C. § 1105 note, Pub. L. 106-554, ' 1(a) (3) [Title VI, ' 624], Dec. 21, 2000, 114 Stat. 2763, 2763A-161. The text of the Regulatory Right-to-Know Act is in Appendix J of this report.

[2] Recommendations for reform are discussed in Chapter II and Appendix C.

A. Estimates of the Total Benefits and Costs of Regulations Reviewed by OMB[3]

Table 1 presents estimates by agency of the benefits and costs[4] of major rules[5] reviewed by OMB over the past year (October 1, 2001 to September 30, 2002). OMB reviewed 31 final major rules over that period. These 31 rules represent less than ten percent of the 330 final rules reviewed by OMB and less than one percent of the 4,153 final rules published in the Federal Register during this 12-month period. However, OMB believes that the costs and benefits of major rules are quantitatively more important than all other rules combined.

Of the 31 rules, 25 implemented Federal budgetary programs, which caused income transfers from one group to another. The remaining six regulations were "social regulations", requiring substantial additional private expenditures and/or providing new social benefits.[6] Four of these six "social regulations" imposed mandates on State and local entities or the private sector. The other two "social regulations" were enabling regulations that did not impose mandates.

Of the six "social regulations," we are able to present estimates of both monetized costs and benefits for three rules.[7] We did not include the three other rules that did not have monetized estimates for either costs or benefits or both. Three agencies—DOE, DOT, and EPA—issued three major regulations adding a combined $2.4 billion to $6.5 billion in annual benefits and $1.6 billion to $2.0 billion in annual costs.

Table 1: Estimates of the Annual Benefits and Costs of Major Federal Rules, October 1, 2001 to September 30, 2002
(millions of 2001 dollars)

Agency	Benefits	Costs
Energy	710	636
Transportation	409 to 944	749 to 1,206
Environmental Protection Agency	1,250 to 4,818	192
Total	**2,369 to 6,472**	**1,577 to 2,034**

Table 2 presents an estimate of the total costs and benefits of all 107 regulations reviewed by OMB over the ten-year period from October 1, 1992 to September 30, 2002 that met two

[3] In previous reports, OMB presented detailed discussions about the difficulty of estimating and aggregating the costs and benefits of different regulations over long time periods and across many agencies. Those discussions are not repeated here. Previous reports are on the OMB website (http://www.whitehouse.gov/omb/inforeg/regpol.html).
[4] In many instances, agencies were unable to quantify all benefits and costs. We attempted to capture the essence of these effects on a rule-by-rule basis in the columns titled "Other Information" in the various tables reporting agency estimates. However, the monetized estimates we present necessarily exclude these unquantified effects.
[5] The Federal Register citations for these major rules are found in Table 4.
[6] Rules that transfer Federal dollars among parties are not included in the benefit-cost totals because transfers are not social costs or benefits. If included, they would add equal amounts to benefits and costs.
[7] OMB used agency estimates where available. If an agency quantified estimates but did not monetize, standard assumptions were used to monetize as explained in Appendix A.

conditions. Each rule generated costs or benefits of at least $100 million annually, and a substantial portion of its costs and benefits were quantified and monetized by the agency or, in some cases, monetized by OMB. The estimates are therefore not a complete accounting of all the costs and benefits of all regulations issued by the Federal government during this period. We calculated Table 2 estimates by adding the estimates in Table 1 above and the estimates from Table 18 (in Appendix A of this report) and Table 8 (in the 2002 OMB report).

We have expanded the number of years covered by our estimates to ten from the six and one-half years presented in last year's report. We provide estimates of the cost and benefits of social regulation (health, safety and environmental regulation) for each rule for the periods covering October 1, 1992 to March 31, 1995 and October 1, 2001 to September 30, 2002 in Appendix A.[8] The estimates of the costs and benefits of Federal regulations over the period October 1, 1992 to September 30, 2002 are based on agency analyses subject to public notice and comments and OMB review under E.O. 12866. OMB has chosen a 10-year period for aggregation because pre-regulation estimates prepared for rules adopted more than ten years ago are of questionable relevance today.

Table 2: Estimates of the Total Annual Benefits and Costs of Major Federal Rules, October 1, 1992 to September 30, 2002
(millions of 2001 dollars)

Agency	Benefits	Costs
Agriculture	3,094 to 6,176	1,643 to 1,672
Education	655 to 813	361 to 610
Energy	4,700 to 4,768	2,472
Health &Human Services	9,129 to 11,710	3,165 to 3,334
Housing & Urban Development	551 to 625	348
Labor	1,804 to 4,185	1,056
Transportation	6,144 to 9,456	4,220 to 6,718
Environmental Protection Agency	120,753 to 193,163	23,359 to 26,604
Total	**146,812 to 230,896**	**36,625 to 42,813**

In last year's report, the aggregate costs of regulations fell within the range of the estimated benefits – albeit at the lower end of the range. The aggregate benefits reported in Table 2, however, are roughly three to five times the aggregate costs and are substantially larger than the aggregate benefits reported in our 2002 report. There are two reasons for this. First, the additional rules cover a 10-year period that included EPA's rule implementing the sulfur dioxide limits of the acid rain provisions in the 1990 Amendments to the Clean Air Act. This rule adds nearly $80 billion per year to the aggregate benefit estimate. Second, in reviewing our estimates, we inadvertently subtracted incorrect cost estimates for EPA's rules establishing National

[8] Agency estimates of the cost and benefits of major regulations for October 1, 1992 to March 31, 1995 are provided in Appendix B. Appendix A contains estimates revised by OMB.

Ambient Air Quality Standards for ozone and particulate matter (PM). This correction reduces the aggregate cost of the rules covered over the 10-year period by roughly $20 billion per year.

It is important to note that of the 107 rules reviewed by OMB over the last ten years, four EPA rules – two rules limiting particulate matter and NO_x emissions from heavy duty highway engines, the Tier 2 rule limiting the emissions from light duty vehicles, and the Acid Rain rule cited above -- account for a substantial fraction of the aggregate benefits reported in Table 2. These four EPA rules have estimated benefits of $101 to $119 billion per year and costs of $8 to $8.8 billion per year.[9] The aggregate benefits and costs for the other 103 rules are $41 to $107 billion and $29 to $34 billion, respectively.

Table 3 provides additional information on aggregate benefits and costs for select agency programs. The reader should not assume that the low (high) end of the benefits estimate corresponds to the low (high) end of the cost estimate. Thus, for example, it is possible that the net benefits of EPA's water rules taken together could range from negative $2 billion to positive $5.7 billion per year.

Based on the information released in previous reports, the total costs and benefits of all Federal rules now in effect (major and non-major, including those adopted more than 10 years ago) could easily be a factor of ten or more larger than the sum of the costs and benefits reported in Table 2. More research is necessary to provide a stronger analytic foundation for comprehensive estimates of total costs and benefits by agency and program.

---

[9] These four EPA rules will reduce ambient levels of fine particulate matter by reducing direct PM emissions and/or the emissions of precursor pollutants like SO_2 and NO_x that contribute to the formation of secondary fine PM. Studies show an association between both short- and long-term exposure to fine PM and a variety of adverse health effects ranging from increases in the frequency of hospital admissions to premature mortality. There are, however, important uncertainties associated with translating this scientific evidence into benefit estimates. There are five key assumptions underlying the benefit estimates. These include the following:

1. The analysis assumes that inhalation of fine particles is causally associated with premature death at concentrations near those experienced by most Americans on a daily basis. Although studies have yet to establish the specific biological mechanisms responsible for such effects, the weight of the available epidemiological evidence supports an assumption of causality.
2. The analysis assumes that all fine particles, regardless of their chemical composition, are equally potent in causing premature mortality. This is an important assumption because fine particles from power plant emissions are chemically different from those directly emitted from both mobile sources and other industrial facilities. However, no clear scientific grounds exist at this time for supporting differential toxicity estimates by particle type.
3. The analysis assumes that the concentration-response function for fine particles is approximately linear within the range of outdoor concentrations under policy consideration. Thus, the analysis estimates health benefits from reducing fine particles in both attainment and non-attainment regions.
4. The analysis assumes that we have the ability to accurately forecast future emissions and associated air quality modeling.
5. The analysis assumes that the valuation of the estimated reduction in mortality risk is appropriately represented by studies of the tradeoff associated with wage premiums for workers facing fatality risks in the labor market.

Further information on these benefits estimates can be found at http://www.epa.gov/air/clearskies/tech_adden.pdf, http://www.whitehouse.gov/omb/inforeg/costbenefitreport1998.pdf, and http://www.whitehouse.gov/omb/inforeg/2000fedreg-report.pdf

In order for comparisons or aggregation to be meaningful, benefit and cost estimates should correctly account for all substantial effects of regulatory actions, not all of which may be reflected in the available estimates. OMB has not made any changes to agency monetized estimates other than converting them to annual equivalents. Any comparison or aggregation across rules should also consider a number of factors that our presentation does not address. To the extent that agencies have adopted different methodologies —for example, different monetized values for effects, different baselines in terms of the regulations and controls already in place, different treatments of uncertainty—these differences remain embedded in Table 2. While we have relied in many instances on agency practices in monetizing costs and benefits, our citation of, or reliance on, agency data in this report should not be taken as an OMB endorsement of all the varied methodologies used to derive benefits and cost estimates.

Many of these major rules have important non-quantified benefits and costs. These qualitative issues are discussed in the agency rulemaking documents, in previous versions of this report, and in Table 4 of this report.

Table 3: Estimates of Annual Benefits and Costs of Major Federal Rules: Selected Programs and Agencies October 1, 1992-September 30, 2002
(millions of 2001 dollars)

Agency	Benefits	Costs
Energy		
Energy Efficiency and Renewable Energy	4,700-4,768	2,472
Health & Human Services		
Food and Drug Administration	2,016-4,551	481-651
Labor		
Occupational Safety and Health Administration	1,804-4,185	1,056
Transportation		
National Highway Traffic Safety Administration	4,321-7,634	2,791-5,288
Coast Guard	72	1,195
Environmental Protection Agency		
Office of Air	117,888-177,330	17,861-20,561
Office of Water	891-8,076	2,418-2,931

B. Estimates of Benefits and Costs of This Year's "Major" Rules

In this section, we examine in detail the benefits and costs of each "major" rule, as required by section 624(a) (1) (C). Our review covers those final regulations on which OMB concluded review during the 12-month period October 1, 2001 through September 30, 2002.

The statutory language that categorizes the rules we consider for this report differs from the definition of "economically significant" in Executive Order 12866 (section 3(f)(1)). It also differs from similar statutory definitions in the Unfunded Mandates Reform Act and subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996—Congressional Review of Agency Rulemaking. Given these varying definitions, we interpreted section 624(a)(1)(C) broadly to include all final rules promulgated by an Executive branch agency that meet any one of the following three measures:

- rules designated as "economically significant" under section 3(f)(1) of Executive Order 12866;
- rules designated as "major" under 5 U.S.C. ' 804(2) (Congressional Review Act); and
- rules designated as meeting the threshold under Title II of the Unfunded Mandates Reform Act (2 U.S.C. ' 1531 - 1538)

Of the 31 rules received by OMB, USDA submitted four; the Veterans Administration, DOE, EPA, OMB, the Social Security Administration, and SBA each submitted one; HHS submitted eight; the Departments of Interior, Justice, Defense, and FEMA each submitted two; and DOT submitted five.

Social Regulation

Of the 31 economically significant rules reviewed by OMB, six are regulations requiring substantial additional private expenditures and/or providing new social benefits. Table 4 summarizes the costs and benefits of these rules and provides other information taken from rule preambles and agency RIAs. Of the six regulations received by OMB, EPA and DOE each submitted one, and DOI and DOT each submitted two. Agency estimates and discussion are presented in a variety of ways, ranging from a mostly qualitative discussion (e.g., the NHTSA light truck corporate average fuel economy (CAFE) standard) to a more complete benefit-cost analysis (e.g., DOE's central air conditioner rule).

1. Benefits Analysis.

Agencies monetized at least some benefit estimates for five of the six rules. In the case of EPA's recreational engines rule, the agency provides some monetized benefit estimates, but discusses other benefits qualitatively. In one case—NHTSA's tire pressure monitoring systems (TPMS) rule—the agency did not monetize all of the quantified benefits. In another case—NHTSA's CAFE rule—the agency did not report any quantified or monetized benefit estimates.

2. Cost Analysis.

For three of the six rules, agencies provided monetized cost estimates. These include DOE's air conditioner rule, NHTSA's TPMS rule, and EPA's recreational vehicle rule. For the remaining three rules (both DOI migratory bird hunting rules and NHTSA's CAFE rule), agencies did not estimate costs.

3. Net Monetized Benefits.

Three of the six rules provided at least some monetized estimates of both benefits and costs.[10] Of these, the estimated monetized benefits of both the DOE air conditioner rule and the EPA recreational engine rule exceed the estimated monetized costs. The magnitude of the net benefits varies from $75 million per year for the air conditioner rule to as much as $4.6 billion per year for the recreational engine rule. One rule, NHTSA's TPMS rule, has negative net monetized benefits ranging from approximately $706 to $862 million per year.

4. Rules Without Quantified Effects.

One rule, NHTSA's CAFÉ rule, is classified as economically significant even though the agency did not provide any quantified estimates of its effects.

[10] See Table 4 for the discussion of benefits and costs that the agency did not monetize.

Table 4. Summary of Agency Estimates for Final Rules October 1, 2001 to September 30, 2002 (As of Date of Completion of OMB Review)				
AGENCY	**RULE**	**BENEFITS**	**COSTS**	**OTHER INFORMATION**
DOE	Energy Conservation Standards for Central Air Conditioners and Heat Pumps (67 FR 36367)	$9.1 billion (present value) in energy savings between 2006 and 2030	$7.3 billion (present value) for purchases between 2006 and 2030	Monetized benefit and cost values are obtained from the "National Energy Savings/Net Present Value/Shipments" spreadsheet, available on DOE's web site: http://www.eren.doe.gov/buildings/codes_standards/applbrf/central_air_conditioner_3.html DOE projects a cumulative reduction in nitrogen oxide emissions of 119.3 thousand metric tons (undiscounted) over the period 2006-2030 and a cumulative reduction in carbon dioxide equivalent emissions of 53.8 million metric tons (undiscounted) over the period 2006-2030 [DOE Technical Support Document Appendix M, Table M.9].
DOI	Early-Season Migratory Bird Hunting Regulations 2002-2003 (66 FR 44009)	$50 million to $192 million/yr.	Not estimated	The analysis was based on the 1996 National Hunting and Fishing Survey and the U.S. Department of Commerce's County Business Patterns, from which it was estimated that migratory bird hunters would spend between $429 million and $1,084 million at small businesses [67 FR 54704]. The listed benefits represent estimated consumer surplus.
DOI	Late-Season Migratory Bird Hunting Regulations 2002-2003 (66 FR 49477)	$50 million to $192 million/yr.	Not estimated	The analysis was based on the 1996 National Hunting and Fishing Survey and the U.S. Department of Commerce's County Business Patterns, from which it was estimated that migratory bird hunters would spend between $429 million and $1,084 million at small businesses [67 FR 54704]. The listed benefits represent estimated consumer surplus.
DOT	Light Truck Average Fuel Economy Standard, Model Year 2004 (67 FR 16052)	Not estimated.	Not estimated	"…[T]he agency has been operating under a restriction on the use of appropriations for the last six fiscal years. The restriction has prevented the agency from gathering and analyzing data relating to fuel economy capabilities and the costs and benefits of improving the level of fuel economy. Particularly since that restriction was lifted only on December 18, 2001, the agency has been unable to prepare a separate economic analysis for this rulemaking. The agency notes, however, that the standard it is setting for the 2004 model year will not make it necessary for the manufacturers with a substantial share of the market to change their product plans." [67 FR 16059]
DOT	Tire Pressure	79 – 124 fatalities	$749 - $1,206	Unquantified Benefits: "The agency cannot quantify the benefits from a

Table 4. Summary of Agency Estimates for Final Rules October 1, 2001 to September 30, 2002 (As of Date of Completion of OMB Review)				
AGENCY	**RULE**	**BENEFITS**	**COSTS**	**OTHER INFORMATION**
	Monitoring Systems (TPMS) (67 FR 38703)	and 5,176 - 8,722 injuries prevented per year; $43 - $344 million per year in fuel savings and reduced tire wear	million/yr	reduction in crashes associated with hydroplaning and overloading vehicles. The primary reason that the agency has been unable to quantify these benefits is the lack of crash data indicating tire pressure and how often these conditions are the cause or contributing factors in a crash. The agency does not collect tire pressure in its crash investigations. NHTSA also has not been able to quantify the benefits associated with reductions in property damage and travel delays that will result from fewer crashes or reductions in the severity of crashes." [67 FR 38739] Unquantified Costs: "The agency anticipates that there may be other maintenance costs for both direct and indirect TPMS. For example, with indirect TPMSs, there may be problems with wheel speed sensors and component failures. With direct TPMSs, the pressure sensors may be broken off when tires are changed. The agency requested comments on this issue in the NPRM, but received none. Without estimates of these maintenance problems and costs, the agency is unable to quantify their impact. The agency also notes that in order to benefit from the TPMS, drivers must respond to a warning by re-inflating their tires. To accomplish this, most drivers will either make a separate trip to a service station or take additional time to inflate their tires when they are at a service station for fuel. The process of checking and re-inflating tires is relatively simple, and probably would take from three to five minutes. The time it would take to make a separate trip to a service station would vary depending on the driver's proximity to a station at the time he or she was notified." [67 FR 38741]
EPA	Control of Emissions From Nonroad Large Spark-Ignition Engines, and Recreational Engines (67 FR 68241)	$410 million/yr. in reduced engine operation costs; $900 million to $7.88 billion in air quality benefits in calendar year 2030	$192 million/yr	EPA also lists a variety of other benefit categories that it was not able to quantify or monetize, ranging from infant mortality to damage to urban ornamental plants. [67 FR68328]

Transfer Regulations

Of the 31 economically significant rules reviewed by OMB, Table 5 lists the 25 that implement Federal budgetary programs. The budget outlays associated with these rules are "transfers" to program beneficiaries. Of the transfer rules, HHS promulgated eight rules, most of which implement Medicare and Medicaid policy. Four are USDA rules. Of the four, three are crop assistance and disaster aids for farmers and one is a food stamp program rule. The Department of Transportation issued three transfer rules. The Departments of Defense, Justice, and the Federal Emergency Management Administration issued two each. The Social Security Administration, Veterans Administration, Small Business Administration, and Office of Management and Budget each promulgated one rule.

Table 5. Agency Transfer Rules
October 1, 2001 to September 30, 2002
(As of date of completion of OMB review.)

Office of Management and Budget (OMB)
Regulation for Air Carrier Guaranteed Loan Program
Dept. of Agriculture (USDA)
2000 Crop Agricultural Disaster and Market Assistance
2002 Farm Bill Regulations: Sugar Program
Peanut Quota Buyout Program
Work Provisions of the PRWORA of 1996 and the Food Stamp Provisions of the Balance Budget Act of 1997
Dept. of Defense
CHAMPUS/TRICARE: Partial Implementation of Pharmacy Benefits Programs; NDAA for FY 2001
TRICARE: Sub-Acute Care Program; Uniform Skilled Nursing Benefit; Home Healthcare Benefit; Medicare Payment Methods for Skilled Nursing Facilities
Dept. of Health and Human Services (HHS)
Contraception and Infertility Research Loan Repayment Program
Medicare Program: Revisions to Payment Policies and 5-Year Review and Adjustments to the Relative Value Units Under the Physician Fee Schedule for CY 2002
Medicare Program: Prospective Payment System for Hospital Outpatient Services for CY 2002 and Pro Rata Reduction on Transitional Pass-Through Payments.
Medicaid Program: Modification of the Medicaid Upper Payment Limit for Non-State, Government-Owned or Operated Hospitals
Medicare Program: Modifications to Managed Care Rules Based on Payment Provisions in BIPA and Technical Corrections.
Medicare Program: Notice of Modification of Beneficiary Assessment Requirements for Skilled Nursing Facilities
Changes to Hospital Inpatient Prospective Payment Systems and FY 2003 Rate
Medicaid Managed Care; New Provisions
Social Security Administration

Table 5. Agency Transfer Rules October 1, 2001 to September 30, 2002 (As of date of completion of OMB review.)
Revised Medical Criteria for Determination of Disability Musculoskeletal System and Related Criteria
Department of Justice
Claims Under the Radiation Exposure Compensation Act Amendments of 2000
September 11 Victim Compensation Fund of 2001
Dept. of Transportation
Procedures for Compensation of Air Carriers
Imposition and Collection of Passenger Civil Aviation Security Fees in the Wake of September 11
Aviation Security Infrastructure Fees
Veterans Administration
Diseases Specific to Radiation-Exposed Veterans
Federal Emergency Management Administration
Assistance to Firefighters Grant Program
Disaster Assistance; Federal Assistance to Individuals and Households
Small Business Administration
Disaster Loan Program

Major Rules for Independent Agencies

The congressional review provisions of the Small Business Regulatory Enforcement Fairness Act (SBREFA) require the General Accounting Office (GAO) to submit reports on major rules to the committees of jurisdiction, including rules issued by agencies not subject to Executive Order 12866 (the "independent" agencies). We reviewed the information on the costs and benefits of major rules contained in GAO reports for the period of October 1, 2001 to September 30, 2002.

GAO reported that three independent agencies issued eight major rules during this period. Two agencies did not conduct benefit-cost analyses. One agency considered benefits and costs of its rules. OMB lists the agencies and the type of information provided by them (as summarized by GAO) in Table 6. The Securities and Exchange Commission consistently considered benefits and costs in their rulemaking processes while the Federal Communications Commission and the Nuclear Regulatory Commission did not prepare benefit-cost analyses.

In comparison to the agencies subject to E.O. 12866, the independent agencies provided relatively little quantitative information on the costs and benefits of the major rules. As Table 6 indicates, three of the eight rules included some discussion of benefits and costs. Three of the eight regulations had monetized cost information; one regulation monetized benefits. OMB does not know whether the rigor and the extent of the analyses conducted by the independent agencies

are similar to those of the analyses performed by agencies subject to the Executive Order because OMB does not review rules from independent agencies.

Table 6. Rules for Independent Agencies October 1, 2001 to September 30, 2002

Agency	Rule	Information on Benefits or Costs	Monetized Benefits	Monetized Costs
FCC	Broadcast Services; Digital Television	No	No	No
FCC	Ultra-Wideband Transmission Systems	No	No	No
FCC	Assessment and Collection of Regulatory Fees for Fiscal Year 2002	No	No	No
FCC	Order to Permit Operation of NGSO FSS Systems Co-Frequency with GSO and Terrestrial Systems in the Ku-Band Frequency Range; Authorize Subsidiary Terrestrial Use of the 12.2-12.7 GHz Band by Direct Broadcast Satellite Licensees and Their Affiliates; and in Re-Applications of Broadwave USA, PDC Broadband Corporation, and Satellite Receivers, Ltd. in the 12.2-12.7 GHz Band	No	No	No
NRC	Revision of Fee Schedules; Fee Recovery for FY 2002	No	No	No
SEC	Books and Records Requirements for Brokers and Dealers Under the Securities Exchange Act of 1934	Yes	Yes	Yes
SEC	Certification of Disclosure in Companies' Quarterly and Annual Reports	Yes	No	Yes
SEC	Acceleration of Periodic Report Filing Dates and Disclosure Concerning Web Site Access to Reports	Yes	No	Yes

C. Response to Public Comments

Many comments on the draft report pertained to Chapter I, which presented estimates of costs and benefits of major rules. In general, these comments addressed either (1) the scope/coverage of the rules considered in the report, or (2) the quality of agency or OMB analysis.

Comments on Scope/Coverage

One commenter (12) stated that the report should provide more information—even if only gross estimates—on the effects of Federal regulation on States and municipalities. OMB notes that this report includes the annual report to Congress on Unfunded Mandates on State, local, and tribal entities. Information on rules reviewed by OMB that impose such mandates is included.

One commenter (284) urged OMB to provide information on the benefits and costs of regulations issued by independent agencies. OMB agrees that it is important to assess the benefits and costs of independent agency regulatory actions. Currently, OMB relies on GAO reports as the primary data source to do so. A simple analysis of the GAO reports, however, may not be adequate in all cases. OMB encourages independent agencies to conduct benefit-cost analyses that conform to the OMB's guidelines for regulatory analysis and to submit those analyses of major rules to OMB.

Two commenters (307, 327) recommended that the report should include estimates of the benefits and costs of regulations issued prior to 1992. OMB does not believe that the estimates of the costs and benefits of regulations issued over ten years ago are very reliable or very useful for informing current policy decisions. In future annual reports, OMB will report a rolling total of the benefits and costs of rules for the previous 10 years.

One commenter (327) believed the report should include benefit and cost estimates for non-major rules. OMB believes that major (economically significant) rules account for the vast majority of the total costs of Federal regulation, even though most Federal rules are not considered major.

One commenter (251) asserted that the draft report inappropriately excluded deregulatory actions. OMB notes that the final report includes all final rules reviewed by OMB over a ten-year period from October 1, 1992 to September 30, 2002 that met two conditions: each rule generated costs or benefits of at least $100 million annually, and a substantial portion of its costs and benefits were quantified and monetized by the agency or OMB. All regulations that fit these conditions are included in the final report, even if they are deregulatory.

Several commenters (3, 251, 307, 352) recommended that OMB should provide a better accounting of transfer rules. OMB believes there is merit to this request and is considering the feasibility of providing such information in future reports.

One commenter (251) stated that the draft report inappropriately excludes certain rules with large net benefits. Specifically, this commenter identified three EPA emission rules, OSHA's ergonomics rule, FDA's regulation of tobacco, and EPA's revised national ambient air quality standards for ozone and particulate matter. In this report and in previous reports, OMB has provided a reasoned explanation for the exclusion of certain rules. With respect to the three emission rules (the 1995 municipal waste combustors rule, the 1997 emission standards for new locomotives, and the 1998 emission standards for non-road diesel engines) included previously

(see Tables 5 and 6 of the 2002 report), OMB decided not to include their monetized estimates because of the significant uncertainties associated with benefits transfer described in more detail elsewhere in this report. OMB did not include OSHA's ergonomics rule because it was overturned by Congress. OMB did not include FDA's tobacco rule because it was overturned by the Supreme Court. As noted in last year's report, OMB removed EPA's NAAQS for ozone and particulate matter to prevent double counting of benefits and costs.

Comments on Quality of Analysis

Two commenters (307, 331) questioned estimates of the benefits and costs of several rules, and recommended that OMB rely on an independent analysis of the benefits and costs of regulations, rather than rely on agency estimates. OMB recognizes the importance of objective, expert analysis of regulatory impacts, and has several mechanisms in place to improve and ensure the quality of agency analysis. For example, through the issuance of guidelines, OMB aims to improve the quality of information and analysis that supports rulemaking. In conjunction with the Council on Economic Advisors, OMB recently revised its guidelines and subjected the revised guidelines to interagency review, peer review, and public comment. As a result of this process, OMB has issued its guidelines as Circular A-4, Regulatory Analysis. Appendix D contains this Circular, and Appendix E presents OMB's response to public comments on the revised guidelines.

Through the rule review process, OMB identifies and, where warranted, seeks improvement of agency analysis of regulatory impacts. To ensure consistency in the context of this annual report, OMB adjusts Agency estimates of costs and benefits. Although such procedural steps do not ensure accuracy, they do improve the quality of the analysis supporting rulemaking, while leveraging the data and expertise of the agency issuing the rule.

Two commenters raised issues about the accuracy of pre-regulation estimates of costs and benefits. Commenter 327 stated that the report should account for outcomes known to differ from the agency's original estimates. Commenter 335 recommended that OMB review past estimates of the costs of environmental compliance and compare them with actual costs. OMB agrees that it is useful to compare actual with predicted estimates. In situations where OMB becomes aware of information more reliable than the agency's original estimates, OMB will use such information. Think tanks and universities may be in the best position to undertake this kind of exercise, and OMB encourages such efforts.

One commenter (328) suggested that the report should acknowledge the uncertainty inherent in benefit and cost estimates and should quantify uncertainty in future years' summary reports. OMB notes that the report contains substantial discussion of key uncertainties and will attempt to quantify these uncertainties in future reports in those cases where sufficient data are available. In addition, OMB's revised regulatory analysis guidelines (Circular A-4) includes a recommendation for agencies to undertake formal probability analysis for rules involving threshold annual costs or benefits greater than $1 billion.

One commenter (352) noted that interagency differences in regulatory analysis methods make it difficult to compare results between agencies. This commenter believes that the revised

guidelines should help in this regard, and suggests that OMB could standardize the results across agencies using common methods and values. OMB believes the best way to address this issue will be through its revised guidelines (i.e., Circular A-4, Regulatory Analysis), which are designed to promote consistent analytical approaches.

One commenter (251) asked that OMB clarify the reasons for the differences between estimates of annual benefits and costs presented in Tables 7 and 8 and the corresponding original agency estimates for the same rules in Tables 4, 9, 10, and 11. In this final report, we clarified the nature of the differences between the two sets of estimates. The estimates presented in Tables 4, 9, 10, and 11 reflect what agencies reported in their Regulatory Impact Analyses. These estimates are not consistent in several respects. For example, some agencies reported discounted present values over several years, whereas others reported average annual effects. As explained in the text and on a rule-by-rule basis in the tables, in order to improve comparability, OMB made three types of adjustments. (1) All values were adjusted to year 2001 dollars. (2) Quantified but non-monetized estimates were monetized (consistent with agency past practices). (This explains why, for example, the monetized benefits for the acid rain rule in Table 7 are larger than those in Table 9.) (3) Estimates of net present value were amortized or "annualized" (i.e., converted to average annual effects) to provide an annualized stream of benefits and costs.

One commenter (346) suggested that OMB reevaluate the methodology underlying, and the application of, the adjustment to the value of a statistical life for the age of the affected population. OMB has revised the estimates in this chapter to be consistent with the OIRA Administrator's May 30, 2003 memorandum to the President's Management Council. (A copy can be found on the OMB web site: http://www.whitehouse.gov/omb/inforeg/pmc_benefit_cost_memo.pdf

One commenter (319) recommended that OMB use a value of $120,000 per barrel as an estimate of the social cost of a spilled barrel of oil. OMB has asked the Coast Guard to review this recommendation and will address this issue in next year's report.

One commenter (3) suggested insertion of language regarding the importance of the quantification of benefits and costs to help inform the public and decision makers. OMB has included such language in the final report.

One commenter (12) suggested that the report should provide a case study of a well-done benefit-cost analysis of a regulation. OMB will consider including such a case study in its next annual report.

One commenter (20) stated that the report should note the wide range of benefits estimates for EPA's Office of Water regulations (Table 3). According to this commenter, it is possible that the actual costs of compliance are on the high end of the range presented and the corresponding benefits are on the low end, which would result in negative net benefits. OMB has noted this possibility in the report.

One commenter (284) recommended that the final report include summary information on OMB's regulatory oversight activities, such as return and prompt letters. (284) OMB concurs with this comment, and has provided such information in Appendix G to this report.

OMB received a comment from the Nuclear Regulatory Commission. The commenter believed that Table 6 and the accompanying discussion could lead to the erroneous conclusion that the Nuclear Regulatory Commission (NRC) does not provide benefit and cost information on its rules. OMB does not believe that Table 6, or the accompanying discussion, states or implies that the NRC does not analyze its health and safety rules.

CHAPTER II: STATUS REPORT ON SPECIFIC REGULATORY REFORMS

In last year's report, OMB responded to the Regulatory Right-to-Know Act's requirement that we include recommendations for regulatory reform. We began the process of developing reform recommendations by requesting public nominations of regulatory reforms in the March 2002 draft report. OMB encouraged the public to consider problematic paperwork and guidance document requirements, along with regulatory requirements.

In order to encourage broad public participation and to expand on the response received in 2001, OMB conducted outreach activities to a wide variety of groups. As a result, OMB received approximately 1,700 public comments nominating specific regulations and guidance documents for reform. OMB conducted a preliminary review of the public comments and identified 267 rules and 49 guidance documents nominated for reform by one or more commenters for a grand total of 316 distinct reform nominations.[11]

This chapter provides an overview of how OMB worked with agencies to review the public nominations and describes the follow-up activities that are now underway in the agencies.

A. Process for Reviewing Reform Nominations

In our review of the 316 nominations, OMB found that the rules and guidance documents fell into three categories: (1) issues already subject to recent or current review by Cabinet agencies (and EPA); (2) issues concerning independent agencies; and (3) issues that warranted consideration by Cabinet agencies (and EPA) as reform candidates. This review was based on information available to OMB at the time the public nominations were processed (summer 2002).

A chief purpose of the reform process was to focus agency attention on issues that are not already under active review. OMB found that 92 rules and 12 guidance documents had recently been issued or were already under agency review. This category included some of the nominations designated by OMB in the 2001 report as "high priority review" candidates.[12] Decisions about these issues had been made, or were in the process of being made. OMB did not believe it would be fruitful to ask agencies to consider these rules and guidance documents to be new reform candidates. Accordingly, we simply asked that agencies provide OMB with status updates on the rules and guidance documents in this category.

The second category included 49 rules and 2 guidance documents that raised issues concerning the following independent agencies: the Equal Employment Opportunity Commission, the Federal Communications Commission, the Federal Energy Regulatory Commission, the Federal Reserve Board, the Federal Trade Commission, and the Securities and Exchange Commission. In a memorandum dated January 22, 2003, OMB requested that these

[11] The public comments suggesting candidates for reform—and OIRA's summaries of them—are available on OMB's website at http://www.whitehouse.gov/omb/inforeg/regpol-reports_congress.html.

[12] Appendix C provides updates on the 23 high-priority regulations that OIRA suggested for reform in 2001.

agencies consider the public nominations for which they were responsible and, for those they consider to be possible candidates for reform, place their evaluations on their websites.

The remaining 126 rules and 35 guidance documents made up a third category of nominations that OMB referred to agencies for their evaluation as possible reforms.[13] During the development of this final report, OMB determined that four of these rules and one guidance document should not have been referred to agencies because they were already under active consideration. In Tables 15 and 16, status updates on these four rules and one guidance document are provided along with the other rules and guidance documents that, at the time we issued the 2002 final report, had recently been issued or were already under agency review.[14]

OMB's decision to refer public nominations to agencies for their consideration marked a shift in the approach we adopted in 2001. In the 2001 report, OMB "ranked" the public recommendations for reform and identified a number of "high priority review" candidates. Last year, we decided to change our approach and use an agency-initiated process to evaluate the nominations. We did this for two reasons: (1) the large volume of nominations (316 in 2002 compared to 71 in 2001) strained OMB's ability to develop an informed list of priority nominations for consideration by agencies and (2) giving agencies the task of evaluating the nominations allowed them to bring to bear their extensive knowledge and resources and encouraged them to develop a sense of ownership about reform.

OMB worked with agencies to identify reform opportunities during our inter-agency consultation process. OMB also asked SBA's Office of Advocacy (Advocacy) to review all of the public nominations and identify for agencies those that it thought offered the potential to reduce unjustified regulatory burdens on small businesses.[15] In response to OMB's request, the Office of Advocacy reviewed the rules and guidance documents listed on Tables 13 and 14 of OMB's FY 2002 report, as well as the rules and guidance documents concerning selected independent agencies. While acknowledging that reform of many, if not all, of the regulations and guidance documents would achieve benefits for small business, Advocacy identified a subset of 21 rules, 6 guidance documents, and 3 rules and guidance documents of independent agencies as high priorities for reform for small business.[16] Advocacy made its determinations based on the comments submitted to

---

[13]The regulations and guidance documents that OMB referred to agencies are listed in Tables 13 and 14, respectively, of the 2002 Final Report (pp. 78 and 82).

[14] The four rule nominations are Use of the OASIS for Home Health Agencies (#35), Electronic Storage of I-9 Forms (#71), Forms I-140 and I-485 (#73), and Motor Vehicle Emission Standards for Greenhouse Gases (#180). The one guidance document nomination is HHS Discrimination against Persons with LEP (#7).

[15] The Small Business Administration's Office of Advocacy (Advocacy) funded research to address the proportion of the Federal regulatory burden falling on small business. The research was conducted by Drs. Mark Crain and Thomas Hopkins in 2001. The researchers concluded that considering all federal regulations and all business sectors, federal regulations cost firms with fewer than 20 employees nearly $7,000 per employee per year. Regulations cost medium-size firms about $4,300 and large firms $4,500 per year per employee. Costs per employee thus appear to be 55 to 60 percent higher in small firms than in medium-size and large firms. See Crain, MW and Hopkins, TD (2001), *The Impact of Regulatory Costs on Small Firms*, Office of Advocacy, U.S. Small Business Administration. Advocacy is currently committed to updating these figures in 2004.

[16] Advocacy's February 6 letter to OIRA is available on the Office of Advocacy's website at http://www.sba.gov/advo/laws/comments/omb03_0206.html. Certain high-priority reforms identified by Advocacy

OMB, input received from small businesses in preparing Advocacy's May 28, 2002, comment[17] on OMB's draft report, and Advocacy's direct involvement in agency rulemaking affecting small business.[18] In consultation with OMB, Advocacy sent letters directly to each agency and followed up to offer its expertise and assistance with their review of the regulations and guidance documents identified by Advocacy as high priorities for reform for small business.

B. Agency Categorization of Reform Nominations

As explained in the 2002 final report, OMB sought to ensure that the agency review of nominations was objective, consistent, and grounded in the regulatory principles codified in Executive Order 12866 and the statutory authority of the agencies. To help guide agency review of the public nominations, OMB suggested that agencies rely on three criteria: efficiency, fairness, and practicality. We defined these criteria as follows:

- **Efficiency.** Agencies should give consideration to reforms that present an opportunity to increase regulatory efficiency by maximizing net benefits, including potential quantitative and qualitative improvements to the economy, environment, and public health and safety.
- **Fairness**. In addition to assessing overall costs and benefits, agencies should take into consideration nominations with the potential to increase fairness through desirable distributive impacts and process considerations.
- **Practicality**. Agencies should give greater weight to nominations that (1) they have discretion to implement under existing statutory authority (although potential reforms should not be eliminated simply because implementing them would require new statutory authority) and (2) are judged to be important relative to other regulations and programs under consideration for review. OMB is sensitive to the practicalities (including agency resources) of pursuing certain nominations at this time.

OMB understood that agency assessments of reform nominations would necessarily take into account budgetary considerations, statutory mandates, and other relevant factors. OMB also does not expect agencies to necessarily agree with the analysis or solutions presented by commenters, even for those nominations they identified as reform candidates.

For the 126 rules and 35 guidance documents that OMB viewed as potential reform candidates—and that we explicitly referred to agencies for their consideration—we requested that agencies place them into one of three categories:

---

are not identified in this final report. Specifically, three guidance documents from independent agencies are not identified.

[17] Advocacy's letter is available on the Office of Advocacy's website at http://www.sba.gov/advo/laws/comments/omb03_0604.html

[18] The Office of Advocacy of the U.S. Small Business Administration (SBA) was created in 1976 to represent the views and interests of small business in Federal policy making activities. Pub. L. No. 94-305 (codified as amended at 15 U.S.C. §§634a-g, 637). Because the Office of Advocacy is an independent office within SBA, the views of the Chief Counsel do not necessarily represent the views of the SBA or the Administration.

(1) the nominated regulation or guidance document is a viable reform candidate that the agency is, or soon will be, working on;
(2) the nominated regulation or guidance document warrants further study as a possible reform candidate; or
(3) the nominated regulation or guidance document is either a low priority given other agency activities or is considered to be resolved.

After reviewing the public nominations and consulting with OMB and with the Office of Advocacy, agencies identified 34 rules and 11 guidance documents as "new" reform candidates. These were rules and guidance documents that had not been the focus of recent or current agency reform efforts. They included 8 rules and 2 guidance documents identified by Advocacy as high priorities for reform for small business. These 8 rules and 2 guidance documents—as well as the other Advocacy high priorities—will be noted in the tables that appear throughout this chapter. Agencies are undecided about pursuing reforms of another 26 regulations and 4 guidance documents, but they plan to study them further to determine whether or not they should be reformed. The remaining 62 rules and 19 guidance documents were considered by agencies to address issues that were unnecessary or were lower priority, given the other competing demands on their resources.

Table 7 provides an agency-by-agency summary of how agencies categorized the regulations that OMB referred to them for their review. Collectively, agencies decided to take action on 34 of the rule nominations that OMB explicitly referred to them, with DOT identifying ten and EPA identifying eight rules to reform.

Table 7. Agency Categorization of Nominated Reforms – Regulations

Agency	New	Completed or Ongoing	Undecided	Low Priority or Unnecessary	Total
Agriculture	3	7	1	5	16
Commerce	0	1	0	0	1
Education	0	2	0	1	3
Energy	0	1	0	1	2
HHS	6	8	4	14	32
HUD	0	0	0	2	2
Interior	0	10	0	1	11
Justice	0	5	0	2	7
Labor	5	15	4	6	30
State	0	0	0	1	1
Transportation	10	17	13	13	53
Treasury	2	4	0	5	11
EPA	8	25	3	7	42
NARA	0	0	1	0	1
OPM	0	0	0	1	1
SBA	0	1	0	0	1
Army Corps	0	0	0	2	2
USPS	0	0	0	1	1
Total	34	96	26	62	218

Table 8 summarizes how agencies categorized the guidance documents that OMB referred to them. Agencies decided to take action on nearly one-quarter of these guidance documents. In identifying nine guidance documents as worthy of reform, EPA has taken the lead in reforming its guidance.

Table 8. Agency Categorization of Nominated Reforms – Guidance Documents

Agency	New	Completed or Ongoing	Undecided	Low Priority or Unnecessary	Total
Agriculture	0	1	0	0	1
HHS	0	1	1	6	8
Interior	0	0	0	1	1
Justice	0	0	0	1	1
Labor	1	3	1	0	5
Transportation	1	0	0	1	2
Treasury	0	0	1	0	1
Access Board	0	0	1	0	1
EPA	9	5	0	8	22
OMB	0	2	0	1	3
SBA	0	0	0	1	1
Army Corps	0	1	0	0	1
Total	11	13	4	19	47

C. New Reforms Planned or Underway

When OMB asked agencies to tell us which regulations and guidance documents they believed were promising reform candidates, we requested that they provide us with information about their plans to pursue nominations within the next year. When possible, agencies told us which actions they had planned (e.g., advanced notice of proposed rulemaking, or ANPRM) and when they expected to take them.

The information that agencies gave OMB about the expected next steps for new reforms planned or underway is provided in Tables 9 and 10. Summary information about these regulations and guidance documents, as well as a listing of commenters and the issues they raised, is available in a document that OMB issued with the 2002 final report: "Summaries of Public Suggestions for Reform of Regulations and Guidance Documents."[19]

[19]This document is available on the OMB website at www.whitehouse.gov/omb/inforeg/summaries_nominations_final.pdf.

Table 9. New Reforms Planned or Underway – Regulations			
Agency	**Regulation**	**Next Step(s)**	**Ref. Number***
Agriculture	Salmonella Performance Standards	FSIS expects to begin regulatory activity in late 2003 or early 2004. FSIS is considering a petition on posting Salmonella testing results for firms by name. The petition is to be published for comment, with a decision in 2003.	6
Agriculture	Phytosanitary Certificates for Seeds	APHIS will propose to amend the nursery stock regulations by allowing the importation of small lots of seed under an import permit with specific conditions, instead of requiring a phytosanitary certificate from the government of the exporting country.	12
Agriculture	Swine Production Contract Library	USDA is in the process of implementing the swine contract library. OMB recently concluded review on the final rule. USDA has developed an electronic system to receive and summarize information and provide public reports. This system will be operated when the rule is published.	13
HHS/CMS	75% Rule	This issue was discussed at a Town Hall meeting on 5/19/03. CMS obtained information from affected entities and is using the information to develop an NPRM.	26
HHS/CMS	One-Hour Restraint Rule	In October 2002, CMS convened a Town Hall Meeting with affected industry groups, professional organizations, and advocates to gain input regarding reducing burden while maintaining patient protections. CMS is using this information to develop an NPRM to be published in 2003.	31 SBA
HHS/FDA	Standard of Chemical Quality – Arsenic	FDA is considering how to best address this issue.	38
HHS/FDA	Standard of Chemical Quality – Uranium	FDA published a final rule on March 3, 2003.	39
HHS/FDA	Labeling of Carmine	FDA will address this issue in the Fall 2004 Unified Agenda.	47
HHS/FDA	Labeling of Food Allergens	FDA is considering how best to address this issue.	50
Labor	Medical Certification	ESA is considering changes to the FMLA medical certification form as part of the ongoing FMLA regulatory review.	77
Labor	FLSA Administrative Exception	ESA is including changes to the administrative exemption in the comprehensive NPRM on the 29 C.F.R. Part 541 regulations, which was published for comment March 31, 2003.	80 SBA
Labor/OSHA	Explosives and Process Safety Management	OSHA added this issue (standards improvement) to the Semiannual Regulatory Agenda in December 2002. OSHA plans to publish an NPRM by July 2004.	90
Labor/OSHA	Sling Standard	OSHA has underway a project to update standards that are based upon or refer to outdated voluntary consensus standards. This standard is part of that project. OSHA plans to publish an NPRM and/or direct final rule by September 2004.	96 SBA

Table 9. New Reforms Planned or Underway – Regulations			
Agency	**Regulation**	**Next Step(s)**	**Ref. Number***
Labor/OSHA	Bloodborne Pathogens Standard	OSHA will be initiating the next cycle of review this year for this standard.	100
DOT/FAA	Improved Flammability Standards for Thermal/Acoustic Material	OMB concluded its review of this rule in April 2003. DOT anticipates issuing the rule in 2003.	112
DOT/FHWA	Contract Requirements for Minor Transportation Projects	FHWA has already published transportation enhancement program guidance. The guidance included several memoranda which exempt transportation enhancement (TE) projects from several highway requirements, and these are highlighted at www.fhwa.dot.gov/environment/te_meas.htm FHWA is exploring legislative options to streamline administrative procedures for TE activities.	113
DOT/FHWA	Historic Preservation Regulations	The issues raised by the commenter are actively under consideration as FHWA develops its legislative reauthorization proposal.	114
DOT/FHWA	Traffic Operations	Final rule is scheduled for October 2003.	117
DOT/FHWA	Highway Work Zone Safety	DOT issued an NPRM in May 2003.	118
DOT/NHTSA	Roof Crush	NHTSA is developing a comprehensive plan to address rollover, including roof crush. In October 2001, NHTSA issued a request for comments to assist in upgrading the requirements of FMVSS No. 216. The notice asked the public for its views and comments on what changes, if any, are needed to the roof crush resistance standard. The agency has completed its review of the comments submitted in response to that notice and expects to publish an NPRM in early 2004.	137
DOT/NHTSA	Door Locks	NHTSA is currently preparing an NPRM that will propose to upgrade the existing FMVSS No. 206. As a part of an international committee under the auspices of the United Nations/Economic Commission for Europe, NHTSA is currently working with other governments' experts to develop a global standard for the performance of door, door retention components and door locks. NHTSA expects to incorporate its international work with its own work on this subject and issue a proposed upgrade of its door latch and lock standard by 2004.	139
DOT/NHTSA	Bumper Strength	Evaluation of the bumper standard is approximately 15 years old. Based on the length of time that has passed, NHTSA believes it may be appropriate to reevaluate the existing bumper standard.	148
DOT/NHTSA	Side-Impact Protection	The agency has initiated a new rulemaking to require enhanced head, chest, and abdominal protection in side impacts under FMVSS No. 214.	152
DOT/RSPA	Hazardous Materials Training	RSPA anticipates submitting the draft final rule to OMB in 2003.	158 SBA

Table 9. New Reforms Planned or Underway – Regulations			
Agency	**Regulation**	**Next Step(s)**	**Ref. Number***
Treasury/IRS	Flexible Spending Accounts	The Administration has proposed statutory modifications that would address concerns about unnecessary year-end purchases of medical care to avoid forfeiture. These proposals would allow (1) up to $500 in unused benefits in a FSA to be carried forward to the next year and (2) up to $500 in unused benefits in a FSA to be transferred to a 401(k), 403(b), 457(b) SARSEP, SIMPLE IRA, and/or MSA.	162 SBA
Treasury/IRS	Mortgage Revenue Bond Purchase Price Limits	Treasury is currently researching different options to address this issue.	167
EPA	Regulatory Reform for Handling Refrigerants	EPA plans to issue an "Alternate Refrigerants" final rule in 2003; a "Split System" final rule in 2004, and Limited "Field Reclamation" final rule in 2003.	170
EPA	Chemical Plant Safety Standards	EPA will determine an approach to collecting information from facilities that have deregistered or changed their RMP and establish a mechanism for information collection. EPA will collect and analyze information in June 2004 and issue the results in September 2004.	171
EPA	Protections for Farm Children from Pesticide Exposures	EPA's response to the petition filed pursuant to the Agency's hearing and objections process under FFDCA is expected in late 2003.	178
EPA	Definition of Volatile Organic Compound	Possible revision to policy on control of VOCs–ANPRM is planned in 2003.	179
EPA	TRI Alternate Reporting Threshold (Form A)	EPA plans a stakeholder outreach process to evaluate issues relating to the alternative threshold and the Form A Certification Statement. EPA will issue a discussion paper on the Stakeholder Dialog Phase 2 for a 60-day comment period in 2003 and then determine next steps (e.g., development and publication of proposed rule).	188 SBA
EPA	Export Notification Requirements	EPA is considering how best to address this issue.	190 SBA
EPA	Storage for Reuse	At the present time, EPA is working with the regulatory community to identify appropriate ways to minimize the potential burden resulting from these regulations. EPA will seek public comment in 2003.	192 SBA
EPA	TRI Form R Reporting	EPA has published a notice soliciting public comment on form changes designed to address concerns regarding the categorization and aggregation of release and waste management data; appropriate changes will be reflected in the ICR renewal, expected for review at OMB in September 2003; as part of the Stakeholder Dialog discussed under Form A above, EPA will also explore burden reduction options that may affect Form R, such as alternate year reporting for small businesses.	209

*Refers to numbers assigned to nominations in Section I of "Summaries of Public Suggestions for Reform of Regulations and Guidance Documents" (www.whitehouse.gov/omb/inforeg/summaries_nominations_final.pdf).
[SBA]This nomination was identified by SBA's Office of Advocacy as a high priority.

Table 10. New Reforms Planned or Underway – Guidance Documents			
Agency	**Guidance Document**	**Next Step(s)**	**Ref. Number***
Labor/OSHA	Multi-Employer Citation Policy	OSHA's longstanding enforcement policy was clarified in a 1999 directive. OSHA has initiated discussions with several organizations (including the petitioners) on developing additional guidance to further clarify the responsibilities of the general contractor.	16
DOT/Coast Guard (note: Coast Guard is now part of newly formed DHS)	Marine Safety Manual	The Department is continuing to review this nomination.	18
EPA	EPA Index of Applicability Decisions	EPA's action on this issue was completed with the publication of a notice on February 13, 2003.	21
EPA	"Once In, Always In" Policy	The NPRM was issued in May 2003, and the final rule is expected in May 2004.	23
EPA	TRI Reporting Forms and Instructions	EPA's initial evaluation will be focused on reform of the TRI Alternate Reporting Threshold (Form A) and TRI Form R Reporting.	26 [SBA]
EPA	TRI Reporting Questions and Answers	EPA is currently reviewing and updating the *1998 Q&A* guidance document. It expects to publish an updated Q&A guidance document in 2003.	27 [SBA]
EPA	Waterborne Diseases	In summer 2003, EPA plans to issue a notice on the Status of Waterborne Disease epidemiological studies that are underway and/or nearing completion. In fall 2003, EPA will publish the results of two of the research studies. In fall 2004, EPA plans to publish the Waterborne Disease Estimate by EPA and CDC.	28
EPA	Integrated Risk Information System	EPA expects to hire 10 new IRIS staff and complete 13 assessments in FY 2003. New/updated assessments for 5 chemicals were added to the IRIS data base through March 2003. Assessments for another 8 chemicals are projected to be completed in FY 2003. An EPA Science Advisory Board (SAB) review for these assessments is scheduled for 2003, and a contractor report is expected in 2003 for approximately 160 IRIS chemicals. Summary results of literature screening is expected to be entered into the IRIS data base by 2003.	30
EPA	Economic Benefit of Noncompliance in Civil Penalty Cases	EPA expects to complete peer review of proposed changes to the BEN Model in 2003 and publish a notice in 2003.	32

Table 10. New Reforms Planned or Underway – Guidance Documents			
Agency	**Guidance Document**	**Next Step(s)**	**Ref. Number***
EPA	Site-Specific Risk Assessments in RCRA	EPA will issue a memo to regional offices reiterating the appropriate use of (1) the SSRA policy and technical guidance and (2) requesting review of regional documents to ensure that such documents do not imply mandatory requirements. EPA will also propose a response to the CKRC Rulemaking Petition in the MACT Phase I Replacement Standards/Phase II. An NPRM is expected no later than the end of 2003/early 2004. EPA will make a final decision on the CKRC Rulemaking Petition no later than the MACT Phase I Replacement Standards/Phase II Final Rule no later than June 2005.	35
EPA	Submetering Water Systems	EPA distributed a briefing paper to Regional Offices to get comments on options for addressing issues. Further action(s) will be determined by EPA.	40

*Refers to numbers assigned to nominations in Section II of "Summaries of Public Suggestions for Reform of Regulations and Guidance Documents" (www.whitehouse.gov/omb/inforeg/summaries_nominations_final.pdf).
[SBA]This nomination was identified by SBA's Office of Advocacy as a high priority.

Since OMB's guidance to agencies did not require that they agree with the analysis or solutions presented by commenters, the specific reforms that agencies implement may or may not be consistent with the recommendations made by the public. This outcome is based, in part, on the fact that some rules and guidance documents were nominated for reform by multiple commenters who advocated opposing views and solutions. It also reflects the emphasis OMB placed on the ability of agencies to decide which issues merited priority and what types of reforms were most appropriate. With respect to the implementation of regulatory reforms, of course, agencies will continue to involve the public through the formal notice and comment rulemaking process.

D. Reforms That Agencies Have Not Yet Decided to Pursue

As agencies reviewed the public nominations of rules and guidance documents that OMB referred to them, there were many cases in which they could not make a final determination about whether or not to pursue a reform. Frequently, agencies were undecided simply because they did not have sufficient information to accept or reject a specific nomination. In these cases, we asked that agencies conduct further research into the issues raised by commenters so that they could decide if the nominated regulation or guidance document merited reform. To the extent possible, agencies provided OMB with their specific plans over the next year for investigating the viability of these possible reforms.

Tables 11 and 12 list the rules and guidance documents, respectively, that agencies will be examining. They also indicate what specific next steps are planned.

Table 11. Undecided Reforms – Regulations			
Agency	**Regulation**	**Next Step(s)**	**Ref. Number***
Agriculture	Animal Identification	USDA plans to study animal identification and traceback procedures and consider updating them to ensure they provide the most meaningful information in the interest of fair trade, animal health, and public health.	3
HHS/CMS	Medicare Secondary Payer Provision	CMS will continue to review whether to require hospitals to complete the MSP instrument for reference lab services.	24
HHS/CMS	Physician Certification for Non-Emergency Ambulance Services	A review to ensure that there are no legal obstacles to the removal of this requirement will be completed in 2003. CMS has developed an internal task force to address this issue.	25
HHS/CMS	Converted Bed Rule	CMS will conduct a study of the impact on utilization, and on beneficiary access to services, of the implementation of the inpatient rehab PPS.	27
HHS/CMS	Exemption Date Rule	CMS will conduct a study of the impact on utilization, and on beneficiary access to services, of the implementation of the inpatient rehab PPS.	28
Labor	SCA Wage Increases and Benefit Improvements	ESA believes addressing this concern may require regulatory change. The Wage and Hour Division likely will not be able to address SCA issues until 2004 or 2005 due to resource constraints and other priorities.	84
Labor	Explosives	MSHA agrees there are inconsistencies between MSHA and DOT definitions for explosives, detonators, and blasting agents. MSHA expects to reach a decision soon as to whether to include this item on the next Regulatory Agenda.	88
Labor/OSHA	Hazard Communication	OSHA already explicitly recognizes electronic availability of MSDSs as satisfying the requirement for employee access. The agency is preparing additional compliance assistance materials, and plans to request public comment on issues related to MSDSs, including that raised by the comment, later this year.	92
Labor/OSHA	Lead in Construction	OSHA notes that the provisions would not apply where no lead exists. OSHA will initiate a 610 review under the Regulatory Flexibility Act as soon as it completes one of the 610 reviews on its current agenda.	93[SBA]
DOT/FAA	General Definitions	DOT/FAA is continuing to review this issue.	107
DOT/FHWA	Commercial Size and Weight	The FHWA considered the need to revise reporting requirements for State certification of their enforcement of Federal and State size and weight statutes and regulations and issued an NPRM in September 2000. Recommendations from the May 2002 National Research Council report have broadened the discussion of possible reform needed to both Federal and State truck size and weight programs. In light of recommendations in this report, the FHWA terminated the rulemaking proceeding.	119

Table 11. Undecided Reforms – Regulations			
Agency	**Regulation**	**Next Step(s)**	**Ref. Number***
DOT/FMCSA	Inspection, Repair, and Maintenance	DOT/FMCSA is continuing to review this issue	121
DOT/NHTSA	Passenger Vehicle Compatibility	The agency recently established an integrated project team to consider all aspects of compatibility and develop an agency plan to address them. On June 18, 2003, NHTSA published a notice requesting comments on possible measures to address vehicle compatibility problems.	135
DOT/NHTSA	Lamps, Reflective Devices and Associated Equipment	NHTSA is thoroughly evaluating this standard. Part of the review is a safety problem assessment.	143
DOT/NHTSA	Commercial Vehicle Operator Visibility	NHTSA is currently preparing a request for public comment on existing and future object detection systems.	144
DOT/NHTSA	On-Board Crash Recorders	Over the past several years, NHTSA has been actively involved with Event Data Recorders (EDRs) in motor vehicles. The agency has sponsored two working groups, and is using data from EDRs as part of its crash investigations and in research and development. Since both working groups have completed their work, NHTSA is considering what future role the agency should take related to the continued development and installation of EDRs in motor vehicles. NHTSA has issued a request for comments on this technology. A determination on whether any future action is merited will be made after NHTSA has had an opportunity to evaluate those comments.	145
DOT/NHTSA	Driver Distractions	NHTSA has been conducting research for several years on driver distractions in general and specific distractions associated with in-vehicle displays and other technologies. This work has been funded in part by the Intelligent Vehicle Initiative program and involves use of the National Advanced Driver Simulator in some instances. Based on this research, NHTSA may ultimately decide to move forward with regulations designed to address driver distractions.	146
DOT/NHTSA	Pedestrian Crash Protection	NHTSA has agreed to work with the international community in developing a Global Technical Regulation that addresses pedestrian injuries. Current data do not allow NHTSA to issue a regulation that effectively addresses the risk of injury. Accordingly, regulatory action in this sphere may be several years away.	147
DOT/NHTSA	Commercial Vehicle Brakes	NHTSA is engaged in preliminary research assessing new technologies that may help reduce the risk of rollover in heavy trucks.	149
DOT	Commercial Vehicle Rollover	The FHWA and NHTSA are awaiting results of current passenger vehicle rollover testing to discern whether the same principles could apply to commercial motor vehicles. The Agencies will continue to address new rollover technologies as they become available.	151

Table 11. Undecided Reforms – Regulations			
Agency	**Regulation**	**Next Step(s)**	**Ref. Number***
DOT	Commercial Vehicle Design Compatibility	NHTSA is actively monitoring heavy vehicle compatibility as part of its compatibility initiative. However, given the preliminary nature of this review, regulatory activity in this area may be several years distant.	155
DOT/RSPA	Emergency Preparedness Grants	DOT will provide information on this issue in the next Regulatory Agenda.	157[SBA]
EPA	PCB Spill Cleanup Policy	EPA is currently conducting an internal review of its PCB program, which it expects to complete by late 2003. EPA will provide an opportunity for public review and comment on any changes to its PCB policies resulting from this review.	191
EPA	Spill Prevention Plans	EPA issued a final rule in April 2003 extending compliance dates and outreach. EPA plans to conduct outreach.	194
EPA	Removal Credits for POTWs	EPA will develop an issue paper on options to remove perceived impediments to POTWs' use of removal credits in 2003. EPA expects to finalize the issue paper and brief management on pros and cons of issuing guidance in late 2003.	203
NARA	Disposition of Federal Record	NARA, in partnership with stakeholders, will survey small businesses to assess their ability to meet the current standard to determine if amending the standard is necessary.	253[SBA]

*Refers to numbers assigned to nominations in Section I of "Summaries of Public Suggestions for Reform of Regulations and Guidance Documents" (www.whitehouse.gov/omb/inforeg/summaries_nominations_final.pdf).
[SBA]This nomination was identified by SBA's Office of Advocacy as a high priority.

Table 12. Undecided Reforms – Guidance Documents			
Agency	**Guidance Document**	**Next Step(s)**	**Ref. Number***
HHS/CMS	Medicare Carrier Manual/Medicare Intermediary Manual	A review to ensure that there are no legal obstacles to the removal of this requirement will be conducted.	2
Labor	Coordination of FMLA with other Leave Policies	ESA notes that existing FMLA rules provide some guidance, and EEOC, which administers the ADA, has issued technical guidance. Revisions to FMLA regulations are planned. Further guidance on coordination with ADA could be issued thereafter.	12[SBA]

Table 12. Undecided Reforms – Guidance Documents			
Agency	**Guidance Document**	**Next Step(s)**	**Ref. Number***
Treasury/IRS	Low-Income Housing Tax Credit	The commenter suggests that the IRS issue regulations regarding certain issues addressed in the identified Technical Advice Memoranda (TAMs). Issuance of formal guidance on these issues is not necessary because the positions taken in the TAMs generally are based on general tax principles. Nonetheless, the Service is considering publishing a revenue ruling addressing these issues.	19
Access Board	ADA/ABA Guidelines	The Board is reviewing a draft proposal.	20

*Refers to numbers assigned to nominations in Section II of "Summaries of Public Suggestions for Reform of Regulations and Guidance Documents" (www.whitehouse.gov/omb/inforeg/summaries_nominations_final.pdf).
[SBA]This nomination was identified by SBA's Office of Advocacy as a high priority.

E. Reforms That Agencies Have Decided Not to Pursue

In their review of the public reform nominations, agencies had to assess the relative merits of each nomination, using the OMB-recommended criteria of efficiency, fairness, and practicality. Since agencies do not have the resources to pursue reforms of all of the rules and guidance documents nominated for reform, they had to prioritize and determine which ones to not pursue, given the competing demands on their resources and the potential of particular nominations to lead to substantive improvements in regulatory policy. Tables 13 and 14 list, respectively, the nominated regulations and guidance documents that agencies decided not to pursue.

Table 13. Reforms that Agencies Decided Not To Pursue – Regulations		
Agency	**Regulation**	**Ref. Number***
Agriculture	Child Nutrition Program	1
Agriculture	National Organic Program	7
Agriculture	Badge as Identification of Inspectors	10
Agriculture	National Forests Land Use: Special Uses	14
Agriculture	Low Cost Timber Sales and Grazing Fees	16
Education	Title IX and Collegiate Sports Participation	18
Energy	Energy Conservation Standards for Clothes Washers	21
HHS/CMS	Special Treatment: Direct Graduate Medical Education Payments	23
HHS/CMS	Medical Director Rule	29
HHS/CMS	Minimum Staffing Standards for Nursing Homes	30
HHS/CMS	Revisions to Medicare Payment Policies	32 [SBA]
HHS/CMS	Certificates of Medical Necessity	33 [SBA]
HHS/CMS	Clinical Laboratory Improvement Act Rules	36

Table 13. Reforms that Agencies Decided Not To Pursue – Regulations		
Agency	**Regulation**	**Ref. Number***
HHS/FDA	Labeling Genetically Modified Foods	41
HHS/FDA	Hormones in the Food Supply	42
HHS/FDA	Antibiotics in Food Supply	43
HHS/FDA	Food Identity Standards	44
HHS/FDA	Medical Drug and Device Regulations	45
HHS/FDA	Labeling of Sorbitol	48
HHS/FDA	Labeling of Caffeine Content	49
HHS/FDA	Investigational New Drug (IND) Regulations	51
HUD	Predatory Lending	55
HUD	Insured Ten-Year Protection Plans	56
Interior	National Landscape Conservation System	62
Justice	Hemp Food Products	68 SBA
Justice/INS	Driver's Privacy Protection Act	70
Labor	Computer Professional Exemption under FLSA	78 SBA
Labor	SCA/Wage Determination Process/Wage Surveys	82
Labor	FLSA Medical Leave	85
Labor/OSHA	Process Safety Management/Highly Hazardous Chemicals	99
Labor/OSHA	Metalworking Fluids	101
Labor/EBSA	Claims Procedures	104
State	Flight Simulators	105 SBA
DOT	Disadvantaged Business Enterprise Program	106 SBA
DOT/FAA	Design and Construction	108
DOT/FAA	Seats, Berths, Safety Belts, and Harnesses	110
DOT/FHWA	Outdoor Advertising Control	115
DOT/FHWA	Highway Design	116
DOT/FTA	Buy America Pre-Award and Post Delivery Certification	125
DOT/FTA	Set-Aside for Intercity Bus	126
DOT/MARAD	Vessel Financing Assistance	127
DOT/NHTSA	Lower Interior Front Impact Protection	134
DOT/NHTSA	Passenger Vehicle Brakes	138
DOT/NHTSA	Glazing Materials and Crash Avoidance	142
DOT/NHTSA	Consumer Information	150
DOT	Emergency Response and Auto Crash Notification	154
Treasury	Currency and Foreign Financial Accounts	159
Treasury/IRS	Employer Identification Numbers	161
Treasury/IRS	Monthly Tax Deposits	166 SBA

Table 13. Reforms that Agencies Decided Not To Pursue – Regulations		
Agency	**Regulation**	**Ref. Number***
Treasury/IRS	Partnership Investments in Small Business Stock	168 [SBA]
Treasury/IRS	Business Use of Home	169
EPA	Withdrawal of State Delegations	184
EPA	Collection of Health Screening Data	189
EPA	NPDES and Sewage Sludge Monitoring Reports	195
EPA	Stormwater Phase I	201
EPA	Stormwater Phase II	202
EPA	Drinking Water Standards for Radionuclides	207
EPA	TRI: Lowering Reporting Thresholds for PBT Chemicals	210 [SBA]
OPM	Federal Employees Health Benefits	254
US Army Corps	Nationwide Permits	265
US Corps, EPA	Definition of Fill Material	266
USPS	Commercial Mail Receiving Agencies	267 [SBA]

*Refers to numbers assigned to nominations in Section I of "Summaries of Public Suggestions for Reform of Regulations and Guidance Documents" (www.whitehouse.gov/omb/inforeg/summaries_nominations_final.pdf).
[SBA]This nomination was identified by SBA's Office of Advocacy as a high priority.

Table 14. Reforms that Agencies Decided Not To Pursue – Guidance Documents		
Agency	**Guidance Document**	**Ref. Number***
HHS/CMS	Signature on File Requirement for Ambulance Services	3
HHS/CMS	Payment to Health Care Delivery System	4
HHS/CMS	Individual Health Insurance Rules	5
HHS/CMS	Guidance to Surveyors - Long Term Care	6
HHS/FDA	Nine-Compounds Monitoring	8
HHS/FDA	Coverage of Personal Importations	9
Interior	Endangered Species Act Survey Protocols	10
Justice	Guidance on Federal Prison Industries	11 [SBA]
DOT/FAA	General Operating and Flight Rules	17
EPA	Improving Air Quality Through Land Use Activities	24
EPA	Food Quality Protection Act Policy Papers	29
EPA	Investigating Title VI Administrative Complaints	31
EPA	TRI Lead Reporting	33
EPA	Pesticide Registration Notices	34

Table 14. Reforms that Agencies Decided Not To Pursue – Guidance Documents		
Agency	**Guidance Document**	**Ref. Number***
EPA	RCRA Spent Catalyst Policy	37
EPA	Superfund Indirect Costs	38
EPA	Ecoregional Nutrient Criteria Documents	39
OMB	Cost Accounting Standards for Educational Institutions	47
SBA	Guidance on Credit Unions	48 [SBA]

*Refers to numbers assigned to nominations in Section II of "Summaries of Public Suggestions for Reform of Regulations and Guidance Documents" (www.whitehouse.gov/omb/inforeg/summaries_nominations_final.pdf).
[SBA]This nomination was identified by SBA's Office of Advocacy as a high priority.

F. Status Updates on Reforms Agencies Had Completed or Were Already Underway

As mentioned above, OMB wanted agencies to focus their attention on reforms of regulations and guidance documents that had not been recently reviewed or were in the process of being reviewed. This was necessary given the large number of public nominations of regulations and guidance documents that, as of the December 2002 release of OMB's final report, were already the subject of recent or ongoing agency review. OMB is, however, providing status information on these rules and guidance documents, which agencies provided to us at our request. Tables 15 and 16 present this information.

Table 15. Status Updates on Reforms Completed or Ongoing as of December 2002: Regulations			
Agency	**Regulation**	**Status**	**Ref. Number***
Agriculture	Pathogen Reduction and Hazard Analysis and Critical Control Point (HACCP) Systems	FSIS has refrained from mandating critical control points in its HACCP regulations. The issue of defining when a product leaves an establishment's control was dealt with in an administrative instruction to filed inspection personnel issued in 2001. In 2002, FSIS published policy notices and issued administrative instructions to its field personnel that, among other things, addressed the relationship between sanitation standard operating procedures and other prerequisite programs or good manufacturing practices and an establishment's HACCP plans. The agency believes this issue is on its way to resolution.	2

Table 15. Status Updates on Reforms Completed or Ongoing as of December 2002: Regulations			
Agency	**Regulation**	**Status**	**Ref. Number***
Agriculture	Post Mortem Inspection: Extent and Time of Post Mortem Inspection - Staffing Standards	FSIS is testing a new HACCP-based system of inspection in volunteer plants. The new system is intended to accommodate new technologies and allow increased operational efficiencies. If the results of the testing justify a new system, FSIS will consider appropriate amendments to its regulations. Regarding inspector overtime, FSIS is legally authorized to collect fees from establishments for overtime and holiday inspection work. Because of current budgetary exigencies, FSIS is likely to continue to collect such fees.	4
Agriculture	Zero Tolerance for *Listeria monocytogenes* and Performance Standards	FSIS aired the scientific and other issues relating to *Listeria* as a contaminant of processed products in a November 14, 2002, public meeting. The agency is studying options for proceeding on this matter and expects to be in position to publish a decision in 2003.	5
Agriculture	Nutrition Labeling of Ground or Chopped Meat and Poultry Products	On January 18, 2001, FSIS published a proposed rule to require nutrition information either on labels or at the point-of-purchase for the major cuts of single-ingredient, raw meat and poultry products, unless an exemption applies. FSIS also proposed to require nutrition labels on all ground or chopped meat and poultry products, unless an exemption applies. FSIS has been considering the comments received in response to the proposal and expects to publish its decision on this matter by December 2003.	8
Agriculture	Plant Pest Regulations	The issue identified by the commenter regarding restrictions on butterflies was part of a proposed rule. APHIS intends to address comments on the proposed rule in the final rule.	9
Agriculture	Mad Cow Disease	On January 17, 2002, the agency published a notice announcing the availability of its current thinking paper on measures that could be implemented to minimize human exposure to materials that could potentially contain the BSE agent. A rulemaking addressing equipment and procedures used at some slaughterhouses that could result in contamination of carcasses with BSE risk materials is under consideration within USDA. USDA has asked Harvard University to re-evaluate its 2001 BSE risk assessment in light of the single case of BSE in Canada.	11
Agriculture	Roadless Area Conservation	USDA is enjoined from implementing this rule.	15
Commerce	Annual Capital Expenditures Survey	During OMB's review of this survey under the Paperwork Reduction Act, OMB confirmed that the information collected on this survey cannot be obtained from IRS.	17
Education	Title IX and Single-Sex Schools	The Department is considering changes to the regulations implementing title IX of the Education Amendments of 1972. The Department anticipates publishing a notice of proposed rulemaking in November 2003.	19

Table 15. Status Updates on Reforms Completed or Ongoing as of December 2002: Regulations			
Agency	**Regulation**	**Status**	**Ref. Number***
Education	Federal Family Education Loan Program	In developing the Federal Family Education Loan Program regulations through the negotiated rulemaking process, ED developed a list of proposed regulatory changes from advice and recommendations submitted by individuals and organizations in response to a May 24, 2001 request for recommendations on improving the Title IV student assistance programs from Representatives Howard "Buck" McKeon and Patsy Mink. ED's intent in amending these regulations was to reduce administrative burden for program participants, to provide benefits to students and borrowers, and to protect taxpayers' interests. The final regulations for the rules that were proposed in both of the negotiated NPRMs were published on November 1, 2002.	20
Energy	Energy Conservation Standards for Central Air Conditioners and Heat Pumps	The Department issued a final rule on May 23, 2002 that withdrew its previous final rule and increased the minimum energy efficiency levels by 20 percent. No further changes to the standard are planned.	22
HHS	Medicare Program Prospective Payment System for Hospital Outpatient Services	A final rule (to amend existing regulations implementing the Emergency Treatment and Active Labor Act of 1998) has been sent to OMB for review	34
HHS/CMS	Use of the OASIS for Home Health Agencies	CMS has streamlined the OASIS instrument. As a result of these changes, the number of items in the OASIS was reduced by 28%. The amount of time to complete the OASIS was reduced by 25%.	35
HHS	Health Insurance Portability and Accountability Act Claims Processing Standards	HHS does not agree that health plans must accept a HIPAA-compliant claim as a "clean claim" for purposes of contractual provisions with other entities under HIPAA, and for State and Federal prompt-pay requirements. HHS views the requirements of HIPAA statue and regulations as separate and distinct from various State and Federal "clean claim" requirements. The requirements of one do not necessarily fulfill the requirements of the other. Further action is therefore unlikely.	37
HHS/FDA	Standard of Microbiological Quality—Total Coliform	The 1993 proposal to establish standards for coliform was cited in an April 22, 2003 notice announcing FDA's intent to withdraw 84 regulatory proposals whose publications dates were five years ago or longer. Public comments were solicited on this set of withdrawals, and the comment period closed on July 21, 2003. Currently, FDA is considering the merits of re-proposing the establishment of coliform standards, taking advantage of scientific information that has emerged since the 1993 proposal.	40
HHS/FDA	Premarket Notice for Bioengineered Foods	This rulemaking has been withdrawn, as announced in Spring 2003 Regulatory Agenda.	46

Table 15. Status Updates on Reforms Completed or Ongoing as of December 2002: Regulations			
Agency	**Regulation**	**Status**	**Ref. Number***
HHS/FDA	Pediatric Rule	The rule was overturned, as exceeding FDA's statutory authority, by court decision on October 17, 2002, and is no longer in effect.	52
HHS	Individually Identifiable Health Information	HHS is constantly issuing guidance on implementation of the privacy rules that went into effect on April 17, 2003. Changes in the codified text of the rules are, however, not currently contemplated.	53
HHS	Protection of Human Subjects	The rule is still under consideration within the agency.	54
Interior	Digital Aircraft Radios	The agency has decided to delay the implementation of the requirement to switch to a digital narrow band radio to January 1, 2008. The agency expects the cost of these radios to decline over the next few years.	57
Interior	Conservation Use in Grazing	The BLM has issued an ANPRM soliciting comments on removing this provision from its grazing regulations.	58
Interior	Surface Management of Mining Claims	Both the definition of "unnecessary and [sic] undue degradation" and the 2000 performance standards were amended in 2001. The BLM went through a rulemaking process in 2001 to make both changes which the commenter criticizes. Interior did so because the definition of unnecessary or undue degradation may well have exceeded BLM's authority and because the 2000 performance standards, in some cases, went beyond that which is necessary to allow environmentally safe exploration and development.	59
Interior	Endangered Species Act	This rule (50 CFR Part 17) is codified, and the agency believes it does not require reform.	60
Interior	Endangered Species Act Delisting	The Service proposed the bald eagle for delisting in 1999. There has been a delay in issuing the final rule due to processing the large amount of information and comments that were generated during the public comment period. The Service has finalized the reclassification of the wolf to threatened and identified three Distinct Population Segments (DPS). An Advanced Notice of Proposed Rulemaking was published in the Federal Register announcing Interior's intention to publish a proposed rule to de-list the Eastern Distinct Population Segment (DPS) of the gray wolf. The Eastern DPS includes the Great Lakes region. The grizzly bear is federally listed as threatened throughout its entire range in the lower 48 United States.	61

Table 15. Status Updates on Reforms Completed or Ongoing as of December 2002: Regulations			
Agency	**Regulation**	**Status**	**Ref. Number***
Interior	Possessory Interest Assets	The current regulations do not reference the term "book value" for determining the value of capital improvements by a concessioner. The current legislation implemented in 1998 provides for Leasehold Surrender Interest (LSI) for reimbursement of capital improvements. The NPS believes that using book value would be a clearer method of determining reimbursement value but is held to language included in the legislation. Nonetheless, the NPS has created an interdisciplinary workgroup to listen to concerns about LSI from the NPS Hospitality Association and others and try to resolve those concerns. The legislation provides that in 2007 the NPS will be able to readdress the issue of LSI with Congress and potentially modify how reimbursements for capital improvements are valued.	63
Interior	Snowmobiles in Yellowstone and Grand Teton National Parks and the John D. Rockefeller, Jr. Parkway	The NPS has selected a preferred alternative in the March 2003 Record of Decision that would require the public and commercial businesses to utilize best available engine technology for snowmobiles entering the parks (to help minimize impacts from emissions on air, sound and water), to require operators be accompanied by a guide (to help minimize conflicts between machines and animals and improve visitor safety) and to set maximum numbers of visitors to enter the park at various points (to disperse use). Most significantly, this alternative provides for adaptive management so that any one element of the alternative can be adjusted to further reduce impacts to the parks, if necessary. The NPS is expected to issue a proposed rulemaking addressing snowmobile access to the Parks in summer 2003.	64
Interior	Snowmobiles in the Rocky Mountain National Park	The NPS began consultation with the City of Grand Lake, snowmobile users and environmental groups early on in the development of this proposed rule and EA.	65
Interior	Wild and Scenic Rivers—Water Resources Projects	The agency published proposed rules regarding water resource projects. The Wild and Scenic Rivers Act conveys authority to the Department of the Interior, and in some circumstances the USDA Forest Service, to make final determinations on Section 7 of the Act.	66
Interior	Cooperative Conservation Initiative	The FY 2003 budget, as enacted, increases funding to existing programs cost share programs rather than create new programs as requested in the President's budget. The submission in 2004 is expected to be similar to what Congress has enacted. Thus, no agency action is needed.	67
Justice	List of Terrorist Organizations	The agency does not believe that reform of this rule is necessary.	69
Justice	Electronic Storage of I-9 Forms	A final rule is under development.	71[§]
Justice	Admission Period for B-1/B-2 Visitors	Withdrawn by agency on June 3, 2002. No further action will be taken on this rule.	72

Table 15. Status Updates on Reforms Completed or Ongoing as of December 2002: Regulations			
Agency	**Regulation**	**Status**	**Ref. Number***
Justice	Forms I-140 and I-485	The agency published an interim final rule on July 31, 2002.	73[§]
Justice	I-9 Employment Verification	The proposed rule was published on February 2, 1998. The final rule is pending at the agency.	74
Labor	Birth and Adoption Unemployment Compensation	DOL has issued an NPRM to repeal the Birth and Adoption UC rule. The final rule has been submitted to OMB.	75
Labor	Family and Medical Leave Act (FMLA) Regulations	DOL has conducted stakeholder meetings and is drafting a NPRM for submission to OMB.	76
Labor	White Collar Exemption	DOL has conducted stakeholder meetings and drafted an NPRM, which was published March 31, 2003.	79
Labor	Permanent Labor Certification	ETA is currently reviewing comments received on the NPRM and developing final regulations.	81
Labor	Davis Bacon Act/Service Contract Act B Inclusion of Pension and Benefit Plans	ESA notes the $2,000 threshold is a statutory rather than a regulatory issue. Current SCA and DBA regulations do not prohibit the use of self-insured fringe benefit programs.	83
Labor	Across the Board Penalties	ESA is considering changes to the existing FMLA categorical penalty provisions as part of the ongoing FMLA regulatory review.	86
Labor	H-1B LCA	ESA's Wage and Hour Division is evaluating the comments received in response to the interim final rule.	87
Labor	Affirmative Action and EO Survey	OFCCP has engaged an outside contractor to study the EO Survey. At the conclusion of the study, anticipated to be in 2004, the Department will determine the best course of action for the EO Survey.	89
Labor/OSHA	Hexavalent Chromium	OSHA is under a court order to publish a final rule by 2006. They plan to initiate a SBREFA Panel in January 2004.	91
Labor/OSHA	Payment for Personal Protective Equipment	OSHA is considering how to address this issue.	94
Labor/OSHA	Exposure to Crystalline Silica	OSHA plans to initiate a SBREFA panel for this rule in September 2003.	95
Labor/OSHA	Tuberculosis (TB) Standard	OSHA does not plan to address this issue through rulemaking.	97
Labor/OSHA	Walking/Working Surfaces	OSHA published a Notice of Reopening of the Rulemaking Record in the Federal Register in April 2003.	98
Labor/OSHA	Recordkeeping for Work-Related Injuries, Illnesses and Fatalities	OSHA published a final rule addressing recordkeeping requirements for MSDs on June 30, 2003.	102
Labor/OSHA	Ergonomics Standard	OSHA does not plan to address this issue through rulemaking. OSHA is working on industry-specific guidelines to address occupational ergonomic hazards.	103

Table 15. Status Updates on Reforms Completed or Ongoing as of December 2002: Regulations			
Agency	**Regulation**	**Status**	**Ref. Number***
DOT/FAA	Standards for Approval for High Altitude Operation of Subsonic Transport Airplanes	DOT/FAA is continuing to review this issue.	109
DOT/FAA	Emergency Landing Dynamic Conditions	DOT/FAA is continuing to review this issue.	111
DOT	Transportation Planning and Environmental Review Procedures	Environmental streamlining is a priority for FHWA and FTA. The Department has taken a number of actions to help streamline the environmental review of highway and transit projects. On September 20, 2002, FHWA and FTA partially withdrew the proposed rulemaking amending requirements on State and metropolitan planning. A final rule will be issued in 2003. After reauthorization occurs, the agencies will reconsider the need to revise their regulations.	120
DOT	Background Checks for Truckers Hauling Hazardous Materials	DOT is continuing to review this issue.	122
DOT	Commercial Vehicle Cross-Border Safety	DOT is continuing to review this issue.	123
DOT	Hours of Service for Truckers	FMCSA issued a final rule on April 28, 2003.	124
DOT/NHTSA	Corporate Average Fuel Economy (CAFE) Standards	On March 31, 2003, NHTSA issued a final rule setting new fuel economy standards for model year (MY) 2005-2007 light trucks. NHTSA has expressed its intent to consider reforms to the CAFE system, applicable to both passenger cars and light trucks, consistent with its statutory authority. Possible higher levels and/or program restructuring for CAFE for future year rulemakings will be considered, based on these criteria and other statutory provisions, as well as the impact on safety and American jobs.	128
DOT/NHTSA	Head Restraints	The agency has taken a comprehensive look at occupant protection in rear crashes. As part of this, NHTSA wants to ensure that the head restraint rule is coordinated with our planned proposal to upgrade seat back requirements. We anticipate publication of the final rule in 2003.	129
DOT/NHTSA	Tire Pressure Monitoring Systems	A federal appellate court recently ruled that the statute mandating this rule requires a TPMS system capable of detecting significant under-inflation in any tire. The court vacated the final rule. The agency is conducting expedited rulemaking towards issuance of a final rule consistent with the court's opinion.	130

Table 15. Status Updates on Reforms Completed or Ongoing as of December 2002: Regulations			
Agency	**Regulation**	**Status**	**Ref. Number***
DOT/NHTSA	Advanced Airbags	Since the agency has only recently reviewed and rejected the proposals raised by the submitters, it does not consider this issue suitable for either review or reform at this time.	131
DOT/FHWA	Fuel System Safety Standard B Vehicle Fires	NHTSA expects that the final rule will be published in 2003.	132
DOT/NHTSA	Occupant Crash Protection	In the summer of 2003, the agency plans to issue a request for comment notice on the proposal for amending FMVSS No. 208 to include a high-speed frontal offset crash test requirement. This notice will discuss the results of preliminary tests that the agency has conducted to assess the possibility of disbenefits of the requirement, and seek comment on alternative strategies that could be coupled with a high-speed frontal offset crash test requirement. This rulemaking was the subject of an OMB prompt letter sent to NHTSA in December 2001. On May 12, 2000, NHTSA published a final rule that amended FMVSS No. 208, "Occupant Crash Protection," to upgrade the maximum belted full-frontal rigid barrier crash test requirement up to 35 mph (56 km/h) for the 50th percentile adult male test dummy beginning with MY 2008 vehicles. At that time, NHTSA indicated that it intended to initiate rulemaking that would increase the maximum belted test speed for the 5th percentile adult female test dummy in time to have both dummies tested at the higher speed starting in 2007. NHTSA is currently reviewing a draft NPRM proposing such a change to the existing requirements. The agency anticipates publishing the NPRM in 2003.	133
DOT/NHTSA	Rollover Protection	Rollover is one of NHTSA's four top priority areas for which Integrated Project Teams have been established. Proposals for additional actions to prevent rollover crashes and protect occupants will be published for public comment in spring 2003. In the TREAD Act, Congress required NHTSA to provide consumer information about vehicle performance in driving conditions. We expect to publish the final notice on this by the end of FY 2003 and begin providing information to the public for 2004 model year vehicles. As a part of an international committee under the auspices of the United Nations/Economic Commission for Europe, NHTSA is currently working with other governments' experts to try to develop a global standard for the performance of door, door retention components and door locks. NHTSA expects to incorporate this international work with its own work on this subject and issue a proposed upgrade of its door latch and lock standard. We expect that the proposed upgrade will be published by early 2004.	136
DOT/NHTSA	Child Restraints	NHTSA is currently considering several regulatory solutions designed to address the risks experienced by children between the ages of four and ten.	140

Table 15. Status Updates on Reforms Completed or Ongoing as of December 2002: Regulations			
Agency	**Regulation**	**Status**	**Ref. Number***
DOT/NHTSA	Tire Safety	On June 26, 2003, NHTSA published a final rule to upgrade its tire performance requirements for light vehicles.	141
DOT/NHTSA	.08 Alcohol Incentive Program	NHTSA believes the submitter is unaware of all the provisions of the applicable regulation. NHTSA has called the submitter to explain the scope of the relevant regulation. The submitter, Wisconsin Department of Transportation, stated that NHTSA appears to be applying the compliance criteria of the interim final rule rather than the regulatory text adopted in the subsequent final rule. It noted that the interim final rule states under the 5th compliance criteria that a State must establish a 0.08 BAC per se level under its criminal code. This criteria did not appear in the regulatory text adopted under the final rule. In a subsequent telephone call with agency personnel, the Wisconsin DOT acknowledged that its concerns had already been addressed by a letter sent to it by NHTSA in July 2002. The Wisconsin DOT has no further concerns on this issue.	153
DOT/RSPA	Collection of Annual Registration Fees	On January 9, 2003, RSPA published a final rule reducing registration fees beginning July 1, 2003, to levels that should eliminate the unexpended balance in the Hazardous Materials Emergency Preparedness Grants Fund by 2006 and thereafter produce total receipts equivalent to the annual grants authorized by Congress.	156
Treasury	Alcohol Labeling	Final rule published on March 3, 2002.	160
Treasury/IRS	Government Fleet Fuel Cards	The IRS and Treasury Priority Guidance Plan for the year ending June 30, 2003, includes a project to develop proposed regulations regarding claims for gasoline tax. These proposed regulations are expected to be published in the summer of 2003. The claimant suggests that the issuer of the fleet fueling card be permitted to sell the fuel tax free by reducing its future fuel tax obligation. An alternative approach would be to permit the retailer or wholesale distributor to sell the fuel at a tax-excluded price and claim a refund for the fuel tax paid.	163
Treasury/IRS	Interest Reporting Requirements	Treasury has issued two NPRMs on reporting on interest paid to non-resident aliens.	164

Table 15. Status Updates on Reforms Completed or Ongoing as of December 2002: Regulations			
Agency	**Regulation**	**Status**	**Ref. Number***
Treasury/IRS	Domestic Relations Tax Reform Act Rules	Treasury Decision 9035, January 13, 2003, finalized the regulation. The final regulation applies to redemptions of stock on or after January 13, 2003, that are pursuant to instruments in effect after January 13, 2003. The final regulation also applies to redemptions before January 13, 2003, or that are pursuant to instruments in effect before January 13, 2003, if the spouses or former spouses execute a written agreement on or after August 3, 2001, that satisfies the requirements of section 1.1041-2(c)(1) or (2) of the final regulations. The effective date provision in the final regulation permits taxpayers to avail themselves of the clarifying relief provided by the regulation if the taxpayers enter into an agreement as contemplated by the proposed and final regulation to specify the tax treatment agreed to by the spouses. Applying the provisions of the proposed and final regulations to taxpayers who have not entered into an agreement as contemplated by the regulations would not be consistent with sound tax administration and might result in adverse consequences to taxpayers.	165
EPA	Risk Management Plans (Worst Case Scenario)	EPA published the final rule on August 4, 2000.	172
EPA	Definition of Solid Waste	EPA expects to issue an NPRM in 2003.	173
EPA	RCRA Burden Reduction Initiative	EPA expects to issue a final rule in September 2003.	174
EPA	RCRA Subtitle C Hazardous Waste Regulations	EPA is evaluating how to address this issue given that many different regulations are involved.	175
EPA	Best Available Retrofit Technology	Revisions to the regional haze rule will address concerns raised by DC Circuit regarding best available retrofit technology. Final rule expected April 2005.	176
EPA	1997 EPA Standards for Ozone and Particulate Matter	Regarding the Ozone NAAQS rule, EPA responded to remand on potential health benefits and issued a final rule on January 6, 2003. Regarding the implementation rule for 8-hour ozone NAAQS, EPA issued an NPRM on June 2, 2003 and a final rule is expected December 2003. Regarding the implementation rule for PM2.5 NAAQS, EPA expects to issue an NPRM in September 2003 and the final rule in September 2004.	177
EPA	Motor Vehicle Emission Standards for Greenhouse Gases	In October 1999, 19 groups petitioned EPA to regulate mobile source emissions of four greenhouse gases – CO2, methane, nitrous oxide, and hydroflourocarbon – to reduce the risk of climate change. EPA published a request for public comment on the petition in January 2001. The Agency received almost 50,000 comments. Agency officials are considering how to respond to the petition.	180[§]

Table 15. Status Updates on Reforms Completed or Ongoing as of December 2002: Regulations			
Agency	**Regulation**	**Status**	**Ref. Number***
EPA	Heavy-Duty Engines and Vehicle Standards and Highway Diesel Fuel Sulfur Control Requirements	Final rule was published January 18, 2001.	181
EPA	Protection from Pollution from Diesel Engines	Final rule was published January 18, 2001.	182
EPA	Proposed Tier 2 Motor Vehicle Emission Standards and Sulfur Gasoline Control Requirements	Final rule was published February 10, 2000.	183
EPA	New Source Review	EPA published the Prevention of Significant Deterioration (PSD) and Nonattainment New Source Review (NSR): Baseline Emissions Determination, Actual-to-Future-Actual Methodology, Plantwide Applicability Limitations, Clean Units, Pollution Control Projects Final Rule and the Prevention of Significant Deterioration (PSD) and Non-attainment New Source Review (NSR): Routine Maintenance, Repair and Replacement Proposed Rule on December 31, 2002. EPA received several petitions for reconsideration of the final NSR rule and is currently preparing a response. The comment period for the proposed rule closed on May 2, 2003, and EPA is currently working to draft a final Routine Maintenance, Repair and Replacement rule.	185
EPA	Risk Assessment for Rodenticides	These comments have already been addressed as part of the public comment process for this preliminary risk assessment. Under the Reregistration Process, which includes several opportunities for public comments, and stakeholder meetings, EPA expects other revisions will be made before the risk assessment will be finalized and used in decision-making. Pesticide reregistration decisions will be made based on the final risk assessment, which is also presented for public comment as part of the public review process for the IRED & RED documents. OPP schedules for REDs are posted on the internet.	186

Table 15. Status Updates on Reforms Completed or Ongoing as of December 2002: Regulations			
Agency	**Regulation**	**Status**	**Ref. Number***
EPA	Ban on Chromated Copper Arsenate (CCA)	On March 17, 2003, EPA granted the cancellation and use termination requests affecting virtually all residential uses of CCA-treated wood and has issued the cancellation orders to the registrants for CCA. After December 30, 2003, CCA products cannot be used to treat lumber intended for most residential settings, including play structures, decks, picnic tables, landscaping timbers, residential fencing, patios and walkways/boardwalks. A Federal Register notice announcing the cancellation orders will be published in 2003.	187
EPA	RCRA Cement Kiln Dust (CKD)	Final rule expected in September 2003.	193
EPA	Watershed Rule (Total Maximum Daily Load)	EPA expects to issue its proposed watershed rule in 2003 and the final rule in June 2004.	196
EPA	TRI Lead	Final rule was promulgated in January 2001.	197
EPA	Arsenic in Drinking Water	The arsenic final rule was issued on January 22, 2001, and became effective on May 22, 2001.	198
EPA	Concentrated Animal Feeding Operations	On January 12, 2001, EPA published a proposed rule changing the Clean Water Act permitting requirements for concentrated animal feeding operations (CAFOs) and strengthening the effluent guidelines for those facilities. On February 12, 2003, EPA published the final rule on CAFOs.	199
EPA	Stormwater Construction General Permit	EPA expects to issue the final General Permit in 2003.	200
EPA	Sanitary Sewer Overflows	EPA expects to issue the proposed SSO rule in December 2003 and final rule in December 2005.	204
EPA	Effluent Guidelines for Metal Products and Machinery	EPA issued the proposed MP&M rule on January 3, 2001. The final MP&M Rule was issued in April 2003.	205
EPA	Drinking Water Standards for Emerging Contaminants	The preliminary notice was issued on June 3, 2002. The final notice is expected in 2003.	206
EPA	Radon in Drinking Water	EPA issued the proposed radon rule on November 2, 1999. The final radon rule is expected in December 2004.	208
EPA	Groundwater Rule	EPA issued the proposed rule on May 10, 2000. The final rule is expected in December 2003.	211
EPA	Disinfection Byproducts Rule	EPA expects to issue the proposed rule in 2003 and the final rule in July 2004.	212

Table 15. Status Updates on Reforms Completed or Ongoing as of December 2002: Regulations			
Agency	**Regulation**	**Status**	**Ref. Number***
SBA/FAR	Contract Bundling	The proposed rule was published on January 31, 2002. The comment period ended on April 1, 2003. SBA expects to issue a final rule by the end of the year. The proposed changes would revise the definition of bundling to expressly include multiple award contract vehicles and task and delivery orders under such contracting vehicles; require procuring activities to coordinate with the Small Business Specialist (SBS) proposed acquisition strategies or plans contemplating award of a contract or order above specified dollar thresholds and require the SBS to notify the agency Office of Small and Disadvantaged Business Utilization (OSDBU) when those strategies include contract bundling that is unnecessary, unjustified, or not identified as such by the procuring activity; reduce the threshold and revise the documentation required for "substantial bundling;" require contracting officers to provide bundling justification documentation to the agency OSDBU when "substantial bundling" is involved; and require agency OSDBUs to perform certain oversight functions.	264

*Refers to numbers assigned to nominations in Section I of "Summaries of Public Suggestions for Reform of Regulations and Guidance Documents" (www.whitehouse.gov/omb/inforeg/summaries_nominations_final.pdf).

[§]OMB initially referred these nominations to agencies for their consideration as reform candidates. OMB has since learned that agencies had already concluded or began review of these rules at the time OMB issued its 2002 final report. OMB is therefore providing status updates on them in this report.

Table 16. Status Updates on Reforms Completed or Ongoing as of December 2002: Guidance Documents			
Agency	**Guidance Document**	**Next Step(s)**	**Ref. Number***
USDA	Policy on Beef Contaminated with *E. coli* O157:H7	OSHA's longstanding enforcement policy was clarified in a 1999 directive. Later this year, the Agency will provide additional examples in the directive to further clarify the responsibilities of the general or controlling contractor.	1
HHS	Discrimination Against Persons with LEP	A revised draft guidance was published in 2003.	7[SBA]
DOL	Guidance on Equal Employment Opportunity	OFCCP is reviewing whether there is contradictory guidance on collection of ethnicity information between OFCCP and the U.S. Equal Employment Opportunity Commission.	13
DOL/OSHA	Inspection Procedures and Interpretive Guidance for Control of Hazardous Energy (Lockout/Tagout)	OSHA is working on an updated manual on Lockout/Tagout. Part I of the manual will be available for stakeholder input by the end of 2003.	14

Table 16. Status Updates on Reforms Completed or Ongoing as of December 2002: Guidance Documents			
Agency	**Guidance Document**	**Next Step(s)**	**Ref. Number***
DOL/OSHA	OSHA Directive CPL 2.100, Application of the Permit-Required Confined Spaces (PRCS) Standards	OSHA does not plan to revise the guidance at this time.	15
EPA	New Source Review	On December 31, 2002, EPA published a Prevention of Significant Deterioration (PSD) and Non-attainment New Source Review (NSR): Routine Maintenance, Repair and Replacement Proposed Rule. The comment period for the proposed rule closed on May 2, 2003, and EPA is currently working to draft a final rule.	22
EPA	Improving Air Quality Using Economic Incentive Programs	EPA issued guidance on January 19, 2001, and the States are now using the guidance in developing economic incentive programs.	25
EPA	Cancer Risk Assessment Guidance	The issue is being resolved. Proposed for final comment: March 3, 2003. Finalization by the end of 2003.	36
EPA	Drinking Water Affordability	FACA Committee (NDWAC) has submitted recommendations on how to proceed. EPA is evaluating these recommendations.	41
EPA	Clean Water Act Jurisdiction ("SWANCC Decision")	ANPRM: January 15, 2003.	42
OMB	OMB Analytic Guidance	OMB's revised final guidelines are being issued as Circular A-4 (see Appendix D).	45
OMB	Performance of Commercial Activities	OMB published a draft revision to Circular A-76 in the Federal Register on November 19, 2002. OMB issued the final revision on May 29, 2003.	46
U.S. Army Corps	Wetlands Delineation Guidance Documents	The Corps, in conjunction with the Environmental Protection Agency, the Fish and Wildlife Service, and the Natural Resources Conservation Service, is updating and clarifying its 1987 Wetland Delineation Manual to provide more regionally specific guidance resulting in more precise and consistent wetland delineations.	49

*Refers to numbers assigned to nominations in Section I of "Summaries of Public Suggestions for Reform of Regulations and Guidance Documents" (www.whitehouse.gov/omb/inforeg/summaries_nominations_final.pdf).

G. Next Steps

Over the next year, agencies will take the steps outlined above to implement new reforms of regulations and guidance documents, as well as explore the possibility of reforming other nominated rules and guidance documents. Periodically, OMB will ask agencies for updates on their progress.

CHAPTER III: U.S. APPROACHES TO MANAGEMENT OF EMERGING RISKS

U.S. regulatory agencies often decide on a course of action to protect public health, safety or the environment before science has resolved all the key factual questions about a suspected hazard and the effectiveness of prevention or mitigation efforts. The default action in face of uncertainty is not necessarily inaction. On the contrary, decision makers rely on various science-based precautionary approaches in assessing risks and taking protective regulatory actions.

There is growing international discussion on the appropriate regulatory responses to emerging risks where the likelihood and magnitude of harm are highly uncertain, and the costs to prevent or mitigate these effects are potentially very high. The purpose of this chapter is to describe the current role of precaution in regulatory decision making in the United States while explaining why precaution needs to be exercised wisely on a case-by-case basis.

This chapter has been prepared by an interagency work group co-chaired by the Council on Environmental Quality (CEQ) and the Office of Management and Budget (OMB). The Work Group includes representatives from the Department of Agriculture, the Department of Commerce, the Department of Energy, the Department of Health and Human Services, the Department of the Interior, the Environmental Protection Agency (EPA), and the Office of Science and Technology Policy. This chapter draws on public comments elicited by the OMB in the draft report released in February of this year. This chapter does not define new policy; it describes existing U.S. practices for both domestic and international readers.[20]

A. Risk Management in the United States

In the United States emerging risks are managed through a combined system of social, economic, legal, and regulatory mechanisms. When assessing the overall extent of precaution in U.S. risk management, it is important to consider the cumulative impact of these mechanisms.

All other factors being equal, the public prefers products, technologies, production facilities, and waste-disposal methods that do not pose unreasonable risks to human health, safety, and the environment. This consumer demand for responsible behavior by firms, though limited by the availability of information, exerts influence in competitive markets because firms seek to build a reputation for safety and consumers/shareholders and courts can penalize firms that do not take seriously the need for responsible risk management. In order to provide more discipline to market approaches to risk management, a variety of private – often non-profit – bodies have established voluntary standards for risk management that are built on principles of balance, openness, consensus, and due process. For example, the National Electrical Code is a

[20] In the draft report published in February of 2003, OMB requested comments on current U.S. approaches to analysis and management of emerging risks. Specifically we asked for comments on ways in which "precaution" is embedded in current risk assessment procedures through "conservative" assumptions in estimation of risk, or through explicit "protective" measures in management decisions. We also sought examples of approaches in human and ecological risk assessment and management methods at U.S. regulatory agencies which appear unbalanced, and how the U.S. integrates precautionary approaches to health, safety and environmental risks with other interests such as economic growth and technological innovation. We received numerous comments on this topic from a variety of consumer advocacy groups, academics, and the private sector. Copies of these comments are available on the OMB website at www.whitehouse.gov/omb/inforeg/regpol-reports_congress.html.

voluntary standard to reduce fire and other hazards developed by the private, non-profit National Fire Protection Association that is the basis for procurement specifications set by major manufacturers as well as some State and local building code requirements.[21] Similarly, social norms curb individual actions that impose risks to others such as smoking in public and driving under the influence of alcohol. There are advocacy groups such as Mothers Against Drunk Driving that have launched successful public education campaigns to change attitudes about risky behaviors.[22]

Managing risks entails costs and thus there are limits on the amount of risk prevention that firms and individuals will voluntarily practice. When the actions of one firm pose risks and costs on other firms, the public or the natural environment that are not reflected in a firm's cost of doing business, market demand alone does not lead to a socially efficient level of risk management.

Legal strategies may be necessary to supplement market approaches to risk management. For example, a distinctive feature of the U.S. risk management system is the complex and powerful system of liability law that allows citizens who have incurred damages or may incur damages to seek monetary compensation in the courts from responsible firms or individuals.

The United States also has an extensive regulatory system of risk protection with powers shared to various degrees between the Federal, State, and local governments. The Federal regulatory system is built around a system of delegated rulemaking; Congress passes laws and the Federal regulatory agencies issue regulations that implement the mandates enacted by Congress. A variety of checks and balances in the rulemaking process aims to ensure that decision makers adequately protect the public from risks in a sensible way.

Congress not only writes the laws that govern the decisions of regulatory agencies; once laws are passed, Congress retains important powers of oversight such as the appropriation of executive agency funding and confirmation of key appointees. The President appoints the heads of regulatory agencies and oversees and coordinates regulatory activities (through the OMB and other executive offices), as well as issues specific policy direction to Federal agencies through Executive Orders.

Regulatory agencies are required to follow the notice-and-comment rulemaking procedures prescribed in the Administrative Procedures Act (APA) and related laws designed to encourage a transparent and inclusive process. The APA requires agencies to publish in the *Federal Register* a notice of proposed rulemaking that references the legal authority under which the rule is proposed and a description of the subjects and issues to be addressed by the proposed rule. The APA also instructs agencies to provide the public with an opportunity to submit comments on the proposed rulemaking, and the final rulemaking must address all significant comments. Finally, if affected parties believe a Federal regulatory agency has made an unlawful decision due to procedural and/or substantive error, they may seek a review of the decision in a

[21] National Research Council (1995), *Standards, Conformity Assessment, and Trade: Into the 21st Century*, National Academy Press, Washington, DC.
[22] Institute of Medicine (1998), *Reducing the Burden of Injury: Advancing Prevention and Treatment,* National Academy Press, Washington, DC.

disciplined process of judicial review under the APA. Furthermore, under the Information Quality Act, agencies must issue information quality guidelines "ensuring and maximizing the quality, objectivity, utility, and integrity of information (including statistical information) disseminated by the agency," and stakeholders can seek and obtain correction of information maintained or disseminated by the agency that does not comply with the guidelines.[23] In addition, Federal regulatory agencies may voluntarily subject their analyses and decisions to various formal and informal mechanisms of stakeholder dialogue, external peer review, scientific advisory panels, and reviews from independent bodies such as the National Academies of Science. These mechanisms ensure extensive input from the scientific community and stakeholders before and after the initiation of rulemaking.

Thus, the Federal regulatory framework of the United States is designed to be a responsive, consultative, science-based system, operating synergistically within multiple layers of checks and balances involving social norms, market forces, liability law, voluntary standards, and Federal, State and local regulation with executive, legislative, and judicial oversight. The operation of these forces determines the overall extent of precaution that is applied to a particular emerging risk. Below, we focus on the Federal regulatory system and the variety of precautionary approaches that it uses to prevent, reduce, or mitigate emerging risks to human health, safety, and the environment in the face of uncertain outcomes.

B. Risk Assessment before Risk Management

Making a regulatory decision about an emerging risk is complicated by the dynamics of science; new discoveries at times have shown hazards to be worse than expected, and in others, predictions of doom never materialized or hazards were proven to be less onerous than projected (See Box 1 for examples). The National Research Council[24] report *Risk Assessment in the Federal Government*, commonly referred to as the "Red Book", described the key components of risk assessment and emphasized an important feature of the U.S. regulatory process: decisions about how to respond to a potential hazard are intended to be made after – and are informed and guided by – a scientific risk assessment that is grounded in the weight of the scientific evidence.[25] Regulators have the responsibility of ensuring that an adequate amount of time and resources are devoted to the risk assessment process. There are risks and costs associated with hasty decisions and there are risks and costs incurred when regulators are guilty of "paralysis by analysis." In circumstances where accelerated action in response to imminent threats is warranted, U.S. regulators generally have the authority to expedite the process of regulatory decision making.

[23] P.L. 106-554 §515

[24] National Research Council (1983), *Risk Assessment in the Federal Government: Managing the Process*, National Academy Press, Washington, DC.

[25] National Research Council, a part of the National Academies, is a private, nonprofit institution with a congressional charter to provide science, technology and health policy advice to the Federal government.

Box 1: Dynamics of Science

Early predictions overstated risk:

Malthus' Dismal Theorem. In 1798, Reverend Thomas Robert Malthus observed that the population tended to increase exponentially while sources of subsistence increased arithmetically. He hypothesized that living standards would not rise beyond subsistence levels due to the constant pressures the growing population would place on the food supply. Due in part to technological advancements that Malthus did not foresee, on the whole Malthus' dismal predictions did not come to pass with both population and standard of living greatly increasing over the past two centuries.

Saccharin. In 1981, saccharin was added to the list of chemicals "reasonably anticipated to be a human carcinogen" by the U.S. National Toxicology Program based on evidence of carcinogenicity in controlled experiments on rats. In 2000, however, it was removed from the list after an extensive review determined that the bladder tumors observed in rats were caused by a biological mechanism that is not relevant to humans, and observational evidence in human showed no carcinogenic effects.

Early predictions understated risk:

Thalidomide. Thalidomide was first marketed in Europe in the late 1950's as a sedative, and was considered safe to be prescribed for nausea and insomnia in pregnant women. By 1961, however, evidence began to mount that the drug caused severe birth defects in children whose mothers had taken the drug in the first trimester of pregnancy. Fortunately, the Food and Drug Administration had not yet approved the drug for distribution in the United States. The drug was approved in the United States in 1998 for the treatment of complications caused by leprosy, with stringent controls on the use of the drug to prevent exposure to the drug during pregnancy.

Childhood Lead Poisoning. Ancient Romans were aware that high exposure to lead could cause serious health problems such as madness and death. However, the potential health hazards to children such as impairment of cognitive functions from chronic low-level exposure to the metal in the environment were not documented until the 1940's. In the 1960's, blood lead level above 60 µg/dL was considered toxic. Over the last three decades, as new information about the relationship between the effects of lead on children's IQ emerged, the Centers for Disease Control progressively lowered the recommended action level to the current 10 µg/dL. Due to regulatory effort since the 1970's, major uses of lead in house paint, gasoline, water-distribution systems, and food cans have been eliminated or greatly reduced such that environmental lead contamination are now dramatically lower. Data from the most recent National Health and Nutrition Examination Survey show that the percentage of U.S. children with elevated blood lead levels (>10 µg/dL) has dropped from nearly 90% in the late 1970's to less than 5% in the early 1990's.

The United States employs precautionary approaches throughout the process of risk assessment and management so that the overall level of precaution in a given regulatory decision is appropriate.[26] The first phase is the data collection and other research efforts which are inputs in the risk assessment process. Next, the risk assessment phase synthesizes available information on the likelihood of events and the potential consequences and should represent an objective characterization of risk. When analysts assess risks, they frequently use "conservative" or "default" assumptions or explicitly add safety margins or uncertainty factors to characterize a "plausible" upper bound. In addition, analysts may be required to add safety factors to be

[26] See the FDA and USDA document prepared for OECD Ad Hoc Group on Food Safety "Precaution In U.S. Food Safety Decisionmaking: Annex II to the United States' National Food Safety System Paper" for a specific discussion on how precaution is embedded in the U.S. food safety system. Available at: http://www.foodsafety.gov/~fsg/fssyst4.html

protective of vulnerable populations. The Food Quality Protection Act of 1996 (FQPA) requires the EPA to consider adding a ten-fold uncertainty factor, the "Children's 10X Safety Factor", in assessing children's risks to pesticides unless sound scientific evidence indicates that a different factor would be appropriate. These practices are intended to provide decision makers with an indication of how bad things could be or might become without protective actions (see Box 2 and 3 for examples in chemical risk assessment). However, when estimates of risk are derived through these bounding exercises, they may far exceed the most likely estimate of risk. If these bounding estimates suggest that the risk may be unacceptable under the governing legal criteria, then a more complete assessment of risk – including a full analysis of the data and uncertainties – may be necessary to help determine what decision makers should do.

Box 2: Chemical Risk Assessment: Threshold

For the vast majority of chemicals that do not have sufficient data from human studies, margins of safety are applied to animal data to derive a reference value. Suppose that a safe level of exposure needs to be set for a chemical that has no human data but has been tested for toxicity in laboratory animals from chronic exposure by an inhalation test using a standard test protocol at four concentrations: 0, 10, 500 and 1,000 parts per million (ppm) of air. If no adverse health effects are observed at 0 and 10 ppm, but animals were observed to suffer adverse effects at 500 and 1,000 ppm, how should a safe level of exposure for humans be set?

Assuming that humans are like animals, the experiment suggests that the "safe" level of exposure may lie somewhere between 10 ppm – the "no observed adverse effect level" (NOAEL) – and 500 ppm – the "lowest observed adverse effect level" (LOAEL). Historically, the NOAEL is divided by uncertainty factors to account for the possibility that humans are more sensitive to the chemical than the test animals (animal to human extrapolation), and the possibility that some human sub-populations may be more sensitive than others (human to sensitive human extrapolation) to establish a reference concentration (RfC) or reference dose (RfD), the level of lifetime exposure without an "appreciable" risk of adverse effects.[27] To estimate the RfC, the NOAEL from the chronic study could be divided by a factor of up to 100 to account for the uncertainties which would yield an estimate of 0.1 ppm or 100 parts per billion. Furthermore, if results from multiple species and both genders of animals are available, the species and gender with the most sensitive response (i.e., the lowest NOAEL) is used for establishing the RfC, which adds another element of precaution. Each factor of 10 in the margin of safety requires risk managers to achieve an additional 90% reduction in exposure to reach the desired level of protection; therefore a 100-fold safety factor implies a 99% reduction in exposure compared to the largest concentration that did not harm the most sensitive group of test animals. More recent assessments use a Benchmark Dose (BMD) or Concentration (BMC), a statistical lower confidence limit on the dose that produces a predetermined change in response rate of an adverse effect compared to background, rather than the NOAEL since a true "no effect level" is difficult to establish in toxicological studies. The BMD or BMC are then divided by safety factors.

[27] Barnes DG and Dourson M (1988), "Reference Dose (RfD) - Description and Use in Health Risk Assessments," *Regulatory Toxicology and Pharmacology*, 8 (4), 471-486.

Box 3: Chemical Risk Assessment: Non-threshold

Consider a hazard whose adverse health effect declines in frequency and severity as dose declines yet a non-zero dose that produces "no harm" is not observable. A slight degree of toxicity could occur even at tiny doses, suggesting that only a zero dose would not violate the "no harm" standard. Yet zero dose may be technically impossible to achieve given factors such as background exposure to the hazard, or may not be desirable since zero dose may only be achieved through banning a particular beneficial activity. The size of the additional risk that is considered negligible varies from one context to another depending upon the number of people exposed to the hazard and other factors. Agencies such as EPA often define acceptable lifetime cancer risk as a range from one in ten-thousand (10^{-4}) to one in a million (10^{-6}).[28] When human data are not available, EPA's guidelines for cancer risk assessment produce an upper bound estimate of cancer potency through several conservative assumptions. For example, all tumors – not just malignant tumors – are used towards estimating a carcinogenic response, and rather than the Maximum Likelihood Estimator (MLE) – the best unbiased estimate of cancer potency – the 95% upper confidence limit of the MLE is used.

In addition, it may be necessary to move beyond single exposure pathways or single chemical assessments and to explore the accumulation of risk. Progress is being made on aggregate exposure and cumulative risk assessment. Aggregate exposure assessment involves the analysis of multiple pathways and routes of exposure such as food, drinking water, ambient and indoor air for a single agent or stressor. Cumulative risk looks at how multiple agents or stressors with a common mode of action interact to pose risk to health or the environment. For example, the FQPA requires the EPA to account for aggregate exposures through food as well as the cumulative effects of pesticides in establishing tolerances for pesticide residue in foods and criteria for registration of pesticides.

The last step is the risk management phase where potential regulatory or other management options may be considered to determine the responses to the potential risk. The application of precaution at this stage must be informed by the best available scientific and economic information, organized and presented in clear, concise, and unbiased fashion. The analytic tools such as risk assessment, cost-effectiveness analysis, and benefit-cost analysis are widely used in the United States to inform decision makers. Specific tools from the field of decision science, devised precisely for the purpose of aiding decision makers faced with dilemmas involving uncertain consequences and difficult value tradeoffs, are of particular importance to the application of precaution to decision making.[29] These tools help shed light on the complex dilemmas that are posed by technological and natural hazards of uncertain

[28] Breyer SG (1993), *Breaking the Vicious Circle: Toward Effective Risk Regulation*, Harvard University Press, Cambridge, MA.

[29] See Clemen, RT (1996), *Making Hard Decisions*, Duxbury Press, Pacific Grove, CA; Howard, RA (1968), "The Foundations of Decision Analysis," *IEEE Transactions on Systems Science and Cybernetics* SSC-4(3), 211-219; and Raiffa H (1968), *Decision Analysis: Introductory Lectures on Choices under Uncertainty*, Random House, New York, NY.

magnitude and can be used in conjunction with a variety of policy objectives from minimizing maximum damage to maximizing net benefits. However, although formal analytic tools can be helpful, they cannot substitute for responsible policy judgments by decision makers who make decisions under specific statutory frameworks and are accountable to the public for their actions.

An important and difficult question for decision makers dealing with emerging risks is how to build an appropriate degree of precaution into policies, recognizing that the science is uncertain and may be changing rapidly. Here, the ability to modify policies as scientific understanding grows is critical to the appropriate application of precaution. The information collection, risk assessment, and risk management phases are not static; the three components are an iterative process where management responses are altered to reflect new information that becomes available. The management approach can be adapted in response to improved scientific information that reduces uncertainty in risk assessment (such as the magnitude and likelihood of consequences) as well as uncertainty in risk management (such as effectiveness of interventions and pace of technological advancements).

C. Precautionary Approaches for Different Management Objectives

Estimates from risk assessments are used to make regulatory decisions within several broad frameworks that reflect the overall goal of the underlying statute. These frameworks, in part, reflect the different characteristics of risks that are important in developing appropriate management strategies such as immediacy, uncertainty, severity, potential for catastrophe, irreversibility, multi-generational impact, voluntariness, and controllability (See, e.g., CEQ, 1989).

The objective of the "risk only" framework is to ensure that the risk from a hazard is kept within a "safe" level. In contrast, the objective of the "feasibility" framework explicitly recognizes the utility of the activity that generates the hazard, and requires the reduction of risk to the extent that is technologically or economically feasible. The objective of the "benefit-cost balancing" framework goes a step further in considering overall societal welfare and attempts to weigh all of the positive consequences against all of the negative consequences of a regulatory measure.

Decision makers use one of these decision frameworks, or some hybrid, as authorized by the legislative mandate to choose the appropriate regulatory action such as notification of the potential hazard, licensing, standard setting, or permitting. In addition, a key issue for decision makers is to determine when there is insufficient information for an informed decision such that further information is necessary before proceeding. Not unexpectedly, precaution has a slightly different role to play in each of these frameworks.

Risk Only Approach

In some cases, statutory requirements instruct U.S. regulatory agencies to look only at the possible risk in determining the course of action. For example, in the Endangered Species Act (ESA) the decision to list threatened or endangered species for special protection to prevent their

irreversible loss is based "solely" on a scientific assessment of the danger of extinction.[30] In the regulation of chemicals, agencies may use conservative assumptions to develop a worst case scenario or plausible upper bound of risk and reduce exposures until it is within a "safe" level (e.g., reasonable certainty of no harm from pesticide residue on foods).[31]

Feasibility Approach

Even without establishing a "safe" level of exposure, decision makers can take precautionary measures by requiring technology-based standards to reduce exposures to potential hazards to the extent feasible through the best available technology and promote the adoption and development of cleaner technologies. For example, the Clean Air Act Amendments of 1990 require the implementation of maximum achievable control technology (MACT) standards to reduce emissions of hazardous air pollutants.[32] These standards are set for major sources of emissions based on currently available control technology, that is, feasibility of reducing emissions guides decisions rather than a quantification of risks. Similarly, the Occupational Safety and Health Administration is directed by statute to regulate occupational exposure to toxic substances "to the extent feasible".[33]

Benefit-Cost Balancing Approach

Presidential Executive Order 12866, which governs OMB review of agency rulemaking, refers explicitly to the net-benefit test and OMB's analytic guidance provides some direction on how analyses and decisions should be conducted under scientific uncertainty about benefits and costs.[34] Unless required to do otherwise by law, U.S. regulatory agencies are directed by the executive order to perform benefit-cost analysis of regulatory actions and "select those approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts, and equity)".[35]

Though outcomes are never known with certainty, decision makers can compare the net benefits of regulatory options based on best available estimates of benefits, costs and potential cost savings, and choose the option that yields the highest societal gain. Net-benefit tests have been applied by U.S. regulatory agencies under "unreasonable risk" laws such as the Federal Insecticide, Fungicide, and Rodenticide Act,[36] Toxic Substances Control Act,[37] and the Consumer Product Safety Act.[38] Under these statutes, the level of precaution is reflected in the forgone economic benefit from the chemical or product and/or high cost of control from decisions to ban or limit its use relative to the health benefits gained.

---

[30] 16 U.S.C. § 1533(b)(1)
[31] 21 U.S.C. §346a(c)(2)
[32] 42 U.S.C. §7412
[33] 29 U.S.C. §655(b)(5)
[34] Office of Management and Budget (1996), *Economic Analysis of Federal Regulations under Executive Order 12866*. Available at: http://www.whitehouse.gov/omb/inforeg/riaguide.html
[35] U.S. President (1993), "Executive Order 12866 – Regulatory Planning and Review," *Federal Register* 58(190), 51734-51744.
[36] 7 U.S.C. §136
[37] 15 U.S.C. §2605
[38] 15 U.S.C. §2056

When estimates of risk are highly uncertain, the net benefits of a rule may be positive in some cases and not in others. The expected net benefit test can be applied, following a formal probabilistic assessment of the hazard and potential efficacy of regulatory interventions (see Box 4 for a numerical example).

When decisions are based on the expected value of net benefits, the decision maker is taking a so-called "risk-neutral" stance. When decisions are based on hedging against the possibility of an adverse outcome even though a different decision would lead to higher expected net benefits, the decision maker is taking a precautionary "risk-averse" posture. A policy judgment is necessary when determining the magnitude of a downside loss that justifies a departure from the "risk-neutral" posture.

The expected net-benefit test and its variants are relatively analytically intensive because they require formal probabilistic treatment of both benefits and costs. For regulations with economic effects that exceed more than $1 billion per year, the new OMB guidelines for regulatory analysis require agencies to support rulemakings with formal probabilistic analysis of the key scientific and economic uncertainties regarding costs and benefits.[39]

Box 4: Expected Net Benefits Test

Suppose that the net benefits of a proposed rule to protect public health through administering a vaccine (with unknown efficacy and potentially severe side-effects) is measured in fatalities prevented. (If benefits and costs are expressed in different units, they need to be converted into the same units in order for this approach to be applied.) Now suppose that, without vaccination, the disease will lead to 3,000 fatalities for certain, whereas implementing the vaccination program will lead to either (a) no fatalities (3,000 fatalities prevented compared to doing nothing) if the vaccine is efficacious and side-effects are minimal, or (b) 4,000 fatalities (1,000 additional fatalities compared to doing nothing) if the vaccine is not effective and side-effects are severe. Does the rule pass the expected net-benefit test?

The answer depends on the probability of each outcome, and the risk posture of the decision maker. Under risk neutrality, as long as the probability that the vaccine has minimal side-effects (p) is greater than one-fourth, the expected net benefits of implementing the rule (incremental to doing nothing), in this specific case, will be positive:

$$3{,}000p - 1{,}000(1-p) > 0$$

Under risk aversion, for a certain range of p greater than one-fourth, the decision maker will prefer to not implement the rule to avoid the possibility of doing more harm than good (i.e., administering a vaccine that is not effective and has high side-effects), even if the expected net benefit is greater.

Hybrid Approaches

[39] Office of Management and Budget (2003), OMB Circular A-4, Regulatory Analysis.

There are also hybrid approaches that combine, for example, both a risk-only setting of regulatory goals, and technology-based enforceable standards. When "safe" levels are established by available scientific evidence and inclusion of margins of safety, but are not achievable given engineering limitations, technology-based standards are sometimes set to establish enforceable protective measures. In national drinking water regulations, a maximum contaminant level goal (MCLG) is set to allow for an "adequate margin of safety," but the maximum permissible level of a contaminant in water is based on best available technology to get as close to the MCLG as possible.[40] There are also hybrid approaches that combine both a risk-only setting of policy goals and benefit-cost balancing for specific protective actions. In the protection of endangered species, the decision to list a species as endangered under ESA must be based solely on scientific evidence related to threats to the survival of a species such as population dynamics and habitat loss. In developing plans to protect listed species, economic factors can be, or must be in some cases, considered.[41]

Value of Information Approach

When faced with uncertainty, the most cautious approach may be to wait for more information before taking action, yet a "watchful waiting" approach is a decision with consequences in terms of delay in possible health protection as well as savings from postponing regulatory costs. Value of information (VOI) analysis is an extension of the benefit-cost approach that evaluates the benefit of collecting additional information to reduce or eliminate uncertainty in a specific decision making context and represents the willingness to pay for additional information.[42] A recent Presidential/Congressional Commission on Risk Assessment and Risk Management[43] noted, "when stakes in a decision are large and the uncertainties complex, risk managers or their technical staffs may find it useful to experiment with formal value-of-information tools".

Unlike other analytic tools such as benefit-cost analysis and cost-effectiveness analysis, formal VOI has not yet been widely used in making risk management decisions (see Box 5 for examples of VOI analyses from the peer reviewed literature). The lack of VOI applications in actual management decisions can be partially attributed to the potentially resource intensive nature of the method, complexities in modeling the underlying probabilistic risk assessment, and the difficulties in developing probabilities for different outcomes as well as the results of further research. While VOI analyses can be complex, progress in computer software to support

---

[40] 42 U.S.C. §200g-1

[41] "The Secretary may exclude any area from critical habitat if he determines that the benefits of such exclusion outweigh the benefits of specifying such area as part of the critical habitat, unless he determines, based on the best scientific and commercial data available, that the failure to designate such area as critical habitat will result in the extinction of the species concerned." 16 U.S.C. § 1533(b)(2). Congressional Research Service (2003), *The Endangered Species Act: Consideration of Economic Factors*, CRS Report RL30792, U.S. Library of Congress, Washington, DC.

[42] See Clemen, RT (1996), *Making Hard Decisions*, Duxbury Press, Pacific Grove, CA; Howard, RA (1968), "The Foundations of Decision Analysis," *IEEE Transactions on Systems Science and Cybernetics* SSC-4(3), 211-219; and Raiffa H (1968), *Decision Analysis: Introductory Lectures on Choices under Uncertainty*, Random House, New York, NY.

[43] Presidential/Congressional Commission on Risk Assessment and Risk Management (1997), *Framework for Environmental Health Risk Assessment*, Presidential/Congressional Commission on Risk Assessment and Risk Management, Washington, DC.

decision science has made it more realistic to apply VOI tools to important decisions in the public and private sectors. Given the analytical effort required to conduct VOI analyses, a full VOI analysis is not appropriate for all risk management decisions. However, even without formal analysis, the VOI framework can provide helpful insights for determining the appropriate balance between taking action and waiting for more information.

Box 5: Examples of Value of Information Analyses for Environmental Regulation

North and Merkhofer[44] compared four alternative strategies for controlling pollution emissions from electric power plants with the objective of minimizing total social costs. They evaluated the value of simultaneously resolving two uncertainties in the model: how a unit of emission translates to ambient concentration and the total health cost per unit increase in suspended sulfate concentration.

Reichard and Evans[45] considered the value of monitoring in making a remediation decision for groundwater that may be contaminated by arsenic. There were two uncertainties in their model: the potency of arsenic in causing cancer and the exposure to arsenic in the water. They compared the value of improving exposure information from three different monitoring strategies.

Taylor et al.[46] assessed the value of animal experiments in determining the magnitude of cancer causing potential and improving environmental control decisions. The only source of uncertainty in the analysis was the carcinogenic potency of a chemical. Hypothetical examples were given based on plausible values from empirical evidence to illustrate the framework.

Dakins et al.[47] evaluated the remediation of PCB-contaminated sediments in New Bedford Harbor, Massachusetts. The objective was to choose an optimal level of dredging that will meet a health-based standard for PCB concentration in fish and minimize the remediation cost. The analysis included six sources of uncertainty in determining the concentration in fish such as PCB concentration in the sediment, average water temperature, and growth rate of flounder and estimates the value of resolving all uncertainties. Dakins et al.[48] expanded on the study by evaluating the value of various sampling strategies to measure total PCB body burden in flounder to inform the remediation decision.

Thompson and Evans[49] evaluated the value of national exposure information about perchloroethylene (perc) used in dry cleaning. The analysis compared regulating perc exposure at three different levels of decision making: individual dry cleaning facilities, by particular dry cleaning machine category (defined by type and size), and by particular machine type. The objective was to choose the pollution control option that maximizes net social benefits. The analysis considered fourteen sources of uncertainty and evaluated the value of resolving these uncertainties.

[44] North DW and Merkhofer MW (1976), "A methodology for analyzing emission control strategies," *Computers & Operations Research*, 3(2-3), 185-207.
[45] Reichard EG and Evans JS (1989), "Assessing the Value of Hydrogeologic Information for Risk-Based Remedial Action Decisions," *Water Resources Research,* 25(7), 1451-1460.
[46] Taylor AC, Evans JS, and McKone TE (1993), "The Value of Animal Test Information in Environmental-Control Decisions," *Risk Analysis*, 13(4), 403-412.
[47] Dakins ME, Toll JE, and Small MJ (1994), "Risk-Based Environmental Remediation - Decision Framework and Role of Uncertainty," *Environmental Toxicology and Chemistry* 13(12), 1907-1915.
[48] Dakins ME, Toll JE, Small MJ, and Brand KP (1996), "Risk-Based Environmental Remediation: Bayesian Monte Carlo analysis and the expected value of sample information," *Risk Analysis* 16(1), 67-79.
[49] Thompson KM and Evans JS (1997), "The value of improved national exposure information for perchloroethylene (Perc): A case study for dry cleaners," *Risk Analysis*, 17(2), 253-271.

D. Preventing Excessive Precaution

When applied appropriately, precautionary approaches can promote the protection of public health, safety and the environment by reducing potential threats.[50] However, if precaution is taken to an extreme and rigidly applied, adverse impacts can occur. For example, an important consideration when taking precautionary measures is that decreasing one risk may increase a countervailing risk.[51] For example, regulations that reduce the level of disinfection byproducts in the water supply may reduce potential adverse health effects from by-products of the disinfection process. However, it may also reduce the effectiveness of disinfection and thereby increase the health risk from microorganisms. Likewise, restricting latex use to prevent allergic reaction in health care workers may increase the risk of infections that latex products are used to prevent. Therefore, precaution may be necessary on both sides of the equation and a formal consideration of risk-risk trade-off may be necessary when both risks cannot be easily reduced in tandem.[52]

Resource constraints must also be considered. By being too precautious on some risks, decision makers may not have the resources to take precautions against other risks and, in the long run, fewer risks may be prevented.

E. Conclusion

The U.S. manages emerging risks through an extensive system of local, State, and Federal regulation working in combination with social norms, market forces, voluntary standards, and tort liability law. When dealing with emerging risks, formal risk assessments are often used to inform Federal regulatory decisions and, when science is highly incomplete or uncertain, these assessments may be based on protective assumptions or margins of safety. When Federal decision makers decide the appropriate level of precaution in a specific decision, they need to consider the extent of precaution that is embedded in the methods and assumptions used in the risk assessment. They may also need to consider other factors such as technological and economic feasibility, or more holistic benefit-cost balancing, including considerations of countervailing risks, depending on the overall objective of statutory requirements to protect the public and the environment, and improve societal welfare. Critical to the application of precaution is deciding when additional information is needed before making a final regulatory decision or revising a previous regulatory decision. Since the U.S. regulatory framework relies on an open and transparent system of delegated rulemaking with revisable regulations, the system is able to incorporate the best scientific advice at many steps in the process and respond to changes in information accordingly. This allows for an iterative process of information collection, risk assessment, and risk management when regulating emerging risks. In this

[50] Raffensperger C and Tickner J (1999), eds., Protecting Public Health and the Environment: Implementing the Precautionary Principle, Island Press, Washington, DC.
[51] Wiener, JB (1998), "Managing the Iatrogenic Risks of Risk Management," *Risk: Health, Safety & Environment*, 9, 39-82.
[52] Goklany IM (2002), "From Precautionary Principle to Risk-Risk Analysis," *Nature Biotechnology*, 20(11), 1075. Sunstein CR (2002), *Risk and Reason: Safety, Law and the Environment*, Cambridge University Press, Cambridge. Sunstein, CR (2003), "Beyond the Precautionary Principle", *University of Pennsylvania Law Review*, 151(3), 1003-1058.

iterative process, different levels of precaution are applied early on (when the scientific information is limited) and an appropriate reduction of precautionary consideration is applied as scientific knowledge and experience regarding risks, benefits, and costs increases.

CHAPTER IV: REGULATIONS RELATED TO HOMELAND SECURITY AND RECOVERY FROM THE ATTACKS OF SEPTEMBER 11, 2001

The nation faces an unprecedented regulatory challenge: issuing rules and regulations that effectively combat the threat of terrorism. The analysis of homeland security and recovery activities raises unique and difficult issues. In OMB's draft 2003 Report to Congress, we solicited public comment on how agencies and OMB should analyze homeland security regulatory actions, including how agencies might better forecast the anti-terrorism benefits and the direct and indirect costs of such rules, such as loss of time, convenience, privacy, and economic productivity.

This chapter consists of two parts: The first part describes the government's response to recover from the September 11 attacks and strengthen homeland security, including a list of proposed and final rules. The second part describes the public comments on the analysis of homeland security regulation, and presents a preliminary discussion of the issues agencies will confront when considering the costs and benefits of counter-terrorism and homeland security regulatory activity.

Throughout this chapter, OMB includes examples of statutes and regulations that address both recovery from the September 11 attacks and homeland security as defined in the *National Strategy for Homeland Security* and the OMB *Report to Congress on Combating Terrorism*. The public comments address many regulatory issues across this range. For instance, OMB has categorized assistance put in place for victims and other parties impacted by the September 11, 2001 attacks as recovery rather than homeland security, as these deal with a specific event rather than the nation's enduring capability to prepare for, respond to, or recover from a terrorist event. In a broad benefit-cost context, it is useful to examine recovery and homeland security together. This chapter is not meant to introduce a new definition of the term "homeland security;" however, OMB acknowledges here and in the 2002 report that the boundaries of what is considered homeland security are not always clear, and that we may need to occasionally refine the definition used to establish those boundaries.

A. Summary of Federal Homeland Security and Recovery Activity

After the attacks of September 11, 2001, Americans for the first time in decades began to ask the question: How do we ensure that we are protected at home? Both the Legislative and Executive Branches responded by reorganizing Federal agencies and through a series of new laws and regulations designed to deter terrorism, minimize the potential effects of terrorist acts, provide assistance, and address potential post-attack liability concerns.

Governmental Reorganization

At the President's request, Congress passed The Homeland Security Act of 2002 (P.L. 107-296), which established the Department of Homeland Security, a cabinet-level department consolidating 22 different agencies into four major directorates: information analysis and infrastructure protection, science and technology, border and transportation security, and

emergency preparedness and response. Agencies placed under the Department's authority include the Immigration and Naturalization Service, U.S. Coast Guard, U.S. Customs Service, Federal Emergency Management Agency, U.S. Secret Service, Transportation Security Administration, and the border inspection section of the Animal and Plant Health Inspection Service. The consolidation of these related agencies under the leadership of one Cabinet secretary is designed to strengthen the government's ability to reduce America's vulnerability to terrorism and minimize the damage from potential attacks.

Statutory Actions

Following the September 11 attacks, Congress and the Administration sought to answer three basic questions: What are the vulnerabilities in our homeland security framework? Who should address these concerns, and how should these concerns be addressed appropriately? Concerned with air, sea, and land entry and travel, the ability of the law enforcement system to catch terrorists, and the Federal Government's current authority over these areas, Congress passed and the President signed into law a series of counter-terrorism and homeland security Acts.

1. Assistance

The Air Transportation Safety and System Stabilization Act (P.L. 107-42) and the Victims of Terrorism Relief Act of 2001 (P.L. 107-134) provided assistance to individuals and companies affected by the attacks of September 11, 2001. The laws afforded financial relief to victims, their families, and air carriers.

2. Law Enforcement: USA PATRIOT

The Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism (USA PATRIOT) (P.L. 107-56) provided Federal officials with enhanced powers to intercept wire, oral and electronic communication relating to terrorism. Further, it required more stringent immigration procedures at the borders, established new Federal crimes related to terrorism, and increased penalties for already defined terrorist acts.

3 Transportation Security

While USA PATRIOT enhanced the law enforcement aspects of deterring terrorism, the Aviation and Transportation Security Act (ATSA) (P.L. 107-71) mandated airline security checks, baggage screenings, and enhanced cockpit doors and secure flight decks, in direct reaction to the terrorists' use of that mode of transportation. It also established the Transportation Security Administration (TSA) under the Department of Transportation, to oversee security issues for all transportation modes. The TSA was later transferred to the new Department of Homeland Security (discussed previously).

In addition, the Maritime Transportation Security Act (P.L. 107-295) required facility and vessel vulnerability assessments, maritime security plans, and enhanced identification requirements and procedures. The Act also mandated that the Department of Transportation

develop and implement a long-range automated vessel tracking system to provide information on vessel positions.

4 Immigration

The Enhanced Border Security and Visa Entry Reform Act of 2002 (P.L.107-173) increased the ability of the Federal government to monitor aliens in the United States, and established more stringent standards to enter and exit the country. Specifically, the Act granted access to and coordination of law enforcement and other information between the Department of State, the former Immigration and Naturalization Service (INS, now part of the Homeland Security Department), and other law enforcement personnel. The Act also directed the development of an integrated entry and exit data system. Further, it strengthened the requirements for monitoring foreign students and exchange visitors, and their sponsoring institutions, by requiring collection of additional information on these institutions and the individuals prior to and during their stay in the United States.

5 Bio-terrorism

The Public Health Security and Bio-terrorism Preparedness and Response Act (P.L. 107-188) focused specifically on national, State, and local preparedness and response planning and security by requiring new controls on biological agents and toxins; putting in place additional safety and security measures on the U.S. food, drug, and water supplies; establishing measures which affect the Strategic National Stockpile; and fostering the development of priority countermeasures to bio-terrorism.

6 Risk Insurance

To ensure that businesses have access to terrorism risk insurance, the Terrorism Risk Insurance Act (November 26, 2002) (P.L. 107-297) established a temporary Federal program that provides shared public and private compensation for insured losses resulting from acts of terrorism. The Act's purpose is to "protect consumers by addressing market disruptions and ensure the continued widespread availability and affordability of property and casualty insurance for terrorism risk and allow for a transitional period for the private markets to stabilize, resume pricing of such insurance, and build capacity to absorb any future losses, while preserving State insurance regulation and consumer protection."

Regulatory and other Executive Branch Actions

The Administration has also responded to the events of September 11 through changes to its regulations. By addressing gaps in the Government's regulatory scheme, the Administration has addressed the nation's immigration, transportation, and border security concerns, in addition to providing assistance to those affected by the September 11 attacks.

As of May 31, 2003, OMB had reviewed a total of 69 draft proposed and final regulations designed to address terrorism, provide post-attack assistance, and promote homeland security. In general, these regulations were designed to reduce the risk of a future terrorist attack, minimize

the damage if such an attack occurred, provide post-attack assistance, or provide post-attack liability protections.

Table 17 summarizes the Federal regulatory activity since September 11, 2001. The table lists the significant regulations that were reviewed by OMB through May 2003. The table contains 69 regulatory actions, with 21 finalized rules, 29 interim final rules, 15 proposed rules, and 4 "other" documents.[53]

[53] Rules that may have been published first as proposed or interim final rules, but were then subsequently finalized, we considered one rulemaking. The 15 rules listed as proposed rules were those which were proposed but neither finalized nor made effective through an interim final rule as of this writing. "Other" documents include notices, internal guidelines, or procedures that OMB reviewed under E.O. 12866, but were not regulatory actions.

Table 17. Regulations Related to Homeland Security									
Rule #	**RIN No.**	**Agency**	**Sub Agency**	**Title**	**Rulemaking Stage**	**Costs**	**Benefits**	**Type of Regulation**	**Statutory Reference**
1	038-AB56	OMB		Regulation for Air Carrier Guarantee Loan Program	Final Rule	NQ	NQ	Assistance	Air Transportation Safety and System Stabilization Act (P.L. 107-42)
2	0579-AB47	USDA	APHIS	Agricultural Bioterrorism Protection Act of 2002; Possession, Use and Transfer of Biological Agents and Toxins - APHIS Docket No. 02-088-1	Interim Final Rule	NQ (estimates provided anecdotally)	NQ	Risk Reduction	Agricultural Bioterrorism Protection Act of 2002.
3	0694-AC50	DOC	BIS	India and Pakistan: Lifting of Sanctions, Removal of Indian and Pakistani Entities, and Revision in License Review Policy[54]	Final Rule	NQ	NQ	Other	N/A
4	0910-AC38	HHS	FDA	Administrative Detention of Food for Human or Animal Consumption under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002	Proposed Rule	$ 0-38 million (reported as annual impact only. 0-$543 million NPV infinite time horizon discount at 7%)	NQ	Impact Mitigation	Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (P.L. 107-188)
5	0910-AC39	HHS	FDA	Establishment and Maintenance of Records Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002	Proposed Rule	$3,660,808,000 NPV infinite time horizon discount at 7%	NQ	Impact Mitigation	Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (P.L. 107-188)
6	0910-AC40	HHS	FDA	Registration of Food Facilities under the Public Health Security and Bioterrorism	Proposed Rule	$3,152,670,000 NPV infinite time horizon discount at 7%	NQ	Impact Mitigation	Public Health Security and Bioterrorism Preparedness and

[54] This regulation supports the broader war on terrorism.

Table 17. Regulations Related to Homeland Security									
Rule #	**RIN No.**	**Agency**	**Sub Agency**	**Title**	**Rulemaking Stage**	**Costs**	**Benefits**	**Type of Regulation**	**Statutory Reference**
				Preparedness and Response Act of 2002					Response Act 2002
7	0910-AC41	HHS	FDA	Prior Notice of Imported Food under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002	Proposed Rule	$ 962,713,000 NPV infinite time horizon discount at 7%	NQ	Impact Mitigation	Public Health Security and Bioterrorism Preparedness and Response Act 2002
8	0920-AA08	HHS	CDC	Possession, Use and Transfer of Select Agents and Toxins	Interim Final Rule	$41 million (annual)	NQ	Risk Reduction	Public Health Safety and Bioterrorism Preparedness and Response Act of 2002 (PL 107-188)
9	0960-AF05	SSA		Evidence Requirement for Assignment of Social Security Administration Numbers (SSNs) and Assignment of SSNs for Nonwork Purposes	Proposed Rule	NQ	NQ	Risk Reduction	N/A
10	1105-AA78	DOJ	LA	DNA Sampling of Federal Offenders Under the USA Patriot Act of 2001	Proposed Rule	NQ	NQ	Risk Reduction	USA PATRIOT (P.L. 107-56)
11	1105-AA79	DOJ	LA	September 11th Victim Compensation Fund of 2001	Prerule	NQ	NQ	Assistance	Air Transportation Safety and System Stabilization Act (P.L. 107-42)
	1105-AA79	DOJ	LA	September 11th Victim Compensation Fund of 2001	Interim Final Rule	NQ	NQ	Assistance	Air Transportation Safety and System Stabilization Act (P.L. 107-42)
	1105-AA79	DOJ	LA	September 11th Victim Compensation Fund of 2001	Final Rule	NQ	NQ	Assistance	Air Transportation Safety and System Stabilization Act (P.L. 107-42)

Table 17. Regulations Related to Homeland Security									
Rule #	**RIN No.**	**Agency**	**Sub Agency**	**Title**	**Rulemaking Stage**	**Costs**	**Benefits**	**Type of Regulation**	**Statutory Reference**
12	1105-AA80	DOJ	LA	Screening of Aliens and Other Designated Individuals Seeking Flight Training	Interim Final Rule	NQ	NQ	Risk Reduction	Aviation and Transportation Security Act (ATSA)(P.L. 107-71)
	1105-AA80	DOJ	LA	Screening of Aliens and Other Designated Individuals Seeking Flight Training	Proposed Rule	NQ	NQ	Risk Reduction	Aviation and Transportation Security Act (ATSA)(P.L. 107-71)
	1105-AA80	DOJ	LA	Screening of Aliens and Other Designated Individuals Seeking Flight Training	Final Rule	NQ	NQ	Risk Reduction	Aviation and Transportation Security Act (ATSA)(P.L. 107-71)
13	1115-AB93	DOJ	INS	Attorney General's Evaluations of the Designations of Belgium, Italy, Portugal, and Uruguay as Participants under the Visa Waiver Program	Interim Final Rule	NQ	NQ	Risk Reduction	N/A
14	1115-AE82	DOJ	INS	Requiring Aliens Ordered Removed from the United States to Surrender to the INS for Removal	Proposed Rule	NQ	NQ	Risk Reduction	N/A
15	1115-AF24	DOJ	INS	Requirements for Biometric Border Crossing Identifications Cards (BCCs) and Elimination of Non-Biometric BCCs on Mexican and Canadian Borders	Interim Final Rule	NQ	NQ	Risk Reduction	N/A

Table 17. Regulations Related to Homeland Security									
Rule #	**RIN No.**	**Agency**	**Sub Agency**	**Title**	**Rulemaking Stage**	**Costs**	**Benefits**	**Type of Regulation**	**Statutory Reference**
16	1115-AF55	DOJ	INS	Retention and Reporting of Information for F, J, and M Nonimmigrants; SEVIS	Final Rule	NQ	NQ	Risk Reduction	Illegal Immigration Reform and Immigrant Responsibility Act (P.L. 104-208)
17	1115-AF56	DOJ	INS	Authorizing Collection of Fee Levied on F, J, and M Nonimmigrant Classifications under Illegal Immigration Reform and Immigrant Responsibility Act	Interim Final Rule	NQ	NQ	Risk Reduction	N/A
18	1115-AG40	DOJ	INS	Custody Procedures	Interim Final Rule	NQ	NQ	Risk Reduction	N/A
19	1115-AG41	DOJ	INS	Review of Custody Determinations	Interim Final Rule	NQ	NQ	Risk Reduction	N/A
20	1115-AG43	DOJ	INS	Limiting the Period of Admission for B Nonimmigrant Aliens (Section 610 Review)	Proposed Rule	NQ	NQ	Risk Reduction	N/A
21	1115-AG55	DOJ	INS	Retention and Reporting of Information for F, J, and M Nonimmigrants; SEVIS	Proposed Rule	NQ	NQ	Risk Reduction	N/A
	1115-AG55	DOJ	INS	Allowing Eligible Schools to Apply for Preliminary Enrollment in the Student and Exchange Visitor Information System (SEVIS)	Interim Final Rule	NQ	NQ	Risk Reduction	N/A

Table 17. Regulations Related to Homeland Security									
Rule #	**RIN No.**	**Agency**	**Sub Agency**	**Title**	**Rulemaking Stage**	**Costs**	**Benefits**	**Type of Regulation**	**Statutory Reference**
22	1115-AG57	DOJ	INS	Carrier Arrival and Departure Electronic Manifest Requirements and Imposition of Fines under Section 231 of the Act	Proposed Rule	$44,232,000 (one time programming costs) plus 1.5B recurring costs NPV over 30 years	NQ	Risk Reduction	Enhanced Border Security and Visa Entry Reform Act of 2002 (P.L.107-173)
23	1115-AG60	DOJ	INS	Requiring Change of Status from B to F-1 or M-1 Nonimmigrant Prior to Pursuing a Course of Study	Interim Final Rule	NQ	NQ	Risk Reduction	N/A
24	1115-AG67	DOJ	INS	Release of Information Regarding INS Detainees in Non-Federal Facilities	Interim Final Rule	NQ	NQ	Risk Reduction	N/A
25	1115-AG70	DOJ	INS	Registration and Monitoring of Certain Nonimmigrants	Proposed Rule	NQ	NQ	Risk Reduction	N/A
	1115-AG70	DOJ	INS	Registration and Monitoring of Certain Nonimmigrants	Final Rule	NQ	NQ	Risk Reduction	N/A
26	1115-AG71	DOJ	INS	Requiring Certification of All Service Approved Schools for Enrollment in the Student and Exchange Visitor Information System (SEVIS)	Interim Final Rule	NQ	NQ	Risk Reduction	N/A
27	1115-AG73	DOJ	INS	Passenger Data Elements for Visa Waiver Program	Interim Final Rule	NQ	NQ	Risk Reduction	N/A

Table 17. Regulations Related to Homeland Security									
Rule #	**RIN No.**	**Agency**	**Sub Agency**	**Title**	**Rulemaking Stage**	**Costs**	**Benefits**	**Type of Regulation**	**Statutory Reference**
28	1115-AG75	DOJ	INS	Reduced Courseload for Certain F and M Nonimmigrant Students in Border Communities	Interim Final Rule	NQ	NQ	Risk Reduction	N/A
29	1120-AB08	DOJ	BOP	National Security: Prevention of Acts of Violence and Terrorism	Interim Final Rule	NQ	NQ	Risk Reduction	N/A
30	1125-AA38	DOJ	EOIR	Protective Orders in Immigration Administrative Proceedings	Interim Final Rule	NQ	NQ	Risk Reduction	N/A
31	1140-AA00	DOJ	ATF	Implementation of the Safe Explosives Act - Title XI, Subtitle C of P.L. 107-296	Interim Final Rule	$4.293 initial cost/ no recurring cost estimate	NQ	Risk Reduction	Homeland Security Act 2002 (P.L. 107-296)
32	1205-AB31	DOL	ETA	Disaster Unemployment Assistance Program Amendment	Interim Final Rule	$1.47 million	NQ	Assistance	N/A
	1205-AB31	DOL	ETA	Disaster Unemployment Assistance Program Amendment; Clarifying Reason for Unemployment	Final Rule	$2.205 million	NQ	Assistance	N/A
33	1400-AB45	State		Student and Exchange Visitor Information System (SEVIS) Rule -- 22 C.F.R. Part 62, Subpart F	Interim Final Rule	NQ	NQ	Risk Reduction	N/A
34	1400-AB48	State		Documentation of Nonimmigrants under the Immigration and Nationality Act, as Amended: Aliens Ineligible to Transit without Visa	Other	NQ	NQ	Risk Reduction	N/A
35	1505-AA98	Treasury	DO	Terrorism Risk Insurance Program	Interim Final Rule	NQ	NQ	Post Event Liability	Terrorism Risk Insurance Act (P.L. 107-297)

Table 17. Regulations Related to Homeland Security									
Rule #	**RIN No.**	**Agency**	**Sub Agency**	**Title**	**Rulemaking Stage**	**Costs**	**Benefits**	**Type of Regulation**	**Statutory Reference**
36	1505-AA99	Treasury	DO	Terrorism Risk Insurance Program	Proposed Rule	NQ	NQ	Post Event Liability	Terrorism Risk Insurance Act (P.L. 107-297)
37	1601-AA14	DHS	OS	Procedures for Handling Critical Infrastructure Information	Proposed Rule	NQ	NQ	Risk Reduction	N/A
38	1992-AA33	DOE	DSA	Polygraph Examination Regulations	Proposed Rule	NQ	NQ	Risk Reduction	N/A
39	2105-AD06	DOT	OST	Procedures for Compensation of Air Carriers	Final Rule	NQ. This rule provided procedures for disbursement of $5 billion in direct assistance for losses incurred between 9/11/01 and 12/31/01	NQ	Assistance	Aviation and Transportation Security Act (ATSA)(P.L. 107-71)
	2105-AD06	DOT	OST	Procedures for Compensation of Air Carriers	Final Rule	NQ	NQ	Assistance	Aviation and Transportation Security Act (ATSA)(P.L. 107-71)
40	2110-AA01	DOT	TSA*	Imposition and Collection of Passenger Civil Aviation Security Fees in the Wake of September 11, 2001	Other	NQ	NQ	Assistance	Aviation and Transportation Security Act (ATSA)(P.L. 107-71)
41	2110-AA02	DOT	TSA	Aviation Security Infrastructure Fees	Interim Final Rule	NQ. This rule provided for collection of fees for Federal security services	NQ	Assistance	Aviation and Transportation Security Act (ATSA)(P.L. 107-71)
42	2110-AA03	DOT	TSA	Civil Aviation Security Rules	Interim Final Rule	NQ	NQ	Risk Reduction	Aviation and Transportation Security Act (ATSA)(P.L. 107-

Table 17. Regulations Related to Homeland Security									
Rule #	**RIN No.**	**Agency**	**Sub Agency**	**Title**	**Rulemaking Stage**	**Costs**	**Benefits**	**Type of Regulation**	**Statutory Reference**
									71); Airport Security Improvement Act (106-528)
43	2110-AA04	DOT	TSA	Security Programs for Aircraft With a Maximum Certificated Takeoff Weight of 12,500 Pounds or More	Interim Final Rule	NQ	NQ	Risk Reduction	Aviation and Transportation Security Act (ATSA)(P.L. 107-71)
44	2110-AA05	DOT	TSA	Private Charter Security Rules	Final Rule	NQ	NQ	Risk Reduction	N/A
	2110-AA05	DOT	TSA	Aviation Security: Private Charter Security Rules	Final Rule	NQ	NQ	Risk Reduction	N/A
45	2110-AA14	DOT	TSA	Threat Assessments Regarding Citizens of the US Who Hold or Apply for a Federal Aviation Administration Certificate	Final Rule	NQ	NQ	Risk Reduction	N/A
46	2110-AA17	DOT	TSA	Threat Assessments Regarding Alien Holders of the US Who Hold or Apply for a Federal Aviation Administration Certificate	Final Rule	NQ	NQ	Risk Reduction	N/A
47	2110-AA18	DOT	TSA	Transportation of Explosives from Canada to the US Visa Commercial Motor Vehicle and Railroad Carrier	Interim Final Rule	NQ	NQ	Risk Reduction	N/A
48	2115-AG36	DOT	USCG	Automatic Identification System Carriage Requirements	Proposed Rule	$79 million, 10 yr. (present value)	$31 million, 10 yr. (present value)	Risk Reduction	N/A
49	2120-AG51	DOT	FAA	Screening of Checked Baggage on Flights within the United	Final Rule (never published)	3.1 billion over 10 years	NQ	Risk Reduction	N/A

Table 17. Regulations Related to Homeland Security									
Rule #	**RIN No.**	**Agency**	**Sub Agency**	**Title**	**Rulemaking Stage**	**Costs**	**Benefits**	**Type of Regulation**	**Statutory Reference**
				States					
50	2120-AH49	DOT	FAA	Aircraft Security under General Operating and Flights Rules	Final Rule	NQ	NQ	Risk Reduction	N/A
51	2120-AH52	DOT	FAA	Flight Crew Compartment Access and Door Designer	Final Rule	NQ	NQ	Risk Reduction	N/A
52	2120-AH53	DOT	FAA	Flight Crew Compartment Access and Door Designs	Final Rule	NQ	NQ	Risk Reduction	N/A
53	2120-AH54	DOT	FAA	Criminal History Background Checks	Final Rule	$27 million NPV. Agency provided only limited cost information, estimating fingerprinting costs for about 1 million workers at $27 million.	NQ	Risk Reduction	N/A
54	2120-AH56	DOT	FAA	Security Considerations in the Design of the Flightdeck on Transport Category Airplanes	Other	$85 - $115 million, 10 yr. pv	NQ	Risk Reduction	Aviation and Transportation Security Act (ATSA)(P.L. 107-71)
55	2120-AH59	DOT	FAA	Security Screeners: Qualifications, Training, and Testing	Other	NQ	NQ	Risk Reduction	Aviation and Transportation Security Act (ATSA)(P.L. 107-71)
56	2120-AH62	DOT	FAA	Enhanced Security Procedures for Operations at Certain Airports in the Washington, DC Metropolitan Area Special Flight Rules Area	Final Rule	$11.44 M (present value) over 2 years	$45.78M (present value) over 2 years	Risk Reduction	N/A

Table 17. Regulations Related to Homeland Security									
Rule #	**RIN No.**	**Agency**	**Sub Agency**	**Title**	**Rulemaking Stage**	**Costs**	**Benefits**	**Type of Regulation**	**Statutory Reference**
57	2120-AH67	DOT	FAA	Transponder Continuous Operation	Proposed Rule	$44.6-$78.9 M (present value over 3 years)	NQ	Risk Reduction	N/A
58	2120-AH70	DOT	FAA	Security Considerations for the Flightdeck on Foreign-Operated transport Category Airplanes	Final Rule	NQ	NQ	Other	N/A
59	2120-AH76	DOT	FAA	Picture Identification Requirements	Final Rule	NQ	NQ	Risk Reduction	N/A
60	2120-AH83	DOT	FAA	Limitation on Construction or Alteration in the Vicinity of the Private Residence of the President of the United States	Interim Final Rule	NQ	NQ	Impact Mitigation	N/A
61	2120-AH84	DOT	FAA	Ineligibility for an Airman Certificate Based on Security Grounds	Final Rule	NQ	NQ	Risk Reduction	N/A
62	2126-AA70	DOT	FMCSA	Limitation on the Issuance of Commercial Driver's Licenses with a Hazardous Materials Endorsement	Interim Final Rule	$485 million, 10 yr., pv	NQ	Risk Reduction	USA PATRIOT (P.L. 107-56)
63	2130-AB38	DOT	FRA	U.S. Locations Requirement for Dispatching of United States Rail Operations	Interim Final Rule	NQ	NQ	Risk Reduction	N/A
64	2137-AD67	DOT	RSPA	Hazardous Materials: Security Requirements for Offerors and Transporters of	Final Rule	$274 million, 10 yr. pv	NQ	Risk Reduction	N/A

Table 17. Regulations Related to Homeland Security									
Rule #	**RIN No.**	**Agency**	**Sub Agency**	**Title**	**Rulemaking Stage**	**Costs**	**Benefits**	**Type of Regulation**	**Statutory Reference**
				Hazardous Materials					
65	3067-AC93	FEMA		National Urban Search and Rescue Response System	Proposed Rule	NQ	NQ	Impact Mitigation	N/A
66	3245-AE56	SBA		Size Standards; Inflation Adjustment	Interim Final Rule	NQ	NQ	Assistance	N/A
67	3245-AE82	SBA		Disaster Loan Program	Interim Final Rule	$250M (loan subsidy, not annualized)	NQ	Assistance	N/A
68	3245-AE93	SBA		Small Business Size Standards; Travel Agencies	Interim Final Rule	NQ	NQ	Assistance	N/A
69		HHS	SAMSA	Substance Abuse and Mental Health Services Administration Mental Health and Substance Emergency Response Criteria	Interim Final Rule	NQ	NQ	Assistance	N/A

Under "type of regulation", OMB has classified regulations under five categories: (1) Risk Reduction - The regulation is intended to reduce the probability of a terrorist attack; (2) Assistance - The regulation is intended to provide assistance to the private or public sector in the event of a terrorist attack; (3) Impact Mitigation - The regulation is intended to minimize the adverse effects of a terrorist attack, in the event that the attack occurs; (4) Post-event Liability - The regulation is intended to define the scope of liability in the event of a terrorist attack; and (5) Other - Regulations that do not fall into any of the above categories.[55] These categories cover the broad scope of homeland security and recovery activities.

Of the 69 regulations, a majority (49 out of 69) were intended to reduce the risk of a future terrorist attack. For example, the legacy Immigration and Naturalization Service (INS) issued an interim final regulation on the use of biometric border crossing cards. The regulation provides immigration officials at the border with a better means of verifying the identity of individuals from Canada or Mexico who use border crossing cards to enter the U.S. The USDA promulgated an interim final regulation that enforces standards and procedures governing the possession, use, and transfer of listed biological agents and toxins, to protect animal and plant health and products, and to minimize the risk of attack using these substances.

Regulations intended to provide or facilitate the provision of assistance to the public were the second largest category (10 out of 69). The Department of Justice final rule on the September 11th Victims Compensation Fund provided an alternative to the risk, expense, and potential delays inherent in civil litigation. The Fund provided Federal financial assistance for surviving victims and the families of deceased victims. The Department of Labor also promulgated regulations that permitted disaster unemployment assistance to reach those individuals who became unemployed as an indirect effect of the September 11 attacks. Individuals who temporarily lost their jobs due to the closure of Reagan National Airport outside of Washington, DC, for example, were able to receive disaster unemployment assistance as a result of this regulatory amendment.

Since September 11, six regulations also mitigate the impact of a future terrorist attack, should such an attack occur. FDA proposed a series of regulations designed to reduce the impact of a terrorist act. One FDA proposed rule, for example, providing for the administrative detention of food, given information or intelligence that such foodstuff has been tampered with or altered. FEMA also proposed the "National Urban Search and Rescue Response System", designed to minimize the loss of life in the wake of a national disaster.

The fourth type of regulation issued relating to homeland security were those intended to address post-event liability issues. The Department of Treasury promulgated regulations regarding terrorism risk insurance, as authorized by the Terrorism Risk Insurance Act of 2002.

[55] In total, there were two regulations that were issued in response to the September 11th attacks that did not fall into any of these categories: a Department of Commerce rule which removed economic sanctions on certain countries, and a Department of Transportation/FAA rule on foreign carriers. Commerce lifted sanctions that had been imposed on certain nations. The INS was required to lower its immigration fees as mandated by the Homeland Security Act. The FAA revision addressed an administrative error that required airline changes for only certain types of domestic air carriers for all foreign carriers. This regulation clarified that requirements were the same for domestic and international carriers.

Summary

In response to the terrorist attacks of September 11, 2001, Congress and the Executive Branch have acted to minimize the risk of future terrorist acts and the potential impact of an attack. The regulatory amendments made since then seek to address vulnerabilities at our borders, security threats through transportation, food, and chemicals, and provide law enforcement with the tools needed to interdict and apprehend potential terrorists. Through the new Department of Homeland Security and future refinements to the government's regulatory scheme, the Executive Branch is enhancing domestic security through a coordination of efforts, a reduction of duplicative efforts, and a consolidation of resources.

B. Response to Public Comments on the Analysis of Homeland Security

OMB received 22 public comments that directly addressed terrorism and homeland security. This section summarizes comments regarding how agencies may tackle some of the difficult issues in this regulatory arena.

For economically significant rules, OMB guidelines require that agencies specify the need for the regulation, explain the market failure, or why private markets or other non-governmental activities cannot provide or would provide inadequately what the regulation would provide. Agencies must also specify and analyze a realistic set of regulatory and non-regulatory alternatives, and analyze the costs and benefits of each alternative relative to a baseline. In the context of homeland security regulations, benefit issues include estimating the impact of the terrorist activity that the regulation would prevent, and cost issues include a wide range of costs, including potential convenience and time loss and the impact on personal privacy. Throughout this discussion, we will draw on examples from the regulations in Table 17.

Applicability of Benefit-Cost and Cost-Effectiveness Tools

Most of the commenters (for example: 15, 16, 234, 252, 255, 256, 258, 270, 284, 292, 328) supported the use of benefit-cost (BCA) and cost-effectiveness analysis (CEA) to inform homeland security regulatory decisions. Two comments (251,333) did not support using these tools for homeland security and terrorism regulation.

OMB believes that it is critical that agencies consider and weigh the effectiveness of their regulatory actions against any costs, risks or burdens on the public. BCA and CEA represent the best regulatory analysis tools available to government, and their application to homeland security issues raises several challenging issues.

Market Failure and the Need for Regulation

Since the private sector continues to make very significant investments in areas that are also impacted by homeland security regulations, comment 307 recommends that agencies discuss the need for the regulation and why the private sector fails to provide what the regulation would

provide. There may be a classic market failure or other social purpose the regulation addresses (these other social purposes could include improving the functioning of government, removing distributional unfairness, and promoting privacy and personal freedom).

Market failures generally take three forms: externalities, market power concerns, and inadequate or asymmetric information. Appendix D contains a fuller discussion of market failure. All of these forms of market failure could be important in homeland security regulation, and many comments discussed the externalities inherent in security investment.

As an example where the private market does not have the incentive to correct an information problem, FDA recently issued a series of proposed rules (Table 17) designed to gather and centralize information on the food supply. FDA theorized that any one food supplier, although having a strong incentive to gather sufficient information to protect its own food products, did not have sufficient incentive in the private market to provide its information to a coordinating body that could track risks to the overall food supply.

Also, the uncertainty about low-probability, high-consequence events such as terrorism may lead market participants to predictably under react or overreact. Comments 12 and 14 stated that people may in practice fundamentally underestimate the impact from terrorism, since they may treat low probability events as if the true probability were zero.

Many different government programs are in place in part because a single private provider would yield considerable market power or because private markets would undersupply the desired output due to the fact that the outputs provide a significant "public good" that extends beyond the benefits that a purchaser would receive. National defense, police protection, and border security are examples of activities with a considerable public good component.

Many comments discussed the externalities inherent in private investments in security, and the general relationship between private security investments and different types of public security investment. Comments 12 and 258 point out that security investments will properly be public-private partnerships, and that companies have already made large investments in security. For example, comment 328 states that the petroleum industry has already taken significant security precautions, and doubtless many other facilities and institutions that consider themselves a risk have invested in security as well. Comment 270 suggested two potential external effects of this type of investment: the investment in security in one facility or system may motivate terrorists to choose "softer" or less protected targets; or conversely, an investment in security may protect other related facilities or systems.

Many comments expand on these arguments. For example, comment 12 argues that private actors may have a fundamental disincentive to make security investments when their security vulnerabilities depend on the actions of others. If security is this type of public good, firms would still be vulnerable to attacks due to a lack of security over which they have no control.

Comments 14, 15, 16, 270, 356 and others point out the "deflection of risk," or the ability of terrorists to observe security precautions and to simply choose the target that has made a

relatively smaller security investment. This suggests that "hardening" a particular target may not always lead to an overall risk reduction from society's perspective.

Comment 16 suggested that the government may want to discourage private and public security investments in a particular target that would simply cause terrorists to attack a less secure but equally valuable target. They recommended government intervention in the terrorism risk insurance market to alleviate the risk deflection problem. Theoretically, if insurers spread the risk of loss due to terrorism over many different targets, they have an incentive to encourage security investments that would not simply shift the risk of attack. Under the suggested approach, selective government intervention might be necessary to align society's risk to the insurer's risk pool.

Comment 15 suggested that regulations that create a barrier of entry to any potential terrorist (for example, visa and passport controls) may be especially effective since they do not suffer from the problem of risk deflection within the United States.

Comment 270 and others recommend game-theoretic models to study the incentives that exist for different parties to provide security. For example, agencies should study where risk and centralized control do not coincide, and coordination may be difficult to arrange in a competitive business environment. For example, computer network users seldom have the choice of how much security they employ on their own terminal; in this case, the person in charge of the overall network seems to have both the proper incentives and the power to maximize security on that network. Airport security may be more problematic to coordinate, since an efficient response may require airlines to coordinate certain activities, such as security in baggage transfer.

With regard to risk deflection, the structure of the market may be very important in determining the total security investment by each potential target. For example, Sandler[56] identifies a possible "arms race" scenario involving countries or firms making decisions on the level of their security investment. Every actor in a market has an incentive to be just slightly more secure than other targets, and that incentive does not change regardless of the overall level of security investment. Thus, every possible target may ratchet up their security response. If companies, however, do not have information on the security precautions other targets are taking (for example, ports can look at other ports and judge their security, but literally thousands of buildings may be potential targets), they would not have a benchmark of security that they could go just beyond in order to deflect their risk. They presumably would fall back to damage limitation measures and some absolute assessment of their vulnerability. Finally, as the number of "competitors" decreases to a certain level, they may be better able to coordinate a security response through a credible incentive structure without centralized intervention.

This suggests many possible effects, depending on the structure of the market. In a highly disbursed market or in a market where information on security investment is not readily observable, the incentive to over-invest in security seems blunted. As the number of potential targets decreases and the visibility increases of a potential target set, the deflection strategy will look attractive to all market participants simultaneously, leading to a level of investment that may or may not be socially optimal. In other words, the risk reduction may still have external

[56] Sandler T (2003), "Collective Action and Transnational Terrorism," *World Economy,* 26:6, 779-802.

effects not taken into account in the security "arms race." As the number drops further, the possibility of "coordinating" a security response increases, but that coordinated response may not be socially optimal.

Estimating Benefits

A valid prediction of the timing and intensity of a future terrorist attack would be as useful as it is elusive. Professional counter-terrorism experts have always found it difficult to predict with any degree of certainty the probability of a terrorist attack. Comment 284 and several others mention that the probability of an attack on any one target is very low and uncertain, which makes prediction and risk differentiation especially difficult. Comments 15 and 260 mention, however, that probabilistic risk assessment models exist for general terrorism risk and for the risk of attack and damages to specific industrial sectors, and that agencies could avail themselves of these tools. A significant complicating factor here is that terrorists are not "fixed targets", but they can react and respond to the security and other counterterrorism measures that the government and private sector adopt. This increases the difficulty in estimating the likely benefits from a particular regulatory action.

Two comments (255, 256) discussed what they considered was a fundamental misunderstanding of potentially vulnerable targets: ecosystems. They characterize ecosystems as less symbolic than more traditional terrorist targets, but attacks against them could be just as devastating—through psychological, economic and other types of harm—and they are also much harder to protect. Since December 2002, USDA has proposed one rule and FDA has proposed four rules designed to mitigate the impact of a terrorist attack on the food supply (Table 17).

One of the possible impacts of terrorism is an economic shock or slowdown, and researchers have explored these potential "third-party" costs of terrorism. For example, Abadie and Gardeazabal[57] use a natural-experiment approach to demonstrate that the Basque region suffers in economic performance relative to other areas of Spain due to ongoing separatist terrorist activity. These are legitimate costs to be considered in any measurement of the impact of terrorism and the benefits of counterterrorism programs.

Estimating Costs

Homeland Security regulations will impose costs, like other types of regulatory activity. Some of these costs will be relatively straightforward to estimate, such as the need for business to invest in new information systems or hire additional security guards. Yet other major costs of interventions to combat terrorism may be fundamentally more difficult to identify and estimate. These costs broadly fall under the following categories: loss of convenience and time, diminished privacy, and curtailment of civil rights and liberties. Many comments (14, 234, 251, 252, 259, 261, 270, 333, 356 and others) discuss these issues in detail.

1. Time and Convenience

[57] Abadie A and Gardeazabal J (2003), "The Economic Costs of Conflict: A Case Study of the Basque Country." *American Economic Review,* 93(1), 113-132.

Of these possible costs, time and convenience costs have been estimated in other regulatory activity. For example, DOT[58] issued guidance to assist analysts in developing consistent evaluations of actions that save or cost travel time, in which they recommend valuing travel and waiting time using specific percentages of representative wage rates. Losses in time and convenience, however, are difficult to aggregate if a regulatory intervention results in a small time or convenience loss to a large number of people. Comment 292 suggests that standard stated-preference methods should be able to measure convenience valuations.

2. Privacy and Civil Rights and Liberties

As a number of public commenters pointed out, a cost that needs to be identified and considered in developing and evaluating homeland security regulations is the potential impact that the regulation (or regulatory alternative) would have on the privacy, rights and liberties that persons enjoy in this country.

As the public comments also indicated, one aspect of this consideration will involve a legal review. Federal agencies must operate within the legal authorities and legal restrictions that govern their activities, and this governing legal framework is provided by the Constitution and the statutes that Congress has enacted. Thus, in course of its promulgation of any regulation, a Federal agency must conduct a legal review to determine that the agency has the legal authority to issue the regulation in question and that the agency is complying with applicable legal restrictions (both substantive and procedural).

A number of commenters offered their views concerning the nature of the privacy interests, rights and liberties to which persons are legally entitled under the Constitution and Federal statutes. In this regard, a number of commenters expressed their concerns regarding the impact that homeland security regulations have (or could have) on these legal rights and protections. It is not within the scope of this chapter to evaluate the merits of these various perspectives, or to offer OMB's legal analysis or position on the points that the commenters have raised, or to attempt to define or describe the contours of personal privacy interests, rights and liberties. However, we fully agree with the general thrust of these comments, which is the importance of Federal agencies ensuring that homeland security regulations have sound legal authority, comply with constitutional and statutory restrictions, and respect the legally-protected privacy interests, rights and liberties of persons.

A legal analysis that determines that the agency is acting within its legal authority and is respecting legal protections, however, does not conclude the identification and consideration of the costs associated with a homeland security regulation. The fact that a regulation under consideration would be lawful does not mean that the regulation would impose no costs. It is the identification and consideration of the costs that would be imposed by legally-authorized regulations that constitutes the lion's share of regulatory analyses that agencies conduct.[59]

---

[58] Department of Transportation Memorandum from Frank Kruesi to Secretarial Officers and Modal Administrators, 1997. "Departmental Guidance for the Valuation of Travel Time in Economic Analysis." Available at http://ostpxweb.dot.gov.

[59] Agencies under Executive Order 12866 are also directed to evaluate the benefits and costs of regulatory options that are precluded by the governing regulatory statute. Although agencies in such situations may not rely on such

Thus, in the context of homeland security regulations, the legal conclusion that a regulatory alternative under consideration would not violate a constitutional or statutory protection does not mean that the regulatory alternative would impose no costs with respect to persons' privacy interests, rights, or liberties. For example, as the courts have held, requiring individuals in airports and Federal buildings to go through metal detectors, and to have their packages go through x-ray machines, does not violate their Fourth Amendment right against unreasonable searches and seizures. The fact that these metal detector and x-ray inspections are lawful, however, does not mean that these inspections impose no cost in terms of diminished personal privacy. These inspections do diminish personal privacy, and this is indeed a cost of the inspection requirement. The question for the regulatory agency is whether the benefits from these inspections justify their costs, in terms of diminished privacy as well as lost time and convenience.

Metal detector and x-ray inspections are but one example of the types of lawful costs that can be imposed by homeland security regulations, and therefore that regulatory agencies need to identify and consider along with the anticipated benefits from the regulation. Admittedly, it may be difficult for a regulatory agency to evaluate in specific instances the extent of the costs that a regulatory alternative would likely impose. In emergency situations, for example, an agency may not have much time to consider the various alternatives, much less the time to perform a full evaluation of their respective benefits and costs, before the agency must decide on a course of action. In such cases, agencies should conduct as much analysis as the situation permits. In addition, as commenters pointed out, it may be difficult for an agency to express the cost in quantifiable, as opposed to qualitative, terms. However, to the extent that an agency can quantify the regulatory impact, the agency should attempt to do so (e.g., by indicating the number of persons that would likely be affected by the regulation). This additional analysis is helpful in providing as complete a picture as possible of the implications and justification for the proposed regulatory approach.

Summary

Developing Federal regulations involves a series of steps: identifying the nature and extent of the problem; determining whether Federal action is needed or desirable; if it is determined that Federal action is needed or desirable, identifying the relevant legal authorities and the policy options; then evaluating those options based on their "pros" and "cons," which includes an identification and consideration of the anticipated benefits and costs associated with each option; and, finally, concluding with a decision on which course of action to pursue.

Homeland security regulations raise new issues and pose new challenges for Federal agencies. However, the same general framework should apply to the development of homeland security regulations as agencies have applied over the years in their development of other types of regulations. Federal agencies that address homeland security matters need to go through the same general steps in deciding whether Federal action is needed and desirable and, if so, in determining what course of action to pursue. In this regard, these agencies can and should, to the

---

analysis in making their regulatory decisions, this information can be useful to Legislative and Executive Branch decisionmakers in their evaluation of legislative options.

extent possible, use the standard tools of regulatory analysis that have been developed over the years to inform decision makers about the anticipated benefits and costs of the various policy options that they are considering.

In this chapter, we have discussed several of the issues and challenges that Federal agencies confront in their development and analysis of homeland security regulations. These and other issues are discussed in the many public comments that we received on this matter; we appreciate the thought and care that the commenters devoted in responding to our request for public comments. We expect that the issues that have been raised in the comments and in this Chapter will be the subject of continuing inquiry and discussion as Federal agencies, the Congress, and the public gain further experience with the promulgation of homeland security regulations.

APPENDIX A: CALCULATION OF BENEFITS AND COSTS (10/92 – 3/95, 10/01 – 9/02)

Chapter I presents estimates of the annual costs and benefits of selected final major regulations reviewed by OMB between October 1, 1992 and September 30, 2002. OMB presents more detailed explanation of these regulations in several documents. The explanation of the calculations for the major rules reviewed by OMB between April 1, 1995 and March 31, 1999 can be found in Chapter IV of our 2000 report (OMB 2000). Table 19, Appendix E, of the 2002 Report presents OMB's estimates of the benefits and costs of the 20 individual rules reviewed between April 1, 1999 and September 30, 2001. Tables 18 and 19 in this appendix present the results for the remaining intervals of the 10-year time period used in this report: October 1, 1992 to March 31, 1995 (Table 18), and October 1, 2001 to September 30, 2002 (Table 19). All benefit and cost estimates were adjusted to 2001 dollars.

In assembling estimates of benefits and costs, OMB has:

(1) applied a uniform format for the presentation of benefit and cost estimates in order to make agency estimates more closely comparable with each other (for example, annualizing benefit and cost estimates); and
(2) monetized quantitative estimates where the agency has not done so (for example, converting Agency projections of quantified benefits, such as, estimated injuries avoided per year or tons of pollutant reductions per year to dollars using the valuation estimates discussed below).

The adoption of a uniform format for annualizing agency estimates allows, at least for purposes of illustration, the aggregation of benefit and cost estimates across rules. While OMB has attempted to be faithful to the respective agency approaches, the reader should be cautioned that agencies have used different methodologies and valuations in quantifying and monetizing effects. Thus, this aggregation involves the assemblage of benefit and cost estimates that are not strictly comparable.

Table 18. Estimate of Annual Benefits and Costs of 47 Major Rules
October 1, 1992 to March 31, 1995
(millions of 2001 dollars per year)

REGULATION	AGENCY	BENEFITS	COSTS	EXPLANATION
Nutrition Labeling of Meat and Poultry Products	USDA – FSIS	205	25-32	We amortized the agency's present value estimates over 20 years.
Food Labeling (combined analysis of 23 individual rules)	HHS – FDA	438-2,637	159-249	We amortized the agency's present value estimates over 20 years.
Real Estate Settlement Procedures	HUD	258-332	135	
Manufactured Housing Wind Standards	HUD	103	63	

Table 18. Estimate of Annual Benefits and Costs of 47 Major Rules
October 1, 1992 to March 31, 1995
(millions of 2001 dollars per year)

REGULATION	AGENCY	BENEFITS	COSTS	EXPLANATION
Confined Spaces	DOL-OSHA	540	250	We valued each fatality at $5 million and each lost-workday injury at $50,000. We did not value non-lost-workday injuries.
Occupational Exposure to Asbestos	DOL-OSHA	92	448	We assumed a 20-year latency period between exposure and the onset of cancer or asbestosis and valued each death and each case of asbestosis at $5 million.
Vessel Response Plans	DOT- Coast Guard	9	295	We amortized the agency's present value estimates over 30 years. We valued each barrel of oil not spilled at $2,000.
Double-Hull Standards	DOT- Coast Guard	17	583	We amortized the agency's present value estimates over 30 years. We valued each barrel of oil not spilled at $2,000.
Controlled Substances and Alcohol Use and Testing	DOT – FHWA	1,539	114	
Prevention of Prohibited Drug Use in Transit Operations	DOT	107	37	We amortized the agency's present value estimates over 10 years.
Stability Control of Medium and Heavy Vehicles During Braking	DOT-NHTSA	1,650-2,539	694	We valued each "equivalent fatality" at $3 million.
Oil and Gas Extraction	EPA	35-129	35	We amortized the agency's first-year costs over 15 years and added these to annual (15^{th} year) costs.
Acid Rain Permits Regulations	EPA	78,454-78,806	1,109-1,871	We valued SO_2 reductions at $7,800 per ton.
Vehicle Inspection and Maintenance (I/M)	EPA	247-1,120	671	We used the estimates of cost and emission reductions of the new I/M program compared to the baseline of no I/M program. We valued VOC reductions at $600-$2,700 per ton. We did not assign a value to CO reductions.

Table 18. Estimate of Annual Benefits and Costs of 47 Major Rules
October 1, 1992 to March 31, 1995
(millions of 2001 dollars per year)

REGULATION	AGENCY	BENEFITS	COSTS	EXPLANATION
Evaporative Emissions from Light-Duty Vehicles, Light-Duty Trucks, and Heavy-Duty Vehicles.	EPA	274-1,246	161-248	We assumed the VOC emission reductions began in 1995 and rise linearly until 2020, after which point they remain at the 2020 level. Annualizing this stream results in an average of 468,000 tons per year. We valued these tons at $600-$2,700 per ton.
Onboard Diagnostic Systems	EPA	702-3,423	226	We amortized the agency's emission reduction and cost estimates over 15 years. We valued VOC reductions at $600-$2,700 per ton and NO_x reductions at $1,100-$5,500 per ton.
Phase II Land Disposal Restrictions	EPA	26	240-272	We valued each cancer case at $5 million.
Phase-out of Ozone-Depleting Chemicals and Listing of Methyl Bromide	EPA	1,260-3,993	1,681	We amortized the agency's present value estimates over 16 years.
Reformulated Gasoline	EPA	213-723	1,085-1,395	Estimates are for Phase II, which include Phase I benefits and costs. We used the benefit estimates that assume the enhanced I/M program is in place. We valued VOC reductions at $600-$2,700 per ton and NO_x reductions at $1,100-$5,500 per ton. We valued each cancer case at $5 million. We assumed the phase II aggregate costs are an additional 25 percent of the Phase I costs based on EPA's reported per-gallon cost estimates.
Acid Rain NO_x Title IV CAAA	EPA	1,005-5,347	372	Values are for Phase II. We valued NO_x reductions at $1,100 - $5,500 per ton.
Hazardous Organic NESHAP	EPA	600-2,700	292-333	We valued VOC emissions at $600-$2700 per ton and NO_x emissions (which are a cost in this instance) at $550 - $2,800 per ton. We did not value changes in CO emissions.

Table 18. Estimate of Annual Benefits and Costs of 47 Major Rules October 1, 1992 to March 31, 1995 (millions of 2001 dollars per year)				
REGULATION	**AGENCY**	**BENEFITS**	**COSTS**	**EXPLANATION**
Refueling Emissions from Light-Duty Vehicles	EPA	167-760	33	We assumed Stage II controls will remain in place and valued VOC emissions at $600-$2700 per ton.
Non-Road Compression Ignition Engines	EPA	617-3,253	29-70	We annualized the NO_x emissions which yielded an average annual emission reduction of 588,000 tons beginning in 2000. We valued NO_x emissions at $1,100-$5,500 per ton.
Bay/Delta Water Quality Standards	EPA	2-26	37-248	
Deposit Control Gasoline	EPA	420-1,670	197	We valued estimates of combined emission reductions at $600-$2,700 per ton. We amortized the agency's present value cost estimates over 5 years.
Total		**88,981-111,342**	**8,975-10,553**	

Table 19. Estimate of Annual Benefits and Costs of 3 Major Rules October 1, 2001 to September 30, 2002 (millions of 2001 dollars per year)				
REGULATION	**AGENCY**	**BENEFITS**	**COSTS**	**EXPLANATION**
Energy Conservation Standards for Central Air Conditioners and Heat Pumps	DOE	710	636	We amortized the agency's present value estimates over 24 years. We valued NOx emission reductions at $550 - $2,800 per ton.
Tire Pressure Monitoring Systems (TPMS)	DOT	409-944	749-1,206	We valued each equivalent fatality (see p. iv of the Executive Summary of the Final Economic Assessment) at $3 million.

Table 19. Estimate of Annual Benefits and Costs of 3 Major Rules October 1, 2001 to September 30, 2002 (millions of 2001 dollars per year)				
REGULATION	**AGENCY**	**BENEFITS**	**COSTS**	**EXPLANATION**
Control of Emissions From Nonroad Large Spark-Ignition Engines, and Recreational Engines	EPA	1,250-4,818	192	We amortized the benefit estimates in proportion to the estimated NOx emission reductions. The lower end of the range reflects the alternative approach to valuing benefits of EPA rules discussed elsewhere.
Total		**2,032- 6,472**	**1,577-2,034**	

Assumptions: 7 percent discount rate unless another rate explicitly identified by the agency. For DOL: $5 million VSL assumed for deaths averted when not already quantified. Injuries averted valued at $50,000 from Viscusi.[60] All values converted to 2001 dollars. All costs and benefits stated on a yearly basis.

A. Valuation Estimates for Regulatory Consequences[61]

Agencies continue to take different approaches to monetizing benefits for rules that affect small risks of premature death. As a general matter, we continue to defer to the individual agencies' judgment in this area. Except where noted, in cases where the agency both quantified and monetized fatality risks we have made no adjustments to the agency's estimate. In cases where the agency provided a quantified estimate of fatality risk, but did not monetize it, we have monetized these estimates in order to convert these effects into a common unit.

The following is a brief discussion of OMB's valuation estimates for other types of effects that agencies identified and quantified, but did not monetize. As a practical matter, the aggregate benefit and cost estimates are relatively insensitive to the values we have assigned for these rules because the aggregate benefit estimates are dominated by those rules where EPA provided quantified and monetized benefit and cost estimates.

For NHTSA's rules, we adopted NHTSA's approach of converting nonfatal injuries to "equivalent fatalities." These ratios are based on NHTSA's estimates of the value individuals place on reducing the risk of injury of varying severity relative to that of reducing risk of death.[62] For the OSHA rules, we monetized only lost workday injuries using a value of $50,000 per injury averted.

1. Change in Gasoline Fuel Consumption. We valued reduced gasoline consumption at $0.80 per gallon pre-tax. This equates to retail (at-the-pump) prices in the $1.10 - $1.30 per gallon range.

[60] Viscusi WK (1992), *Fatal Tradeoffs: Public & Private Responsibilities for Risk*, Oxford University Press, New York, p. 65.

[61] The following discussion updates the monetization approach used in previous reports and draws on examples from this and previous years.

[62] National Highway Traffic Safety Administration (1994), *The Economic Cost of Motor Vehicle Crashes*, Table A-1. http://www.nhtsa.dot.gov/people/economic/ecomvc1994.html

2. Reduction in Barrels of Crude Oil Spilled. OMB valued each barrel prevented from being spilled at $2,000. This is double the sum of the most likely estimates of environmental damages plus cleanup costs contained in a published journal article (Brown and Savage, "The Economics of Double-Hulled Tankers," *Maritime Policy and Management*, Volume 23(2), 1996, pages 167-175.)
3. Change in Emissions of Air Pollutants. We used estimates of the benefits per ton for reductions in hydrocarbon and nitrogen oxide emissions derived from recent EPA regulatory analyses, as follows (2001$):

Hydrocarbon:	$600 and $2,700 per ton
Nitrogen Oxide (stationary):	$550 and $2,800 per ton
Nitrogen Oxide (mobile):	$1,100 and $5,500 per ton
Sulfur Dioxide:	$7,800 per ton

The estimates for reductions in hydrocarbon emissions were obtained from EPA's RIA for the 1997 rule revising the primary NAAQS for ozone and fine PM. OMB has revised the estimates for reductions in NO_x emissions to reflect a range of estimates from recent EPA analyses for several rules and for proposed legislation. In particular, OMB has adopted different benefit transfer estimates for NO_x reductions from stationary sources (e.g., electric utilities) and from mobile sources. EPA believes that there are a number of reasons to expect that reductions in NO_x emissions from utility sources achieve different air quality improvements relative to reductions from ground-level mobile sources. For example, mobile source tailpipe emissions are located in urban areas at ground level (with limited dispersal) while electric utilities emit NO_x from "tall stacks" located in rural (remote) locations with substantial geographic dispersal (Letter to Don Arbuckle, Deputy Administrator, OIRA from Tom Gibson, Associate Administrator, Office of Policy, Economics and Innovation, EPA, May 16, 2002.) There remain considerable uncertainties with the development of these estimates. The discussion below outlines the various EPA analyses serving as the basis for the NO_x benefit transfer values presented above and discusses the uncertainties that attend these estimates.

Analysis of recent EPA rules yield several estimates for the NO_x benefits per ton from electric utility sources. (See the Regulatory Impact Analyses for the "NO_x SIP Call" and the Section 126 rules, available on the web at http://www.epa.gov/ttn/ecas/econguid.html. In addition, see Memo to NSR Docket from Bryan Hubbell, Senior Economist, Innovative Strategies and Economics Group, EPA.) Based on these studies, the upper end of the range for the benefits of NO_x reductions from stationary sources (electric utilities) is $2,800 per ton. These studies also developed estimates for the benefits associated with reductions in SO_2 from electric utilities. Based on an analysis outlined in a June 20, 2001 EPA memo to the file, "Benefits Associated with Electricity Generating Emissions Reductions Realized Under the NSR Program," we used $7,800 per ton SO_2 emissions for the 1992 EPA Acid Rain rule.

For mobile sources, EPA recently published the final Tier 2/Gasoline Sulfur rule RIA (EPA, 1999) and Heavy Duty Engine/Diesel Fuel RIA (EPA, 2000). For the Tier 2 rule, which affects light-duty vehicles, NO_x reductions account for around 90 percent of PM precursor emissions and 86 percent of ozone precursor emissions. Based on the final Tier 2/Gasoline Sulfur RIA, EPA estimates that NO_x reductions will yield benefits of $5,500/ton (2001$). EPA

believes this analysis provides a more appropriate source for the NO_x benefit transfer value for mobile sources. (Letter from Tom Gibson, pp. B2 and B3, May 16, 2002.) Additional details on the Tier 2 benefits analysis are available in the Tier 2/Sulfur Final Rulemaking RIA, available on the web at http://www.epa.gov/oms/fuels.htm.

The Heavy Duty Engine/Diesel Fuel benefits analysis examined the impacts in 2030 of reducing SO_2 emissions by 141,000 tons and NO_x emissions by 2,750 thousand tons, as well as a 109,000 ton reduction in direct PM emissions. Based on this analysis, EPA estimates a value for NO_x reductions of $10,200/ton in 2030. (Letter from Tom Gibson, p.B3, May 16, 2002.) Complete details of the emissions, air quality, and benefits modeling conducted for the HD Engine/Diesel Fuel Rule can be found at http://www.epa.gov/otaq/diesel.htm and http://www.epa.gov/ttn/ecas/regdata/tsdhddv8.pdf. Because the Heavy Duty Engine/Diesel Fuel estimate includes an adjustment for income growth out to 2030 and involves reductions in several PM-related pollutants, OMB has adopted a value of $5,500 per ton from EPA's analysis of the Tier 2 rule as a benefits transfer value for reductions in NO_x emissions from mobile sources.

Reductions in the risk of premature mortality dominate the benefits estimates in all of these analyses. The size of the mortality risk estimates from the underlying epidemiological studies, the serious nature of the effect itself, and the high monetary value ascribed to prolonging life make mortality risk reduction the most important health endpoint quantified in these analyses.[63] Because of the importance of this endpoint and the considerable uncertainty among economists and policymakers as to the appropriate way to value reductions in mortality risks, EPA has developed alternative estimates for its "Clear Skies" legislation that show the potential importance of some of the underlying assumptions. (See "Human Health and Environmental Benefit Achieved by the Clear Skies Initiative" at http://www.epa.gov/clearskies.) OMB has used this analysis to identify an alternative estimate of the benefits from NO_x reductions. In its Clear Skies analysis, EPA presented alternative benefits estimates of $24 billion and $113 billion per year in 2020, or a difference in the estimates of roughly a factor of five.[64] Using this ratio, an alternative estimate of the benefits of NO_x reductions from stationary sources would be $550 per ton from stationary sources and $1,100 per ton from mobile sources.

---

[63] There are several key assumptions underlying the benefit estimates for reductions in NO_x emissions, including:

1. Inhalation of fine particles is causally associated with premature death at concentrations near those experienced by most Americans on a daily basis. While no definitive studies have yet established any of several potential biological mechanisms for such effects, the weight of the available epidemiological evidence supports an assumption of causality.
2. All fine particles, regardless of their chemical composition, are equally potent in causing premature mortality. This is an important assumption, because fine particles from power plant emissions are chemically different from directly emitted fine particles from both mobile sources and other industrial facilities, but no clear scientific grounds exist for supporting differential effects estimates by particle type.
3. The concentration-response function for fine particles is approximately linear within the range of outdoor concentrations under policy consideration. Thus, the estimates include health benefits from reducing fine particles in both attainment and non-attainment regions.
4. The forecasts for future emissions and associated air quality modeling are valid.
5. The valuation of the estimated reduction in mortality risk is largely taken from studies of wage premiums for hazardous jobs.

[64] The difference between the estimates reflects several assumptions, including differences in the estimation and valuation of mortality risk and the valuation of a reduction in the incidence of chronic bronchitis.

OMB recognizes that there are potential problems and significant uncertainties that are inherent in any benefits analysis based on $/ton benefit transfer techniques. The extent of these problems and the degree of uncertainty depends on the divergence between the policy situation being studied and the basic scenario providing the benefits transfer estimate. Examples of other factors include sources of emissions, meteorology, transport of emissions, initial pollutant concentrations, population density, and baseline incidence rates for health effects. Because of the uncertainties associated with benefits transfer, OMB decided not to include three mobile source rules that are projected to achieve substantial reductions in SO_2 and PM emissions that OMB included in previous years in the monetized estimates presented in Tables 5 and 6 of the 2002 Report.[65]

B. Adjustment for Differences in Time Frame across These Analyses

Agency estimates of benefits and costs cover widely varying time periods. The differences in the time frames used for the various rules evaluated generally reflect the specific characteristics of individual rules, such as expected capital depreciation periods or time to full realization of benefits. In order to allow us to provide an aggregate estimate of benefits and costs, we developed benefit and cost time streams for each of the rules. Where agency analyses provide annual or annualized estimates of benefits and costs, we used these estimates in developing streams of benefits and costs over time. Where the agency estimate provided only annual benefits and costs for specific years, we used a linear interpolation to represent benefits and costs in the intervening years.[66]

C. Further Caveats

In order for comparisons or aggregation to be meaningful, benefit and cost estimates should correctly account for all substantial effects of regulatory actions, including potentially offsetting effects, which may or may not be reflected in the available data. OMB has not made any changes to agency monetized estimates. To the extent that agencies have adopted different monetized values for effects—for example, different values for a statistical life or different discounting methods—these differences remain embedded in the tables. Any comparison or aggregation across rules should also consider a number of factors which our presentation does not address. For example, these analyses may adopt different baselines in terms of the regulations and controls already in place. In addition, the analyses for these rules may well treat uncertainty in different ways. In some cases, agencies may have developed alternative estimates reflecting upper- and lower-bound estimates. In other cases, the agencies may offer a midpoint estimate of benefits and costs. In still other cases the agency estimates may reflect only upper-bound estimates of the likely benefits and costs. While OMB has relied in many instances on agency practices in monetizing costs and benefits, citation of, or reliance on, agency data in this

[65] These are: Municipal Waste Combustors (1995), Emission Standards for New Locomotives (1997), and Emission Standards for Non-Road Diesel Engines (1998).

[66] In other words, if costs were $200 million in 2000 and $400 million in 2020, OMB would assume costs would be $250 million in 2005, $300 million in 2010, and so forth. For example, for the Regional Haze rule, EPA provided only an estimate of benefits and costs in 2015. To develop benefit and cost streams, OMB used a linear extrapolation of benefits and costs beginning in 2009 and scaling up to the reported 2015 estimates

report should not be taken as an OMB endorsement of all the varied methodologies used to derive benefits and cost estimates.

APPENDIX B: AGENCY ESTIMATES OF BENEFITS AND COSTS (10/92 – 3/95)

Chapter 1 in this report now includes quantified benefits and costs of major rules issued from October 1, 1992 to March 31, 1995. As in Chapter 1, Table 4, the tables in this Appendix present unmodified details on all major rules from this time period: Table 20 covers October, 1992 to September, 1993; Table 21 covers October, 1993 to September, 1994; and Table 22 covers October, 1994 to March 1995.

Table 20. Agency Estimates of Benefits and Costs of Major Rules
October 1, 1992 to September 30, 1993

RULE	AGENCY	BENEFITS	COSTS	OTHER INFORMATION
Nutrition labeling of meat and poultry products	USDA-FSIS	$1.75 billion (NPV)	$218-272 million (NPV)	NPV of benefits and costs discounted over 20 years at 7%
Food Labeling: Use of Nutrient Content Claims for Butter	HHS-FDA	$4.4-$26.5 billion	$1.4-$2.3 billion plus $163 million in costs to Federal government	HHS-FDA performed one analysis for the food labeling requirements imposed by this rule and the other 22 HHS-FDA rules in this table related to food labeling.
Food Labeling: Declaration of Ingredients	HHS-FDA	$4.4-$26.5 billion	$1.4-$2.3 billion plus $163 million in costs to Federal government	HHS-FDA performed one analysis for the food labeling requirements imposed by this rule and the other 22 HHS-FDA rules in this table related to food labeling.
Food Labeling, Declaration of Ingredients: Common or Usual Name Declaration for Protein Hydrolysates and Vegetable Broth in Canned Tuna "and/Or" Labeling for Soft Drinks	HHS-FDA	$4.4-$26.5 billion	$1.4-$2.3 billion plus $163 million in costs to Federal government	HHS-FDA performed one analysis for the food labeling requirements imposed by this rule and the other 22 HHS-FDA rules in this table related to food labeling.
Food Labeling: Declaration of Ingredients for Dairy Products and Maple Syrup	HHS-FDA	$4.4-$26.5 billion	$1.4-$2.3 billion plus $163 million in costs to Federal government	HHS-FDA performed one analysis for the food labeling requirements imposed by this rule and the other 22 HHS-FDA rules in this table related to food labeling.
Food Labeling: Nutrient Content Claims, Definition of Term	HHS-FDA	$4.4-$26.5 billion	$1.4-$2.3 billion plus $163 million in costs to Federal	HHS-FDA performed one analysis for the food labeling requirements imposed by this rule and the other 22 HHS-FDA rules in this table related to food labeling.

Table 20. Agency Estimates of Benefits and Costs of Major Rules October 1, 1992 to September 30, 1993				
RULE	**AGENCY**	**BENEFITS**	**COSTS**	**OTHER INFORMATION**
Healthy			government	
Food Labeling: Label Statements on Foods for Special Dietary Use	HHS-FDA	$4.4-$26.5 billion	$1.4-$2.3 billion plus $163 million in costs to Federal government	HHS-FDA performed one analysis for the food labeling requirements imposed by this rule and the other 22 HHS-FDA rules in this table related to food labeling.
Food Labeling: Health Claims, Zinc and Immune Function in the Elderly	HHS-FDA	$4.4-$26.5 billion	$1.4-$2.3 billion plus $163 million in costs to Federal government	HHS-FDA performed one analysis for the food labeling requirements imposed by this rule and the other 22 HHS-FDA rules in this table related to food labeling.
Food Labeling, Reference Daily Intakes and Daily Reference Values (Decision)	HHS-FDA	$4.4-$26.5 billion	$1.4-$2.3 billion plus $163 million in costs to Federal government	HHS-FDA performed one analysis for the food labeling requirements imposed by this rule and the other 22 HHS-FDA rules in this table related to food labeling.
Food Labeling: Health Claims and Label Statements, Sodium and Hypertension	HHS-FDA	$4.4-$26.5 billion	$1.4-$2.3 billion plus $163 million in costs to Federal government	HHS-FDA performed one analysis for the food labeling requirements imposed by this rule and the other 22 HHS-FDA rules in this table related to food labeling.
Food Labeling: Health Claims and Label Statements: Omega-3 Fatty Acids and Coronary Heart Disease	HHS-FDA	$4.4-$26.5 billion	$1.4-$2.3 billion plus $163 million in costs to Federal government	HHS-FDA performed one analysis for the food labeling requirements imposed by this rule and the other 22 HHS-FDA rules in this table related to food labeling.
Food Labeling: Health Claims and Label Statements, Dietary Fat and Cancer	HHS-FDA	$4.4-$26.5 billion	$1.4-$2.3 billion plus $163 million in costs to Federal government	HHS-FDA performed one analysis for the food labeling requirements imposed by this rule and the other 22 HHS-FDA rules in this table related to food labeling.
Food Labeling: Health Claims, Calcium and Osteoporosis	HHS-FDA	$4.4-$26.5 billion	$1.4-$2.3 billion plus $163 million in costs to Federal government	HHS-FDA performed one analysis for the food labeling requirements imposed by this rule and the other 22 HHS-FDA rules in this table related to food labeling.
Food Labeling: Health Claims and Label Statement, Antioxidant Vitamins and Cancer	HHS-FDA	$4.4-$26.5 billion	$1.4-$2.3 billion plus $163 million in costs to Federal government	HHS-FDA performed one analysis for the food labeling requirements imposed by this rule and the other 22 HHS-FDA rules in this table related to food labeling.

Table 20. Agency Estimates of Benefits and Costs of Major Rules October 1, 1992 to September 30, 1993				
RULE	**AGENCY**	**BENEFITS**	**COSTS**	**OTHER INFORMATION**
Food Labeling: Health Claims and Label Statements, Dietary Saturated Fat and Cholesterol and Coronary Heart Disease	HHS-FDA	$4.4-$26.5 billion	$1.4-$2.3 billion plus $163 million in costs to Federal government	HHS-FDA performed one analysis for the food labeling requirements imposed by this rule and the other 22 HHS-FDA rules in this table related to food labeling.
Regulation Impact Analysis of the Final Rules to Amend the Food Labeling Regulations	HHS-FDA	$4.4-$26.5 billion	$1.4-$2.3 billion plus $163 million in costs to Federal government	HHS-FDA performed one analysis for the food labeling requirements imposed by this rule and the other 22 HHS-FDA rules in this table related to food labeling.
Food Labeling: Health Claims and Label Statements, Folic Acid and Neural Tube Defects	HHS-FDA	$4.4-$26.5 billion	$1.4-$2.3 billion plus $163 million in costs to Federal government	HHS-FDA performed one analysis for the food labeling requirements imposed by this rule and the other 22 HHS-FDA rules in this table related to food labeling.
Food Labeling: Health Claims and Label Statements, Dietary Fiber and Cardiovascular Disease	HHS-FDA	$4.4-$26.5 billion	$1.4-$2.3 billion plus $163 million in costs to Federal government	HHS-FDA performed one analysis for the food labeling requirements imposed by this rule and the other 22 HHS-FDA rules in this table related to food labeling.
Food Labeling: Health Claims and Label Statements, Dietary Fiber and Cancer	HHS-FDA	$4.4-$26.5 billion	$1.4-$2.3 billion plus $163 million in costs to Federal government	HHS-FDA performed one analysis for the food labeling requirements imposed by this rule and the other 22 HHS-FDA rules in this table related to food labeling.
Food Labeling, General Requirements for Health Claims for Food	HHS-FDA	$4.4-$26.5 billion	$1.4-$2.3 billion plus $163 million in costs to Federal government	HHS-FDA performed one analysis for the food labeling requirements imposed by this rule and the other 22 HHS-FDA rules in this table related to food labeling.
Food Labeling, Mandatory Status of Nutrition Labeling and Nutrient Content Revision, Form for Nutrition Label	HHS-FDA	$4.4-$26.5 billion	$1.4-$2.3 billion plus $163 million in costs to Federal government	HHS-FDA performed one analysis for the food labeling requirements imposed by this rule and the other 22 HHS-FDA rules in this table related to food labeling.

Table 20. Agency Estimates of Benefits and Costs of Major Rules October 1, 1992 to September 30, 1993				
RULE	**AGENCY**	**BENEFITS**	**COSTS**	**OTHER INFORMATION**
Food Labeling, Nutrient Content Claims, General Principles, Petitions, Definition of Terms, Definitions of Nutrient Content Claims for the Fat, Fatty Acid, and Cholesterol	HHS-FDA	$4.4-$26.5 billion	$1.4-$2.3 billion plus $163 million in costs to Federal government	HHS-FDA performed one analysis for the food labeling requirements imposed by this rule and the other 22 HHS-FDA rules in this table related to food labeling.
Food Labeling Regulation Implementing the Nutrition Labeling and Education Act of 1990, Opportunity for Comments	HHS-FDA	$4.4-$26.5 billion	$1.4-$2.3 billion plus $163 million in costs to Federal government	HHS-FDA performed one analysis for the food labeling requirements imposed by this rule and the other 22 HHS-FDA rules in this table related to food labeling.
Food Labeling- Metric Labeling Requirements	HHS-FDA	$4.4-$26.5 billion	$1.4-$2.3 billion plus $163 million in costs to Federal government	HHS-FDA performed one analysis for the food labeling requirements imposed by this rule and the other 22 HHS-FDA rules in this table related to food labeling.
Real Estate Settlement Procedures Act (Regulation X), FR-1942	HUD	$119,014,950 annually in greater competition in title insurance business $89.1-148.5 million net benefit annually in reducing transaction costs by packaging services with affiliated services	Cost of duplicate good-faith-estimates: $56,824,627 per year Cost of new disclosure for controlled business arrangements: $48,147,000 per year Cost of computerized loan originations: $3,607,890 per year	

Table 20. Agency Estimates of Benefits and Costs of Major Rules October 1, 1992 to September 30, 1993				
RULE	**AGENCY**	**BENEFITS**	**COSTS**	**OTHER INFORMATION**
			Cost of two additional years for storage (discount rate=6%): $24,305	
Manufactured Housing Construction and Safety Standards	HUD	$103 million	$63 million	
Final frameworks for early-season migratory bird hunting regulations	DOI	Not Estimated	Not Estimated	
Migratory bird hunting, final frameworks for late-season migratory bird hunting regulations	DOI	Not Estimated	Not Estimated	
The Family and Medical Leave Act of 1993	DOL-ESA	Not Estimated	$674 million annually	Estimate provided by U.S. General Accounting Office (Parental Leave: Estimated Costs of H.R. 925, the Family and Medical Leave Act of 1987—GAO/HRD-88-34, Nov. 10, 1987)
Permit Required Confined Spaces	DOL-OSHA	Reduced annually: 54 fatalities; 5,931 lost-workday injury and illness cases; 5,908 non-lost-workday cases	$202.4 million annually	"OSHA anticipates that improved worker productivity as a result of the standard will help to lower production costs and contribute to higher quality output. Although OSHA did not quantify these cost offsets, the Agency believes they will be substantial" (RIA, pp. I-10, I-13). "OSHA anticipates that greater use of mechanical ventilation to reduce atmospheric hazard in permit spaces may result in additional release of hazardous substances to the air. Incremental release quantities related to the permit space standard are not determinable at present, but are expected to be minor relative to current overall releases" (RIA, pp. I-17 – I-18).
Lead Exposure in Construction	DOL-OSHA	Near-term avoided annual health effects Reduced nerve conduction velocity: 16,199-22,831 cases; Reduced blood	$365-445 million annually plus one-time start-up costs of $150-$183 million.	

Table 20. Agency Estimates of Benefits and Costs of Major Rules October 1, 1992 to September 30, 1993				
RULE	**AGENCY**	**BENEFITS**	**COSTS**	**OTHER INFORMATION**
		ALA-D levels: 130,056-164,044 cases; Increased urinary ALA: 60,389-78,676 cases; Gastrointestinal disturbances: 1,135-4,413 cases; Detected blood-lead levels above MRP trigger: 24,262-35,163 cases Long-term avoided health effects over 10 years Fatal/nonfatal infractions: 2,164-2,322 cases; Fatal/nonfatal stroke: 644-698 cases; Renal disease: 1,258-2,157 cases		
Response Plans for Marine Transportation-Related Facilities	DOT-USCG	58,838 barrels of oil not spilled (NPV)	$176,105,666 (NPV)	Timeline of the analysis: 1996-2025 Discount Rate: 7%; $1996
Vessel Response Plans	DOT-USCG	50,312 barrels of oil not spilled (NPV)	$3,245,869,985 (NPV)	Timeline of the analysis: 1996-2025 Discount Rate: 7%; $1996
Light Truck Average Fuel Economy Standard for Model Year 1995	DOT	Not Estimated	Not Estimated	
Water quality standards regulation: Compliance with CWA Section 303(C)(2)(B) Amendments	EPA	Not Estimated	Not Estimated	"The analysis performed was limited to assessing only the potential reduction in cancer risk; no assessment of potential reductions in risks due to reproductive, developmental, or other chronic and subchronic toxic effects was conducted. However, given the number of pollutants, there could be: (1) Decreased incidence of systemic toxicity to vital organs such as liver and

Table 20. Agency Estimates of Benefits and Costs of Major Rules October 1, 1992 to September 30, 1993				
RULE	**AGENCY**	**BENEFITS**	**COSTS**	**OTHER INFORMATION**
				kidney; (2) decreased extent of learning disability and intellectual impairment due to the exposure to such pollutants as lead; and (3) decreased risk of adverse reproductive effects and genotoxicity." (57 FR 60848-) "The ecological benefits that can be expected from today's rule include protection of both fresh and salt water organisms, as well as wildlife that consume aquatic organisms…In addition, the rule would result in the propagation and productivity of fish and other organisms, maintaining fisheries for both commercial and recreational purposes. Recreational activities such as boating, water skiing, and swimming would also be preserved along with he maintenance of an aesthetically pleasing environment" (57 FR 60848-) "EPA acknowledges that there will be a cost to some dischargers for complying with new water quality standards as those standards are translated into specific NPDES permit limits…Revised wasteload allocations may result in adjustments to individual NPDES permit limits for point source dischargers, and these adjustments could result in increased wastewater treatment costs or other pollution control activities such as recycling or process changes. The magnitude of these costs depends on the types of treatment or other pollution control, the number and type of pollutants being treated, and the level of control that can be achieved by technology-based effluent limits for each industry. Similar sources of costs and the variables affecting costs may also apply to indirect industrial dischargers to the extent that the industrial discharger is a source of toxic pollutants discharged by the POTW…Nonpoint sources of toxic pollutants may also incur increased costs to the extent that best management practices need to be modified or applied to more sources to reflect the revised water quality standards. Although there is no Federal permit program for nonpoint sources comparable to that for point sources, there are State regulatory programs to control nonpoint source discharges. Monitoring programs are another source of potential incremental costs to dischargers and States." (57 FR 60848-)
Coastal nonpoint pollution control program development and approval guidance (EPA, NOAA), guidance specifying management measures for sources of	EPA	Not estimated	$389,940,000-$590,640,000 (annualized)	The RIA identified generally the types of "off-site benefits" that could be related to water quality improvements, including 4 use benefits (in-stream, near stream, option value, and diversionary) and 3 non-use (intrinsic) benefits (aesthetic, bequest, and existence).

Table 20. Agency Estimates of Benefits and Costs of Major Rules October 1, 1992 to September 30, 1993				
RULE	**AGENCY**	**BENEFITS**	**COSTS**	**OTHER INFORMATION**
nonpoint… Section 6217				
Oil and Gas Extraction Point Source Category, Offershore Subcategory, Effluent Limitations Guidelines and New Source Performance Standards (Final Rule)	EPA	$28.2-103.9 million per year	Total annualized BAT and NSPS costs: 1st year=$122 million, 15th year=$32 million	"Other benefits that are quantified, to the extent possible, but not monetized due to lack of appropriate data, include: (1) Human health risk reductions associated with systemics other than lead, pH-dependent leach rates, carcinogens for which there are no risk factors available, exposure to pollutants via sediment or food chair; (2) ecological risk reductions; (3) fishery benefits; and (4) intrinsic benefits…The non-quantified, non-monetized benefits assessed in this RIA include increased recreational fishing, increased commercial fishing, improved aesthetic quality of waters near the platform, and benefits to threatened or endangered species [the Kemp's Ridley Turtle and the Brown Pelican] in the Gulf of Mexico." (58 FR 12454-)
Acid Rain Permits, Allowance System, Emissions Monitoring, Excess Emissions and Appeals Regulations Under Title IV of the Clean Air Act Amendments of 1990	EPA	10 million tons/year reduction in SO_2 emission (mandated by Title IV) Cost savings: $689-973 million (annualized)	$894-1,509 million (annualized)	SO_2 emission reductions are expected to : (1) reduce acidification of surface waters, thereby increasing the presence an diversity of aquatic species; (2) improve visibility by reducing haze; (3) may improve human health as lower SO_2 emissions reduce air concentrations of acid sulfate aerosols and thus acute and chronic exposure to the acid aerosols that adversely affect human health may even affect even mortality; (4) eliminate damage to forest soils and foliage, especially of high-elevation spruce trees in the eastern U.S. and allow recovery of previously damaged tree populations; (5) may reduce damage to auto paint, reduce soiling of buildings and monuments, and thus the life of some materials and structures may be extended and the costs of maintenance or repair reduced (RIA, pp. 1-5 to 1-6, and 6-1 to 6-3) Engineering costs associated with CEM retrofit were not analyzed (RIA, pp. 4-18) "The annualized costs of the implementation regulations are estimated to increase the annual costs of generating electricity by 0.5 to 1.2 percent." (58 FR 3590-)
Vehicle Inspection and Maintenance Requirements for State Implementation Plan (Final Rule)	EPA	Emission reductions from continuing current I/M program unchanged (baseline=no I/M program)in 2000:	Continuing current I/M program: NET COST=$894 million ($2000)	"These repairs have been found to produce fuel economy benefits that will at least partially offset the cost of repairs. Fuel economy improvements of 6.1% for repair of pressure test failures and 5.7% for repair of purge test failures were observed. Vehicles that failed the transient short test at the established cutpoints were found to enjoy a fuel economy improvement of 12.6% as a result of repairs." (57 FR 52950-)

Table 20. Agency Estimates of Benefits and Costs of Major Rules October 1, 1992 to September 30, 1993				
RULE	**AGENCY**	**BENEFITS**	**COSTS**	**OTHER INFORMATION**
		116016 tons VOC, 1566395 tons CO (annual tons in 2000) Emission reductions from new I/M program in 2000 (baseline=no I/M program): 420415 tons VOC, 2845754 tons CO (annual tons in 2000)	New I/M program: NET COST=$541 million ($2000)	"In conclusion, today's action may cause significant shifts in business opportunities. Small businesses that currently do both inspections and repairs in decentralized I/M programs may have to choose between the two. Significant new opportunities will exist in these areas for small businesses to continue to participate in the inspection and repair industry. This will mean shifts in jobs but an overall increase in jobs in the repair sector and a small to potentially large increase in the inspection sector, depending on State choices." (57 FR 52950-)
Evaporative emission regulations for gasoline-fueled and methanol-fueled light duty vehicles, light-duty trucks, and heavy-duty vehicles —SAN 2969	EPA	Total VOC Reduction in 2020: 1,120,000 metric tons	Annual total program cost without fuel savings: $130-200 million ($1992, NPV to the year of the sale)	"[Emission] projections are made for the year 2020 in order to provide benefit predictions for a fully turned-over fleet and to factor in other known trends, such s the effects of other new Clean Air Act programs. These new programs include high-technology inspection and maintenance and reformulated gasoline. Reformulated gasoline achieving a 25 percent overall VOC emission reduction standard is assumed to be used in 40 percent of the nation." (58 FR 16002-) "[The cost] estimate does not include the offsetting fuel savings." (58 FR 16002-)
Control of air pollution from new motor vehicles and new motor vehicle engines, regulations requiring on-board diagnostic systems on 1994 and later model year light-duty vehicles	EPA	4.0 million tons HC, 30.8 million tons CO, 2.5 million tons NO_x (NPV)	$16.6 billion (NPV) ($1993)	Discount rate: 7% (58 FR 9468-) Timeline: 2005-2020 (58 FR 9468-) "EPA has not been able to adequately quantify some potential cost savings not included in these estimates. Potential cost savings can accrue due to early repairs of malfunction which, if left undetected and unrepaired, could result in the need for even more costly repairs in the future. Also, improved repair effectiveness should reduce the potential for a part to be unnecessarily replaced in attempting to fix a problem. Repair facilities should also benefit from the availability of generic tools for accessing and using the OBD system in problem diagnosis and repair. These service facility benefits could be passed along to the consumer in the form of lower repair costs." (58 FR 9468-)

Table 21. Agency Estimates of Benefits and Costs of Major Rules October 1, 1993 to September 30, 1994				
RULE	**AGENCY**	**BENEFITS**	**COSTS**	**OTHER INFORMATION**
Manufactured Home Construction and Safety Standards on Wind Standards	HUD	$103 million annually	$63 million annually	The cost estimates do not include costs associated with "out of pocket expenses related to deductibles or non-covered losses" (RIA, pp. 1-2). Non-quantified benefits include: "purchasers will experience less dislocation caused by damage to or destruction of their manufactured homes. Fourth, residents who choose to remain in their units during storms will suffer fewer injuries and deaths" (RIA, p. 1) Discount rate used=6.64 percent (RIA, p. 8) Basis for public benefit assessment: Hurricane Andrew (RIA, p. 9)
Designate critical habitat for four endangered Colorado River fishes	DOI	Net benefit: $7.92 million		Increase employment by 710 jobs, increase earnings by $6.62 million, increase government revenue by $3.20 million from 1995-2020 (59 FR 13374-)
Occupational Exposure to Asbestos	DOL-OSHA	Reduction in annual cancer risk: 2.12 cancer deaths in general industry, 40.48 cancer deaths in construction industry, 14.2 cancers among building occupants Reduction in asbestosis: 14 cases annually	$361.4 million annually	Non-quantified benefits include: avoided cases of asbestosis for building occupants and others secondarily exposed, reduced risks of cancer and fires (from rags contaminated with solvent), more rapid building reoccupation, reduced probability of asbestos-related lawsuits (RIA, pp 52-57)
Financial Responsibility for Water Pollution (Vessels)	DOT-USCG	525,316 barrels of oil not spilled (NPV)	$451,440,918 (NPV)	Timeline of the analysis: 1996-2025 Discount Rate: 7%; $1996
Antidrug Program for Personnel Engaged in	DOT-FAA	$206.64 million (NPV)	$138.13 million (NPV)	Timeline of the analysis: 1994-2003 (RIA, p.12) $1992 (RIA, p. 12) Discount rate=7% (RIA, p. 20)

Table 21. Agency Estimates of Benefits and Costs of Major Rules October 1, 1993 to September 30, 1994				
RULE	**AGENCY**	**BENEFITS**	**COSTS**	**OTHER INFORMATION**
Specified Aviation Activities				
Controlled Substances and Alcohol Use and Testing	DOT-FHWA	Reduced fatal accidents: $680 million in 1st year, $952 million per year in 2nd and subsequent years Reduced injury cost: $152.4 million in 1st year, $213.4 million per year in 2nd and subsequent years assuming the highest deterrence scenario Reduced property damage: $47.5 million in 1993, $66.5 million per year from 1994-2002 Reduced traffic delays: $3.5 million in 1993, $4.9 million per year thereafter assuming highest deterrence rate Reduced other costs of freeway accidents: $1.9 million in 1995 and $2.7 million thereafter	$93,947,750 in 1995, and $92,453,950 per year in 1996 and thereafter	
Light Truck Average Fuel Economy Standards, Model Years 1996-1997	DOT	Not Estimated	Not Estimated	
Prevention of Prohibited Drug Use in Transit Operations	DOT	$608,520,643 (NPV)	$208,970,087 (NPV)	Timeline: 1995-2004 Discount rate: 7% $1991
Land disposal restrictions phase II,	EPA	0.22 cancer cases per year avoided from groundwater,	$194-219 million (annualized)	"The timeframe to which these benefits are attributable begins 30 years following promulgation

Table 21. Agency Estimates of Benefits and Costs of Major Rules October 1, 1993 to September 30, 1994				
RULE	**AGENCY**	**BENEFITS**	**COSTS**	**OTHER INFORMATION**
universal treatment standards and treatment standards for organic toxicity, characteristic wastes, and newly listed wastes		0.037 cancer cases per year avoided from air $20 million avoided property value damage (annualized)		of the rule." (59 FR 47982-) "However, there are some benefits which the Agency has not attempted to quantify which are potentially attributable to today's rule. For example, the Agency has not attempted to quantify any potential non-use value benefits from protection of resources through treatment of hazardous wastes. Furthermore, the risk analysis performed by the Agency for today's rule does not account for many other potential benefits from today's rule. Ecological risk reduction from treatment of wastes under today's rule has not been quantified. Nor do the Agency's air and groundwater benefit estimates account for karst terrain, complex flow situations, or other factors which could contribute to underestimates of benefits." (59 FR 47982-)
Accelerated phase-out of ozone depleting chemicals and listing and phase-out of methyl bromide	EPA	Ozone depleting chemicals: $8-24 billion (NPV) Methyl Bromide: $1.6-6.4 billion (NPV)	Ozone depleting chemicals: $12 billion (NPV) Methyl Bromide: $0.8 billion (NPV)	Discount rate: 7% (58 FR 65018-) Timeline for methyl bromide cost: 1994-2010 (58 FR 65018-) Timeline for methyl bromide benefits: 1994-2011 (58 FR 65018-)
Fuel and fuel additives: standards for reformulated gasoline	EPA	Phase I Summertime VOC emission reduction: 90-140 thousand tons per year Reduction in cancer incidence: 16 per year (assuming enhanced I/M in place) or 24 per year (assuming basic I/M in place) Phase II (incremental to Phase I)	Phase I Annual costs: $700-940 million Phase II (incremental to Phase I): Increase gasoline production cost by 1.2 cents/gallon during the VOC control period, since only the toxics standard changes, and there is not expected to	"Reductions in mobile source emissions of the air toxics addressed in the reformulated gasoline program (benzene, 1, 3-butadiene, formaldehyde, acetaldehyde, and POM) may result in fewer cancer incidences. A number of adverse noncancer health effects have also been associated with exposures experience in particular microenvironments such as parking garages and refueling stations. These other health effects include blood disorders, heart ad lung diseases, and eye, nose and throat irritation. Some of the toxics may also be developmental and reproductive toxicants, while very high exposure can cause effects on the brain leading to respiratory paralysis and even death. The uses of reformulated

Table 21. Agency Estimates of Benefits and Costs of Major Rules October 1, 1993 to September 30, 1994				
RULE	**AGENCY**	**BENEFITS**	**COSTS**	**OTHER INFORMATION**
		Summer time VOC emission reduction: approximately 42,000 tons Summer time NO_x emission reduction: approximately 22,000 tons Number of cancer avoided: 3-4 fewer cancer incidence per year	be a cost for year-round toxics control above that required for Phase I EPA doesn't expect non-production related costs, such as distribution costs, recordkeeping and reporting costs, etc., to increase significantly relative to Phase I	gasoline meeting the Phase II standards will likely help to reduce some of these health effects as well." (59 FR 7716-) Phase I: The cost of producing reformulated gasoline is expected to increase by approximately 3-5 cents per gallon in 1995. (59 FR 7716-) The cost of testing, enforcement, and recordkeeping not reflected in the annual cost estimate. (59 FR 7716-)
Acid Rain NO_x Regulations under Title IV of the Clean Air Act Amendments of 1990	EPA	Phase I: 400,000 tons NOx reduced Phase II: 1.89 million tons NO_x reduced	Phase I: $77 million/year Phase II: $300 million/year	Qualitative human health benefits: Lower ambient levels of NO_x (and associated lower PM and lower ozone levels) may mean fewer lost school days, fewer disability days for children; for all, less eye irritation, (and with lower ozone levels) less airway irritation and its associated acute and chronic health effects; for exercising asthmatics, improved pulmonary function. Also ambient concentrations of nitrates will be lower and fewer toxic nitrogenous compounds will be formed. (RIA, pp. 9-1 to 9-4) Qualitative welfare effects: reduced materials damage, increased visibility that is associated with enhanced enjoyment of vistas and fewer aircraft and motor vehicle accidents. The potential ecological effect include minimizing the adverse effects of excess nitrogen deposition in forest soils and surface waters, including the "acid pulses" that precede fish kills and consequently, reduced biodiversity. (RIA, pp. 9-1 to 9-4) "Moreover, EPA expects that most or all utility expenses from meeting NO_x requirements will be passed along to ratepayers…Under today's rule the cost to ratepayers is very small, relative to their

Table 21. Agency Estimates of Benefits and Costs of Major Rules October 1, 1993 to September 30, 1994				
RULE	**AGENCY**	**BENEFITS**	**COSTS**	**OTHER INFORMATION**
				current expenditures on electricity. The average increase in electric rates across the United States is estimated to be only 0.03 and 0.13 percent under Phases I and II respectively." (59 FR 13538-)
Hazardous Organic NESHAP (HON) for the Synthetic Organic Chemical Manufacturing Industry (SOCMI) and Other Processes Subject to the Negotiated Regulation for Equipment Leaks	EPA	HAP reduction: 510,000 tons/year VOC reduction: 1,000,000 tons/year	Total nationwide annual cost: $230 million/year ($1989) CO emission increase: 1,900 tons/year NO_x emission increase: 19,000 tons/year	"Thus, the estimates represent annual impacts occurring in the fifth year." (59 FR 19402-) "As discussed in section III.B.3 of this preamble, the EPA has deferred the final decision regarding control of medium-sized storage vessels at existing sources. Therefore, emission reductions for storage vessels shown in table 1, and consequently the total, may be slightly overstated." (59 FR 19402-) "Because of the EPA's deferral of a final decision on control of medium-sized storage vessels at existing sources, as discussed in section III.B.3 of this preamble, the cost impacts for storage vessels, and consequently the total cost impact, may be slightly overstated." (59 FR 19402-) "Market analyses for a subset of 21 of the chemicals estimated price increases from 0.1 percent to 3.9 percent and quantity decreases from 0.1 percent to 4 percent." (59 FR 19402-)
Control of air pollution from new motor vehicles and new motor vehicle engines, refueling emission regulations for light-duty vehicles and trucks and heavy-duty vehicles	EPA	Without Stage II controls, average VOC annual emission reductions: over 420,000 tons per year; With Stage II phase-out when ORVR and Stage II would cover the same percent of fuel, average annual emission reduction: 378,000 tons; If retain Stage II controls, an incremental emission reduction: 285,000 tons	Without Stage II controls, the average annual cost: -$6 million (1998-2020); With Stage II and phasing out at 2010, the average annual cost: $2 million (1998-2020); With Stage II and no phase out, the average annual cost: $27 million (1998-2020)	"It should be noted that the RIA was completed prior to EPA's decision to delay the requirements for LDTs and to exclude HDVs. These controls were included in the analysis and were assumed to begin in 1998. EPA expects that inclusion of these items in the analysis has no significant effect on the results and does not affect the conclusions which are based on the analysis." (59 FR 16262-) "In the cases where costs are negative, it is because the value of the recovery credits exceeds the hardware and R, D, & T costs." (59 FR 16262-)

Table 21. Agency Estimates of Benefits and Costs of Major Rules October 1, 1993 to September 30, 1994				
RULE	**AGENCY**	**BENEFITS**	**COSTS**	**OTHER INFORMATION**
			In 1998 NPV, costs are $102 million, $264 million and $435 million respectively	
Determination of significance for nonroad sources and emission standards for new nonroad compression ignition engines at or above 37 kilowatts, control of air pollution…--SAN 3112	EPA	NO_x annual reduction in 2010: 800,000 tons NO_x annual reduction in 2025: over 1,200,000 tons	Average annual cost: $29-70 million (59 FR 31306)	"EPA maintains that the impact of this rule on fleet average fuel consumption will be minimal." (59 FR 31306-)

Table 22. Agency Estimates of Benefits and Costs of Major Rules October 1, 1994 to March 31, 1995				
RULE	**AGENCY**	**BENEFITS**	**COSTS**	**OTHER INFORMATION**
The Family and Medical Leave Act of 1993	DOL-ESA	Not Estimated	$674 million annually	Estimate provided by U.S. General Accounting Office (Parental Leave: Estimated Costs of H.R. 925, the Family and Medical Leave Act of 1987—GAO/HRD-88-34, Nov. 10, 1987)
Double Hull Standards for Vessels Carrying Oil in Bulk	DOT-USCG	94,172 barrels of oil not spilled (NPV)	$6,413,027,637 (NPV)	Timeline of the analysis: 1996-2025
FMVSS: Stability and Control of Medium and Heavy Vehicles During Braking	DOT-NHTSA	Equivalent fatalities forgone: 415-683 per year Forgone property damage: $327-394.9 million annually	Total consumer cost=$560.5 million annually	Discount rate: 7%
Bay/Delta water quality standards	EPA	$2.1-21.5 million annually in economic benefits to commercial and recreational fisheries and have associated employment gains of an estimated 145-1585 full-time equivalent jobs annually (RIA ES-7)	For the urban sector, $4.3 million/yr on average and $15.8 million/yr during dry years; $28.3 million/yr on average years and $165.3 million/yr during dry years without water transfers or waterbanks For agriculture sector, $27 million/yr on average, $43 million/year in the driest 10% of years (RIA ES-5) If using sharing approach (spread water supply impacts to entities diverting water from the Sacramento and San Joaquin River systems), -$0.5 million/yr average	"Important benefits of the water quality regulations include the following: Biological productivity and health for many estuarine species are expected to increase. The decline of species is expected to be reversed and the existence of species unique to the Bay/Delta, such as Delta smelt, winter-run Chinook salmon, long fin smelt, and Sacramento splittail, will be protected. Populations of a variety of estuarine species are expected to increase; although the extent of the population increases has not been determined for all species, the increases are anticipated to benefit the recreational and commercial fisheries." (60 FR 4703)

Table 22. Agency Estimates of Benefits and Costs of Major Rules October 1, 1994 to March 31, 1995				
RULE	**AGENCY**	**BENEFITS**	**COSTS**	**OTHER INFORMATION**
			years, -$5.5 million/yr for dry years for agricultural sector, -$10.5 million/yr for average years and -$54 million/year for dry years (RIA ES-6)	
Water quality guidance for the Great Lakes system	EPA	Given the site-specific nature of water quality benefits and the unavailability of site-specific data across the Great Lakes Basin, only case study monetized benefits are estimated in the RIA. Average monetized benefits across the three case studies evaluated are $0.3 million per year to $6.2 million per year, with a midpoint of $2.9 million per year (in 1996 dollars); average annual costs across case studies are also $2.8 million per year (1996 dollars).	$64.0-394.6 million ($1996, annualized)	"The benefit analysis is based on a case study approach, suing benefits transfer applied to three case studies…The case studies include: (1) the lower Fox River drainage, including Green Bay, located on Lake Michigan in northeastern Wisconsin; (2) the Saginaw River and Saginaw Bay, located on Lake Huron in Northeastern Michigan; and (3) the Black River, located on Lake Erie in north-central Ohio…EPA did not attempt to calculate the longer-term benefits to human health, wildlife, and aquatic life once the final Guidance provisions are fully implemented by nonpoint sources as well as point sources and the minimum protection levels are attained in the ambient water." (60 FR 15382) "The three case studies combine to account for nearly 14 percent of the total cost of the final Guidance, nearly 17 percent of the loadings reductions, and from four percent to 10 percent of the benefits proxies (i.e., basin-wide population, recreational angling, nonconsumptive recreation, and commercial fishery harvest." (60 FR15382) "In addition to the cost estimates described above, EPA estimated the cost to comply with requirements consistent with the antidegradation provisions of the final Guidance. This potential future cost is expressed as a 'lost opportunity' cost for facilities impacted by the antidegradation requirements. This cost could result in the addition of about $22 million each year." (60 FR 15381)
Interim	EPA	HC, CO and NO_x	$650 million (NPV,	

Table 22. Agency Estimates of Benefits and Costs of Major Rules October 1, 1994 to March 31, 1995				
RULE	**AGENCY**	**BENEFITS**	**COSTS**	**OTHER INFORMATION**
Requirements for Deposit Control Gasoline Additives, Regulations of Fuels and Fuel Additives		reduction during the 18-month interim period: 700,000 tons (59 FR 54678-) HC, CO and NO_x reduction after the interim period: 600,000 tons per year (59 FR 54678-) Fuel economy savings: 390 million gallons in 1995-2000 (59 FR 54678-)	discount rate=7%, 1995-2000 (59 FR 54678-)	

APPENDIX C: STATUS OF THE 23 HIGH-PRIORITY RULES OMB SUGGESTED FOR REFORM IN 2001

In the draft version of the 2001 annual report, OMB asked for suggestions from the public about specific regulations that should be modified in order to increase net benefits to the public. We received suggestions regarding 71 regulations from 33 commenters involving 17 agencies. In an initial review of the comments, OMB placed the suggestions into three categories: high priority, medium priority, and low priority.

Twenty-three agency actions were rated Category 1, "high priority review" candidates. Since the publication of the 2001 report, OMB has discussed these regulations with the agencies to better understand where they fit with agency priorities. Commenters responding to the March 2002 draft report also nominated some of these rules again in 2002. As detailed below, agencies have already taken action on a number of these suggestions. On others, agencies have agreed to consider the need for reform and will be evaluating specific actions. Finally, for some, agencies believe that reform is unnecessary or not appropriate at this time. A status report on the high priority reviews is provided below.

USDA: Forest Service Planning Rules and Roadless Area Conservation Regulations (Two Rules)—On May 10, 2001, a Federal judge issued an injunction blocking implementation of the roadless rule and a portion of the forest planning rule. In July 2001, the Forest Service issued an advanced notice soliciting comments on possible changes to the roadless rule in light of the court action. The Forest Service has issued two rulemakings in July 2003: an advanced notice of proposed rulemaking seeking to permanently exempt both the Tongass and the Chugash National Forests from the Roadless Areas Conservation Rule, and a proposed rule seeking to temporarily exempt the Tongass National Forest from the Roadless Rule. Both of these rulemakings were issued pursuant to a June 2003 settlement agreement reach between USDA and the State of Alaska. Further action awaits the Forest Service's consideration of comments. The Forest Service has issued a proposed planning rule in December 2002, amending the 2000 planning rule. The Forest Service intends to issue a final rule in Fall 2003.

Department of Education: Regulations Related to Financial Aid—These regulations are the subject of annual regulatory negotiations. For this year the Department has made clear its commitment to streamlining the regulations consistent with statutory requirements. The Department published NPRM's in August 2002 and the final rules in November 2002. The Federal Family Education Loan Program was nominated for reform again last year.

Department of Energy: Central Air Conditioning and Heat Pump Energy Conservation Standards—On January 22, 2001, DOE promulgated a regulation that would have raised the energy efficiency of new central air conditioners by 30 percent. On May 23, 2002, DOE withdrew this rule and issued a final rule raising the minimum energy efficiency levels by 20 percent. This rule was nominated for reform by the public in 2002.

Department of Health and Human Services: Standards for Privacy of Individually Identifiable Health Information—On August 14, 2002, HHS published final revisions to this rule

clarifying some aspects and modifying others. The rule as amended goes into effect on April 12, 2003. This rule was nominated for reform by the public again in 2002.

Department of Health and Human Services: Food Labeling: Trans Fatty Acids in Nutrition Labeling, Nutrient Content and Health Claims—OIRA Administrator John D. Graham sent a prompt letter to FDA on September 18, 2001 urging the agency to finalize this rulemaking. Secretary Thompson responded on November 26, 2001, agreeing that finalization was a high priority. FDA finalized this rule in July 2003.

Department of the Interior: Amendments to National Park Service Snowmobile Regulations (Rocky Mountain)—Interior had issued a proposed rule on January 5, 2001, and a draft environmental impact statement in December 2000. Interior has not issued a final rule. Currently, the proposed rule is under internal departmental review. This rule was nominated for reform by the public again in 2002.

Department of the Interior: Regulations Governing Hardrock Mining Operations—Interior completed a revision of these regulations on October 31, 2001.

Department of Labor: Procedures for Certification of Employment- Based Immigration and Guest Worker Applications—On November 21, 2001, DOL submitted a proposed regulation on this subject to OMB for review. We concluded review on February 19, 2002. DOL published the proposed rule in April 2002. DOL is currently in the process of addressing comments and finalizing the rule.

Department of Labor: Proposal Governing "Helpers" on Davis-Bacon Act Projects—DOL has decided that changes in the Davis-Bacon regulations are not appropriate at this time.

Department of Labor: Overtime Compensation Regulations Under the Fair Labor Standards Act—DOL is considering whether revisions to these regulations would be appropriate.

Department of Labor: Recordkeeping and Notification Requirements Under the Family and Medical Leave Act (FMLA)—DOL is developing proposed revisions to these regulations. Additional aspects of the FMLA rules were nominated for reform by the public again this year.

Department of Labor: Affirmative Action and E.O. Survey—DOL is considering whether modifications to the survey would be appropriate. The Survey was nominated for reform by the public again in 2002.

Department of Transportation: Hours of Service of Drivers—This rule was nominated for reform by the public again in 2002. DOT issued a final rule on April 28, 2003.

Equal Employment Opportunity Commission: Uniform Guidelines for Employee Selection Procedures—EEOC has requested and received several extensions of clearance of these guidelines under the Paperwork Reduction Act to allow further consideration of changes.

Environmental Protection Agency: "Mixture and Derived From" Rule—EPA issued a proposed rule to revise these regulations on April 8, 2003.

Environmental Protection Agency: Proposed Changes to the Total Maximum Daily Load Program—EPA published a notice in October 2001 delaying the effective date of the July 2000 TMDL rule for 18 months, in order to allow time to consider possible revisions to the rule. The agency then conducted extensive "listening sessions" with stakeholders and has now prepared a draft proposed rule that addresses many of the concerns raised. In order to allow additional time for stakeholder input, EPA withdrew the July 2000 rule in April 2003. EPA expects to publish the proposed rule for public comment. This rule was nominated for reform by the public again in 2002.

Environmental Protection Agency: Drinking Water Regulations: Cost Benefit Analyses—OMB is addressing these issues in its revised analytic guidance, which is being issued with this report. This guidance was nominated for reform by the public in 2002.

Environmental Protection Agency: Economic Incentive Program Guidance—EPA issued guidance in January 2001, and the States are now using the guidance in developing economic incentive programs. OMB will consider further review of the guidance after the States have further experience with the current guidelines. This guidance was nominated for reform by the public again in 2002.

Environmental Protection Agency: New Source Review— EPA published the Prevention of Significant Deterioration (PSD) and Nonattainment New Source Review (NSR): Baseline Emissions Determination, Actual-to-Future-Actual Methodology, Plantwide Applicability Limitations, Clean Units, Pollution Control Projects Final Rule and the Prevention of Significant Deterioration (PSD) and Non-attainment New Source Review (NSR): Routine Maintenance, Repair and Replacement Proposed Rule on December 31, 2002. EPA received several petitions for reconsideration of the final NSR rule and is currently preparing a response. The comment period for the proposed rule closed on May 2, 2003, and EPA recently announced a final Routine Maintenance, Repair and Replacement rule. This rule was nominated for reform by the public in 2002.

Environmental Protection Agency: Concentrated Animal Feeding Operations Effluent Guidelines—In December 2000, EPA published a proposed rule changing the Clean Water Act permitting requirements for concentrated animal feeding operations (CAFOs) and strengthening the effluent guidelines for those facilities. In February 2003, EPA published the final rule on CAFOs. This rule was nominated for reform by the public again in 2002.

Environmental Protection Agency: Arsenic in Drinking Water—EPA has decided not to modify this final rule. This rule was nominated for reform by the public again in 2002.

Environmental Protection Agency: Notice of Substantial Risk: *TSCA*—EPA is considering several options to address the issues raised in its last report. EPA has established a new TSCA 8(e) web page that contains guidance, previous 8(e) submissions, and new

submissions posted within two weeks of receipt. EPA is also working on a package that would make policy clarifications.

APPENDIX D: OMB CIRCULAR A-4, REGULATORY ANALYSIS

TO THE HEADS OF EXECUTIVE AGENCIES AND ESTABLISHMENTS

Subject: Regulatory Analysis

This Circular provides the Office of Management and Budget's (OMB's) guidance to Federal agencies on the development of regulatory analysis as required under Section 6(a)(3)(c) of Executive Order12866, "Regulatory Planning and Review," the Regulatory Right-to-Know Act, and a variety of related authorities. The Circular also provides guidance to agencies on the regulatory accounting statements that are required under the Regulatory Right-to-Know Act.

This Circular refines OMB's "best practices" document of 1996 (http://www.whitehouse.gov/omb/inforeg/riaguide.html), which was issued as a guidance in 2000 (http://www.whitehouse.gov/omb/memoranda/m00-08.pdf), and reaffirmed in 2001 (http://www.whitehouse.gov/omb/memoranda/m01-23.html). It replaces both the 1996 "best practices" and the 2000 guidance.

In developing this Circular, OMB first developed a draft that was subject to public comment, interagency review, and peer review. Peer reviewers included Cass Sunstein, University of Chicago; Lester Lave, Carnegie Mellon University; Milton C. Weinstein and James K. Hammitt of the Harvard School of Public Health; Kerry Smith, North Carolina State University; Jonathan Weiner, Duke University Law School; Douglas K. Owens, Stanford University; and W. Kip Viscusi, Harvard Law School. Although these individuals submitted comments, OMB is solely responsible for the final content of this Circular.

A. Introduction

This Circular is designed to assist analysts in the regulatory agencies by defining good regulatory analysis – called either "regulatory analysis" or "analysis" for brevity – and standardizing the way benefits and costs of Federal regulatory actions are measured and reported. Executive Order 12866 requires agencies to conduct a regulatory analysis for economically significant regulatory actions as defined by Section 3(f)(1). This requirement applies to rulemakings that rescind or modify existing rules as well as to rulemakings that establish new requirements.

The Need for Analysis of Proposed Regulatory Actions[67]

Regulatory analysis is a tool regulatory agencies use to anticipate and evaluate the likely consequences of rules. It provides a formal way of organizing the evidence on the key effects – good and bad – of the various alternatives that should be considered in developing regulations. The motivation is to (1) learn if the benefits of an action are likely to justify the costs or (2) discover which of various possible alternatives would be the most cost-effective.

[67] We use the term "proposed" to refer to any regulatory actions under consideration regardless of the stage of the regulatory process.

A good regulatory analysis is designed to inform the public and other parts of the Government (as well as the agency conducting the analysis) of the effects of alternative actions. Regulatory analysis sometimes will show that a proposed action is misguided, but it can also demonstrate that well-conceived actions are reasonable and justified.

Benefit-cost analysis is a primary tool used for regulatory analysis.[68] Where all benefits and costs can be quantified and expressed in monetary units, benefit-cost analysis provides decision makers with a clear indication of the most efficient alternative, that is, the alternative that generates the largest net benefits to society (ignoring distributional effects). This is useful information for decision makers and the public to receive, even when economic efficiency is not the only or the overriding public policy objective.

It will not always be possible to express in monetary units all of the important benefits and costs. When it is not, the most efficient alternative will not necessarily be the one with the largest quantified and monetized net-benefit estimate. In such cases, you should exercise professional judgment in determining how important the non-quantified benefits or costs may be in the context of the overall analysis. If the non-quantified benefits and costs are likely to be important, you should carry out a "threshold" analysis to evaluate their significance. Threshold or "break-even" analysis answers the question, "How small could the value of the non-quantified benefits be (or how large would the value of the non-quantified costs need to be) before the rule would yield zero net benefits?" In addition to threshold analysis you should indicate, where possible, which non-quantified effects are most important and why.

Key Elements of a Regulatory Analysis

A good regulatory analysis should include the following three basic elements: (1) a statement of the need for the proposed action, (2) an examination of alternative approaches, and (3) an evaluation of the benefits and costs—quantitative and qualitative—of the proposed action and the main alternatives identified by the analysis.

To evaluate properly the benefits and costs of regulations and their alternatives, you will need to do the following:

- Explain how the actions required by the rule are linked to the expected benefits. For example, indicate how additional safety equipment will reduce safety risks. A similar analysis should be done for each of the alternatives.
- Identify a baseline. Benefits and costs are defined in comparison with a clearly stated alternative. This normally will be a "no action" baseline: what the world will be like if the proposed rule is not adopted. Comparisons to a "next best" alternative are also especially useful.
- Identify the expected undesirable side-effects and ancillary benefits of the proposed regulatory action and the alternatives. These should be added to the direct benefits and costs as appropriate.

[68] See Mishan EJ (1994), *Cost-Benefit Analysis*, fourth edition, Routledge, New York.

With this information, you should be able to assess quantitatively the benefits and costs of the proposed rule and its alternatives. A complete regulatory analysis includes a discussion of non-quantified as well as quantified benefits and costs. A non-quantified outcome is a benefit or cost that has not been quantified or monetized in the analysis. When there are important non-monetary values at stake, you should also identify them in your analysis so policymakers can compare them with the monetary benefits and costs. When your analysis is complete, 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.

As you design, execute, and write your regulatory analysis, you should seek out the opinions of those who will be affected by the regulation as well as the views of those individuals and organizations who may not be affected but have special knowledge or insight into the regulatory issues. Consultation can be useful in ensuring that your analysis addresses all of the relevant issues and that you have access to all pertinent data. Early consultation can be especially helpful. You should not limit consultation to the final stages of your analytical efforts.

You will find that you cannot conduct a good regulatory analysis according to a formula. Conducting high-quality analysis requires competent professional judgment. Different regulations may call for different emphases in the analysis, depending on the nature and complexity of the regulatory issues and the sensitivity of the benefit and cost estimates to the key assumptions.

A good analysis is transparent. It should be possible for a qualified third party reading the report to see clearly how you arrived at your estimates and conclusions. For transparency's sake, you should state in your report what assumptions were used, such as the time horizon for the analysis and the discount rates applied to future benefits and costs. It is usually necessary to provide a sensitivity analysis to reveal whether, and to what extent, the results of the analysis are sensitive to plausible changes in the main assumptions and numeric inputs.

A good analysis provides specific references to all sources of data, appendices with documentation of models (where necessary), and the results of formal sensitivity and other uncertainty analyses. Your analysis should also have an executive summary, including a standardized accounting statement.

B. The Need for Federal Regulatory Action

Before recommending Federal regulatory action, an agency must demonstrate that the proposed action is necessary. If the regulatory intervention results from a statutory or judicial directive, you should describe the specific authority for your action, the extent of discretion available to you, and the regulatory instruments you might use. Executive Order 12866 states that "Federal agencies should promulgate only such regulations as are required by law, are necessary to interpret the law, or are made necessary by compelling 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 ... ."

Executive Order 12866 also states that "Each agency shall identify the problem that it intends to address (including, where applicable, the failures of private markets or public institutions that warrant new agency action) as well as assess the significance of that problem." Thus, you should try to explain whether the action is intended to address a significant market failure or to meet some other compelling public need such as improving governmental processes or promoting intangible values such as distributional fairness or privacy. If the regulation is designed to correct a significant market failure, you should describe the failure both qualitatively and (where feasible) quantitatively. You should show that a government intervention is likely to do more good than harm. For other interventions, you should also provide a demonstration of compelling social purpose and the likelihood of effective action. Although intangible rationales do not need to be quantified, the analysis should present and evaluate the strengths and limitations of the relevant arguments for these intangible values.

Market Failure or Other Social Purpose

The major types of market failure include: externality, market power, and inadequate or asymmetric information. Correcting market failures is a reason for regulation, but it is not the only reason. Other possible justifications include improving the functioning of government, removing distributional unfairness, or promoting privacy and personal freedom.

1. Externality, common property resource and public good

An externality occurs when one party's actions impose uncompensated benefits or costs on another party. Environmental problems are a classic case of externality. For example, the smoke from a factory may adversely affect the health of local residents while soiling the property in nearby neighborhoods. If bargaining were costless and all property rights were well defined, people would eliminate externalities through bargaining without the need for government regulation.[69] From this perspective, externalities arise from high transactions costs and/or poorly defined property rights that prevent people from reaching efficient outcomes through market transactions.

Resources that may become congested or overused, such as fisheries or the broadcast spectrum, represent common property resources. "Public goods," such as defense or basic scientific research, are goods where provision of the good to some individuals cannot occur without providing the same level of benefits free of charge to other individuals.

2. Market Power

Firms exercise market power when they reduce output below what would be offered in a competitive industry in order to obtain higher prices. They may exercise market power collectively or unilaterally. Government action can be a source of market power, such as when regulatory actions exclude low-cost imports. Generally, regulations that increase market power for selected entities should be avoided. However, there are some circumstances in which government may choose to validate a monopoly. If a market can be served at lowest cost only when production is limited to a single producer – local gas and electricity distribution services,

[69] See Coase RH (1960), *Journal of Law and Economics*, 3, 1-44.

for example – a natural monopoly is said to exist. In such cases, the government may choose to approve the monopoly and to regulate its prices and/or production decisions. Nevertheless, you should keep in mind that technological advances often affect economies of scale. This can, in turn, transform what was once considered a natural monopoly into a market where competition can flourish.

3. Inadequate or Asymmetric Information

Market failures may also result from inadequate or asymmetric information. Because information, like other goods, is costly to produce and disseminate, your evaluation will need to do more than demonstrate the possible existence of incomplete or asymmetric information. Even though the market may supply less than the full amount of information, the amount it does supply may be reasonably adequate and therefore not require government regulation. Sellers have an incentive to provide information through advertising that can increase sales by highlighting distinctive characteristics of their products. Buyers may also obtain reasonably adequate information about product characteristics through other channels, such as a seller offering a warranty or a third party providing information.

Even when adequate information is available, people can make mistakes by processing it poorly. Poor information-processing often occurs in cases of low probability, high-consequence events, but it is not limited to such situations. For instance, people sometimes rely on mental rules-of-thumb that produce errors. If they have a clear mental image of an incident which makes it cognitively "available," they might overstate the probability that it will occur. Individuals sometimes process information in a biased manner, by being too optimistic or pessimistic, without taking sufficient account of the fact that the outcome is exceedingly unlikely to occur. When mistakes in information processing occur, markets may overreact. When it is time-consuming or costly for consumers to evaluate complex information about products or services (e.g., medical therapies), they may expect government to ensure that minimum quality standards are met. However, the mere possibility of poor information processing is not enough to justify regulation. If you think there is a problem of information processing that needs to be addressed, it should be carefully documented.

4. Other Social Purposes

There are justifications for regulations in addition to correcting market failures. A regulation may be appropriate when you have a clearly identified measure that can make government operate more efficiently. In addition, Congress establishes some regulatory programs to redistribute resources to select groups. Such regulations should be examined to ensure that they are both effective and cost-effective. Congress also authorizes some regulations to prohibit discrimination that conflicts with generally accepted norms within our society. Rulemaking may also be appropriate to protect privacy, permit more personal freedom or promote other democratic aspirations.

Showing That Regulation at the Federal Level Is the Best Way to Solve the Problem

Even where a market failure clearly exists, you should consider other means of dealing with the failure before turning to Federal regulation. Alternatives to Federal regulation include antitrust enforcement, consumer-initiated litigation in the product liability system, or administrative compensation systems.

In assessing whether Federal regulation is the best solution, you should also consider the possibility of regulation at the State or local level. In some cases, the nature of the market failure may itself suggest the most appropriate governmental level of regulation. For example, problems that spill across State lines (such as acid rain whose precursors are transported widely in the atmosphere) are probably best addressed by Federal regulation. More localized problems, including those that are common to many areas, may be more efficiently addressed locally.

The advantages of leaving regulatory issues to State and local authorities can be substantial. If public values and preferences differ by region, those differences can be reflected in varying State and local regulatory policies. Moreover, States and localities can serve as a testing ground for experimentation with alternative regulatory policies. One State can learn from another's experience while local jurisdictions may compete with each other to establish the best regulatory policies. You should examine the proper extent of State and local discretion in your rulemaking context.

A diversity of rules may generate gains for the public as governmental units compete with each other to serve the public, but duplicative regulations can also be costly. Where Federal regulation is clearly appropriate to address interstate commerce issues, you should try to examine whether it would be more efficient to retain or reduce State and local regulation. The local benefits of State regulation may not justify the national costs of a fragmented regulatory system. For example, the increased compliance costs for firms to meet different State and local regulations may exceed any advantages associated with the diversity of State and local regulation. Your analysis should consider the possibility of reducing as well as expanding State and local rulemaking.

The role of Federal regulation in facilitating U.S. participation in global markets should also be considered. Harmonization of U.S. and international rules may require a strong Federal regulatory role. Concerns that new U.S. rules could act as non-tariff barriers to imported goods should be evaluated carefully.

The Presumption Against Economic Regulation

Government actions can be unintentionally harmful, and even useful regulations can impede market efficiency. For this reason, there is a presumption against certain types of regulatory action. In light of both economic theory and actual experience, a particularly demanding burden of proof is required to demonstrate the need for any of the following types of regulations:

- price controls in competitive markets;

- production or sales quotas in competitive markets;
- mandatory uniform quality standards for goods or services if the potential problem can be adequately dealt with through voluntary standards or by disclosing information of the hazard to buyers or users; or
- controls on entry into employment or production, except (a) where indispensable to protect health and safety (e.g., FAA tests for commercial pilots) or (b) to manage the use of common property resources (e.g., fisheries, airwaves, Federal lands, and offshore areas).

C. Alternative Regulatory Approaches

Once you have determined that Federal regulatory action is appropriate, you will need to consider alternative regulatory approaches. Ordinarily, you will be able to eliminate some alternatives through a preliminary analysis, leaving a manageable number of alternatives to be evaluated according to the formal principles of the Executive Order. The number and choice of alternatives selected for detailed analysis is a matter of judgment. There must be some balance between thoroughness and the practical limits on your analytical capacity. With this qualification in mind, you should nevertheless explore modifications of some or all of a regulation's attributes or provisions to identify appropriate alternatives. The following is a list of alternative regulatory actions that you should consider.

Different Choices Defined by Statute

When a statute establishes a specific regulatory requirement and the agency is considering a more stringent standard, you should examine the benefits and costs of reasonable alternatives that reflect the range of the agency's statutory discretion, including the specific statutory requirement.

Different Compliance Dates

The timing of a regulation may also have an important effect on its net benefits. Benefits may vary significantly with different compliance dates where a delay in implementation may result in a substantial loss in future benefits (e.g., a delay in implementation could result in a significant reduction in spawning stock and jeopardize a fishery). Similarly, the cost of a regulation may vary substantially with different compliance dates for an industry that requires a year or more to plan its production runs. In this instance, a regulation that provides sufficient lead time is likely to achieve its goals at a much lower overall cost than a regulation that is effective immediately.

Different Enforcement Methods

Compliance alternatives for Federal, State, or local enforcement include on-site inspections, periodic reporting, and noncompliance penalties structured to provide the most appropriate incentives. When alternative monitoring and reporting methods vary in their benefits and costs, you should identify the most appropriate enforcement framework. For example, in

some circumstances random monitoring or parametric monitoring will be less expensive and nearly as effective as continuous monitoring.

Different Degrees of Stringency

In general, both the benefits and costs associated with a regulation will increase with the level of stringency (although marginal costs generally increase with stringency, whereas marginal benefits may decrease). You should study alternative levels of stringency to understand more fully the relationship between stringency and the size and distribution of benefits and costs among different groups.

Different Requirements for Different Sized Firms

You should consider setting different requirements for large and small firms, basing the requirements on estimated differences in the expected costs of compliance or in the expected benefits. The balance of benefits and costs can shift depending on the size of the firms being regulated. Small firms may find it more costly to comply with regulation, especially if there are large fixed costs required for regulatory compliance. On the other hand, it is not efficient to place a heavier burden on one segment of a regulated industry solely because it can better afford the higher cost. This has the potential to load costs on the most productive firms, costs that are disproportionate to the damages they create. You should also remember that a rule with a significant impact on a substantial number of small entities will trigger the requirements set forth in the Regulatory Flexibility Act. (5 U.S.C. 603(c), 604).

Different Requirements for Different Geographic Regions

Rarely do all regions of the country benefit uniformly from government regulation. It is also unlikely that costs will be uniformly distributed across the country. Where there are significant regional variations in benefits and/or costs, you should consider the possibility of setting different requirements for the different regions.

Performance Standards Rather than Design Standards

Performance standards express requirements in terms of outcomes rather than specifying the means to those ends. They are generally superior to engineering or design standards because performance standards give the regulated parties the flexibility to achieve regulatory objectives in the most cost-effective way. In general, you should take into account both the cost savings to the regulated parties of the greater flexibility and the costs of assuring compliance through monitoring or some other means.

Market-Oriented Approaches Rather than Direct Controls

Market-oriented approaches that use economic incentives should be explored. These alternatives include fees, penalties, subsidies, marketable permits or offsets, changes in liability or property rights (including policies that alter the incentives of insurers and insured parties), and required bonds, insurance or warranties. One example of a market-oriented approach is a

program that allows for averaging, banking, and/or trading (ABT) of credits for achieving additional emission reductions beyond the required air emission standards. ABT programs can be extremely valuable in reducing costs or achieving earlier or greater benefits, particularly when the costs of achieving compliance vary across production lines, facilities, or firms. ABT can be allowed on a plant-wide, firm-wide, or region-wide basis rather than vent by vent, provided this does not produce unacceptable local air quality outcomes (such as "hot spots" from local pollution concentration).

Informational Measures Rather than Regulation

If intervention is contemplated to address a market failure that arises from inadequate or asymmetric information, informational remedies will often be preferred. Measures to improve the availability of information include government establishment of a standardized testing and rating system (the use of which could be mandatory or voluntary), mandatory disclosure requirements (e.g., by advertising, labeling, or enclosures), and government provision of information (e.g., by government publications, telephone hotlines, or public interest broadcast announcements). A regulatory measure to improve the availability of information, particularly about the concealed characteristics of products, provides consumers a greater choice than a mandatory product standard or ban.

Specific informational measures should be evaluated in terms of their benefits and costs. Some effects of informational measures are easily overlooked. The costs of a mandatory disclosure requirement for a consumer product will include not only the cost of gathering and communicating the required information, but also the loss of net benefits of any information displaced by the mandated information. The other costs also may include the effect of providing information that is ignored or misinterpreted, and inefficiencies arising from the incentive that mandatory disclosure may give to overinvest in a particular characteristic of a product or service.

Where information on the benefits and costs of alternative informational measures is insufficient to provide a clear choice between them, you should consider the least intrusive informational alternative sufficient to accomplish the regulatory objective. To correct an informational market failure it may be sufficient for government to establish a standardized testing and rating system without mandating its use, because competing firms that score well according to the system should thereby have an incentive to publicize the fact.

D. Analytical Approaches

Both benefit-cost analysis (BCA) and cost-effectiveness analysis (CEA) provide a systematic framework for identifying and evaluating the likely outcomes of alternative regulatory choices. A major rulemaking should be supported by both types of analysis wherever possible. Specifically, you should prepare a CEA for all major rulemakings for which the primary benefits are improved public health and safety to the extent that a valid effectiveness measure can be developed to represent expected health and safety outcomes. You should also perform a BCA for major health and safety rulemakings to the extent that valid monetary values can be assigned to the primary expected health and safety outcomes. In undertaking these analyses, it is important to keep in mind the larger objective of analytical consistency in

estimating benefits and costs across regulations and agencies, subject to statutory limitations. Failure to maintain such consistency may prevent achievement of the most risk reduction for a given level of resource expenditure. For all other major rulemakings, you should carry out a BCA. If some of the primary benefit categories cannot be expressed in monetary units, you should also conduct a CEA. In unusual cases where no quantified information on benefits, costs and effectiveness can be produced, the regulatory analysis should present a qualitative discussion of the issues and evidence.

Benefit-Cost Analysis

A distinctive feature of BCA is that both benefits and costs are expressed in monetary units, which allows you to evaluate different regulatory options with a variety of attributes using a common measure.[70] By measuring incremental benefits and costs of successively more stringent regulatory alternatives, you can identify the alternative that maximizes net benefits.

The size of net benefits, the absolute difference between the projected benefits and costs, indicates whether one policy is more efficient than another. The ratio of benefits to costs is not a meaningful indicator of net benefits and should not be used for that purpose. It is well known that considering such ratios alone can yield misleading results.

Even when a benefit or cost cannot be expressed in monetary units, you should still try to measure it in terms of its physical units. If it is not possible to measure the physical units, you should still describe the benefit or cost qualitatively. For more information on describing qualitative information, see the section "*Developing Benefit and Cost Estimates.*"

When important benefits and costs cannot be expressed in monetary units, BCA is less useful, and it can even be misleading, because the calculation of net benefits in such cases does not provide a full evaluation of all relevant benefits and costs.

You should exercise professional judgment in identifying the importance of non-quantified factors and assess as best you can how they might change the ranking of alternatives based on estimated net benefits. If the non-quantified benefits and costs are likely to be important, you should recommend which of the non-quantified factors are of sufficient importance to justify consideration in the regulatory decision. This discussion should also include a clear explanation that support designating these non-quantified factors as important. In this case, you should also consider conducting a threshold analysis to help decision makers and other users of the analysis to understand the potential significance of these factors to the overall analysis.

[70] Mishan EJ (1994), *Cost-Benefit Analysis*, fourth edition, Routledge, New York.

Cost-Effectiveness Analysis[71]

Cost-effectiveness analysis can provide a rigorous way to identify options that achieve the most effective use of the resources available without requiring monetization of all of relevant benefits or 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).

Cost-effectiveness results based on averages need to be treated with great care. They suffer from the same drawbacks as benefit-cost ratios. The alternative that exhibits the smallest cost-effectiveness ratio may not be the best option, just as the alternative with the highest benefit-cost ratio is not always the one that maximizes net benefits. Incremental cost-effectiveness analysis (discussed below) can help to avoid mistakes that can occur when policy choices are based on average cost-effectiveness.

CEA can also be misleading when the "effectiveness" measure does not appropriately weight the consequences of the alternatives. For example, when effectiveness is measured in tons of reduced pollutant emissions, cost-effectiveness estimates will be misleading unless the reduced emissions of diverse pollutants result in the same health and environmental benefits.

When you have identified a range of alternatives (e.g., different levels of stringency), you should determine the cost-effectiveness of each option compared with the baseline as well as its incremental cost-effectiveness compared with successively more stringent requirements. Ideally, your CEA would present an array of cost-effectiveness estimates that would allow comparison across different alternatives. However, analyzing all possible combinations is not practical when there are many options (including possible interaction effects). In these cases, you should use your judgment to choose reasonable alternatives for careful consideration.

When constructing and comparing incremental cost-effectiveness ratios, you should be careful to determine whether the various alternatives are mutually exclusive or whether they can be combined. If they can be combined, you should consider which might be favored under different regulatory budget constraints (implicit or explicit). You should also make sure that inferior alternatives identified by the principles of strong and weak dominance are eliminated from consideration.[72]

The value of CEA is enhanced when there is consistency in the analysis across a diverse set of possible regulatory actions. To achieve consistency, you need to carefully construct the two key components of any CEA: the cost and the "effectiveness" or performance measures for the alternative policy options.

---

[71] For a full discussion of CEA, see Gold, ML, Siegel, JE, Russell, LB, and Weinstein, MC (1996), *Cost Effectiveness in Health and Medicine: The Report of the Panel on Cost-Effectiveness in Health and Medicine*, Oxford University Press, New York.

[72] Gold ML, Siegel JE, Russell LB, and Weinstein MC (1996), *Cost Effectiveness in Health and Medicine: The Report of the Panel on Cost-Effectiveness in Health and Medicine*, Oxford University Press, New York, pp. 284-285.

With regard to measuring costs, you should be sure to include all the relevant costs to society – whether public or private. Rulemakings may also yield cost savings (e.g., energy savings associated with new technologies). The numerator in the cost-effectiveness ratio should reflect net costs, defined as the gross cost incurred to comply with the requirements (sometimes called "total" costs) minus any cost savings. You should be careful to avoid double-counting effects in both the numerator and the denominator of the cost-effectiveness ratios. For example, it would be incorrect to reduce gross costs by an estimated monetary value on life extension if life-years are already used as the effectiveness measure in the denominator.

In constructing measures of "effectiveness", final outcomes, such as lives saved or life-years saved, are preferred to measures of intermediate outputs, such as tons of pollution reduced, crashes avoided, or cases of disease avoided. Where the quality of the measured unit varies (e.g., acres of wetlands vary substantially in terms of their ecological benefits), it is important that the measure capture the variability in the value of the selected "outcome" measure. You should provide an explanation of your choice of effectiveness measure.

Where regulation may yield several different beneficial outcomes, a cost-effectiveness comparison becomes more difficult to interpret because there is more than one measure of effectiveness to incorporate in the analysis. To arrive at a single measure you will need to weight the value of disparate benefit categories, but this computation raises some of the same difficulties you will encounter in BCA. If you can assign a reasonable monetary value to all of the regulation's different benefits, then you should do so. But in this case, you will be doing BCA, not CEA.

When you can estimate the monetary value of *some* but not all of the ancillary benefits of a regulation, but cannot assign a monetary value to the primary measure of effectiveness, you should subtract the monetary estimate of the ancillary benefits from the gross cost estimate to yield an estimated net cost. (This net cost estimate for the rule may turn out to be negative – that is, the monetized benefits exceed the cost of the rule.) If you are unable to estimate the value of some of the ancillary benefits, the cost-effectiveness ratio will be overstated, and this should be acknowledged in your analysis. CEA does not yield an unambiguous choice when there are benefits or costs that have not been incorporated in the net-cost estimates. You also may use CEA to compare regulatory alternatives in cases where the statute specifies the level of benefits to be achieved.

The Effectiveness Metric for Public Health and Safety Rulemakings

When CEA is applied to public health and safety rulemakings, one or more measures 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, and cases of paraplegia prevented. Sometimes these measures 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.

The main advantage of the integrated measures of effectiveness is that they account for a rule's impact on morbidity (nonfatal illness, injury, impairment and quality of life) as well as premature death. The inclusion of morbidity effects is important because (a) some illnesses (e.g., asthma) cause more instances of pain and suffering than they do premature death, (b) some population groups are known to experience elevated rates of morbidity (e.g, the elderly and the poor) and thus have a strong interest in morbidity measurement[73], and (c) some regulatory alternatives may be more effective at preventing morbidity than premature death (e.g., some advanced airbag designs may diminish the nonfatal injuries caused by airbag inflation without changing the frequency of fatal injury prevented by airbags).

However, the main drawback of these integrated measures is that they must meet some restrictive assumptions to represent a valid measure of individual preferences.[74] For example, a QALY measure implicitly assumes that the fraction of remaining lifespan an individual would give up for an improvement in health-related quality of life does not depend on the remaining lifespan. Thus, if an individual is willing to give up 10 years of life among 50 remaining years for a given health improvement, he or she would also be willing to give up 1 year of life among 5 remaining years. To the extent that individual preferences deviate from these assumptions, analytic results from CEA using QALYs could differ from analytic results based on willingness-to-pay-measures.[75] Though willingness to pay is generally the preferred economic method for evaluating preferences, the CEA method, as applied in medicine and health, does not evaluate health changes using individual willingness to pay. When performing CEA, you should consider using at least one integrated measure of effectiveness when a rule creates a significant impact on both mortality and morbidity.

When CEA is performed in specific rulemaking contexts, you should be prepared to make appropriate adjustments to ensure fair treatment of all segments of the population. Fairness is important in the choice and execution of effectiveness measures. For example, if QALYs are used to evaluate a lifesaving rule aimed at a population that happens to experience a high rate of disability (i.e., where the rule is not designed to affect the disability), the number of life years saved should not necessarily be diminished simply because the rule saves the lives of people with life-shortening disabilities. Both analytic simplicity and fairness suggest that the estimated number of life years saved for the disabled population should be based on average life expectancy information for the relevant age cohorts. More generally, when numeric adjustments are made for life expectancy or quality of life, analysts should prefer use of population averages rather than information derived from subgroups dominated by a particular demographic or income group.

---

[73] Russell LB and Sisk JE (2000), "Modeling Age Differences in Cost Effectiveness Analysis", *International Journal of Technology Assessment in Health Care*, 16(4), 1158-1167.

[74] Pliskin JS, Shepard DS, and Weinstein MC (1980), "Utility Functions for Life Years and Health Status," *Operations Research*, 28(1), 206-224.

[75] Hammitt JK (2002), "QALYs Versus WTP," *Risk Analysis*, 22(5), pp. 985-1002.

OMB does not require agencies to use any specific measure of effectiveness. In fact, OMB encourages agencies to report results with multiple measures of effectiveness that offer different insights and perspectives. The regulatory analysis should explain which measures were selected and why, and how they were implemented.

The analytic discretion provided in choice of effectiveness measure will create some inconsistency in how agencies evaluate the same injuries and diseases, and it will be difficult for OMB and the public to draw meaningful comparisons between rulemakings that employ different effectiveness measures. As a result, agencies should use their web site to provide OMB and the public with the underlying data, including mortality and morbidity data, the age distribution of the affected populations, and the severity and duration of disease conditions and trauma, so that OMB and the public can construct apples-to-apples comparisons between rulemakings that employ different measures.

There are sensitive technical and ethical issues associated with choosing one or more of these integrated measures for use throughout the Federal government. The Institute of Medicine (IOM) may assemble a panel of specialists in cost-effectiveness analysis and bioethics to evaluate the advantages and disadvantages of these different measures and other measures that have been suggested in the academic literature. OMB believes that the IOM guidance will provide Federal agencies and OMB useful insight into how to improve the measurement of effectiveness of public health and safety regulations.

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). Benefits and costs of a regulation may also be distributed unevenly over time, perhaps spanning several generations. Distributional effects may arise through "transfer payments" that stem from a regulatory action as well. For example, the revenue collected through a fee, surcharge in excess of the cost of services provided, or tax is a transfer payment.

Your 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. Executive Order 12866 authorizes 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. You should be alert for situations in which regulatory alternatives result in significant changes in treatment or outcomes for different groups. Effects on the distribution of income that are transmitted through changes in market prices can be important, albeit sometimes difficult to assess. Your analysis should also present information on the streams of benefits and costs over time in order to provide a basis for assessing intertemporal distributional consequences, particularly where intergenerational effects are concerned.

E. Identifying and Measuring Benefits and Costs

This Section provides guidelines for your preparation of the benefit and cost estimates required by Executive Order 12866 and the "Regulatory Right-to-Know Act." The discussions in previous sections will help you identify a workable number of alternatives for consideration in your analysis and an appropriate analytical approach to use.

General Issues

1. Scope of Analysis

Your analysis should focus on benefits and costs that accrue to citizens and residents of the United States. Where you choose to evaluate a regulation that is likely to have effects beyond the borders of the United States, these effects should be reported separately. The time frame for your analysis should cover a period long enough to encompass all the important benefits and costs likely to result from the rule.

2. Developing a Baseline

You need to measure the benefits and costs of a rule against a baseline. This baseline should be the best assessment of the way the world would look absent the proposed action. The choice of an appropriate baseline may require consideration of a wide range of potential factors, including:

- evolution of the market,
- changes in external factors affecting expected benefits and costs,
- changes in regulations promulgated by the agency or other government entities, and
- the degree of compliance by regulated entities with other regulations.

It may be reasonable to forecast that the world absent the regulation will resemble the present. If this is the case, however, your baseline should reflect the future effect of current government programs and policies. For review of an existing regulation, a baseline assuming "no change" in the regulatory program generally provides an appropriate basis for evaluating regulatory alternatives. When more than one baseline is reasonable and the choice of baseline will significantly affect estimated benefits and costs, you should consider measuring benefits and costs against alternative baselines. In doing so you can analyze the effects on benefits and costs of making different assumptions about other agencies' regulations, or the degree of compliance with your own existing rules. In all cases, you must evaluate benefits and costs against the same baseline. You should also discuss the reasonableness of the baselines used in the sensitivity analyses. For each baseline you use, you should identify the key uncertainties in your forecast.

EPA's 1998 final PCB disposal rule provides a good example of using different baselines. EPA used several alternative baselines, each reflecting a different interpretation of existing regulatory requirements. In particular, one baseline reflected a literal interpretation of EPA's 1979 rule and another the actual implementation of that rule in the year immediately preceding the 1998 revision. The use of multiple baselines illustrated the substantial effect changes in

EPA's implementation policy could have on the cost of a regulatory program. In the years after EPA adopted the 1979 PCB disposal rule, changes in EPA policy -- especially allowing the disposal of automobile "shredder fluff" in municipal landfills -- reduced the cost of the program by more than $500 million per year.

In some cases, substantial portions of a rule may simply restate statutory requirements that would be self-implementing, even in the absence of the regulatory action. In these cases, you should use a pre-statute baseline. If you are able to separate out those areas where the agency has discretion, you may also use a post-statute baseline to evaluate the discretionary elements of the action.

3. Evaluation of Alternatives

You should describe the alternatives available to you and the reasons for choosing one alternative over another. As noted previously, alternatives that rely on incentives and offer increased flexibility are often more cost-effective than more prescriptive approaches. For instance, user fees and information dissemination may be good alternatives to direct command-and-control regulation. Within a command-and-control regulatory program, performance-based standards generally offer advantages over standards specifying design, behavior, or manner of compliance.

You should carefully consider all appropriate alternatives for the key attributes or provisions of the rule. The previous discussion outlines examples of appropriate alternatives. Where there is a "continuum" of alternatives for a standard (such as the level of stringency), you generally should analyze at least three options: the preferred option; a more stringent option that achieves additional benefits (and presumably costs more) beyond those realized by the preferred option; and a less stringent option that costs less (and presumably generates fewer benefits) than the preferred option.

You should choose reasonable alternatives deserving careful consideration. In some cases, a regulatory program will focus on an option that is near or at the limit of technical feasibility. In this case, the analysis would not need to examine a more stringent option. For each of the options analyzed, you should compare the anticipated benefits to the corresponding costs.

It is not adequate simply to report a comparison of the agency's preferred option to the chosen baseline. Whenever you report the benefits and costs of alternative options, you should present both total and incremental benefits and costs. You should present incremental benefits and costs as differences from the corresponding estimates associated with the next less-stringent alternative.[76] It is important to emphasize that incremental effects are simply differences between successively more stringent alternatives. Results involving a comparison to a "next best" alternative may be especially useful.

[76] For the least stringent alternative, you should estimate the incremental benefits and costs relative to the baseline. Thus, for this alternative, the incremental effects would be the same as the corresponding totals. For each alternative that is more stringent than the least stringent alternative, you should estimate the incremental benefits and costs relative to the closest less-stringent alternative.

In some cases, you may decide to analyze a wide array of options. In 1998, DOE analyzed a large number of options in setting new energy efficiency standards for refrigerators and freezers and produced a rich amount of information on their relative effects. This analysis -- examining more than 20 alternative performance standards for one class of refrigerators with top-mounted freezers -- enabled DOE to select an option that produced $200 more in estimated net benefits per refrigerator than the least attractive option.

You should analyze the benefits and costs of different regulatory provisions separately when a rule includes a number of distinct provisions. If the existence of one provision affects the benefits or costs arising from another provision, the analysis becomes more complicated, but the need to examine provisions separately remains. In this case, you should evaluate each specific provision by determining the net benefits of the proposed regulation with and without it.

Analyzing all possible combinations of provisions is impractical if the number is large and interaction effects are widespread. You need to use judgment to select the most significant or relevant provisions for such analysis. You are expected to document all of the alternatives that were considered in a list or table and which were selected for emphasis in the main analysis.

You should also discuss the statutory requirements that affect the selection of regulatory approaches. If legal constraints prevent the selection of a regulatory action that best satisfies the philosophy and principles of Executive Order 12866, you should identify these constraints and estimate their opportunity cost. Such information may be useful to Congress under the Regulatory Right-to-Know Act.

4. Transparency and Reproducibility of Results

Because of its influential nature and its special role in the rulemaking process, it is appropriate to set minimum quality standards for regulatory analysis. You should provide documentation that the analysis is based on the best reasonably obtainable scientific, technical, and economic information available. To achieve this, you should rely on peer-reviewed literature, where available, and provide the source for all original information.

A good analysis should be transparent and your results must be reproducible. You should clearly set out the basic assumptions, methods, and data underlying the analysis and discuss the uncertainties associated with the estimates. A qualified third party reading the analysis should be able to understand the basic elements of your analysis and the way in which you developed your estimates.

To provide greater access to your analysis, you should generally post it, with all the supporting documents, on the internet so the public can review the findings. You should also disclose the use of outside consultants, their qualifications, and history of contracts and employment with the agency (e.g., in a preface to the RIA). Where other compelling interests (such as privacy, intellectual property, trade secrets, etc.) prevent the public release of data or key elements of the analysis, you should apply especially rigorous robustness checks to analytic results and document the analytical checks used.

Finally, you should assure compliance with the Information Quality Guidelines for your agency and OMB's "Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies" ("data quality guidelines") http://www.whitehouse.gov/omb/fedreg/reproducible.html.

Developing Benefit and Cost Estimates

1. Some General Considerations

The analysis document should discuss the expected benefits and costs of the selected regulatory option and any reasonable alternatives. How is the proposed action expected to provide the anticipated benefits and costs? What are the monetized values of the potential real incremental benefits and costs to society? To present your results, you should:

- include separate schedules of the monetized benefits and costs that show the type and timing of benefits and costs, and express the estimates in this table in constant, undiscounted dollars (for more on discounting see "*Discount Rates*" below);
- list the benefits and costs you can quantify, but cannot monetize, including their timing;
- describe benefits and costs you cannot quantify; and
- identify or cross-reference the data or studies on which you base the benefit and cost estimates.

When benefit and cost estimates are uncertain (for more on this see "*Treatment of Uncertainty*" below), you should report benefit and cost estimates (including benefits of risk reductions) that reflect the full probability distribution of potential consequences. Where possible, present probability distributions of benefits and costs and include the upper and lower bound estimates as complements to central tendency and other estimates.

If fundamental scientific disagreement or lack of knowledge prevents construction of a scientifically defensible probability distribution, you should describe benefits or costs under plausible scenarios and characterize the evidence and assumptions underlying each alternative scenario.

2. The Key Concepts Needed to Estimate Benefits and Costs

"Opportunity cost" is the appropriate concept for valuing both benefits and costs. The principle of "willingness-to-pay" (WTP) captures the notion of opportunity cost by measuring what individuals are willing to forgo to enjoy a particular benefit. In general, economists tend to view WTP as the most appropriate measure of opportunity cost, but an individual's "willingness-to-accept" (WTA) compensation for not receiving the improvement can also provide a valid measure of opportunity cost.

WTP and WTA are comparable measures under special circumstances. WTP and WTA measures may be comparable in the following situations: if a regulation affects a price change rather than a quantity change; the change being evaluated is small; there are reasonably close

substitutes available; and the income effect is small.[77] However, empirical evidence from experimental economics and psychology shows that even when income/wealth effects are "small", the measured differences between WTP and WTA can be large.[78] WTP is generally considered to be more readily measurable. Adoption of WTP as the measure of value implies that individual preferences of the affected population should be a guiding factor in the regulatory analysis.

Market prices provide rich data for estimating benefits and costs based on willingness-to-pay if the goods and services affected by the regulation are traded in well-functioning competitive markets. The opportunity cost of an alternative includes the value of the benefits forgone as a result of choosing that alternative. The opportunity cost of banning a product -- a drug, food additive, or hazardous chemical -- is the forgone net benefit (i.e., lost consumer and producer surplus[79]) of that product, taking into account the mitigating effects of potential substitutes.

The use of any resource has an opportunity cost regardless of whether the resource is already owned or has to be purchased. That opportunity cost is equal to the net benefit the resource would have provided in the absence of the requirement. For example, if regulation of an industrial plant affects the use of additional land or buildings within the existing plant boundary, the cost analysis should include the opportunity cost of using the additional land or facilities.

To the extent possible, you should monetize any such forgone benefits and add them to the other costs of that alternative. You should also try to monetize any cost savings as a result of an alternative and either add it to the benefits or subtract it from the costs of that alternative. However, you should not assume that the "avoided" costs of not doing another regulatory alternative represent the benefits of a regulatory action where there is no direct, necessary relationship between the two. You should also be careful when the costs avoided are attributable to an existing regulation. Even when there is a direct relationship between the two regulatory actions, the use of avoided costs is problematic because the existing regulation may not maximize net benefits and thus may itself be questionable policy. (See the section, "Direct Use of Market Data," for more detail.)

Estimating benefits and costs when market prices are hard to measure or markets do not exist is more difficult. In these cases, you need to develop appropriate proxies that simulate market exchange. Estimates of willingness-to-pay based on revealed preference methods can be quite useful. As one example, analysts sometimes use "hedonic price equations" based on multiple regression analysis of market behavior to simulate market prices for the commodity of interest. The hedonic technique allows analysts to develop an estimate of the price for specific

[77] See Hanemann WM (1991), *American Economic Review*, 81(3), 635-647.
[78] See Kahneman D, Knetsch JL, and Thaler RH (1991), "Anomalies: The Endowment Effect, Loss Aversion, and Status Quo Bias," *Journal of Economic Perspectives* 3(1), 192-206.
[79] Consumer surplus is the difference between what a consumer pays for a unit of a good and the maximum amount the consumer would be willing to pay for that unit. It is measured by the area between the price and the demand curve for that unit. Producer surplus is the difference between the amount a producer is paid for a unit of a good and the minimum amount the producer would accept to supply that unit. It is measured by the area between the price and the supply curve for that unit.

attributes associated with a product. For instance, a house is a product characterized by a variety of attributes including the number of rooms, total floor area, and type of heating and cooling. If there are enough data on transactions in the housing market, it is possible to develop an estimate of the implicit price for specific attributes, such as the implicit price of an additional bathroom or for central air conditioning. This technique can be extended, as well, to develop an estimate for the implicit price of public goods that are not directly traded in markets. An analyst can develop implicit price estimates for public goods like air quality and access to public parks by assessing the effects of these goods on the housing market. Going through the analytical process of deriving benefit estimates by simulating markets may also suggest alternative regulatory strategies that create such markets.

You need to guard against double-counting, since some attributes are embedded in other broader measures. To illustrate, when a regulation improves the quality of the environment in a community, the value of real estate in the community generally rises to reflect the greater attractiveness of living in a better environment. Simply adding the increase in property values to the estimated value of improved public health would be double counting if the increase in property values reflects the improvement in public health. To avoid this problem you should separate the embedded effects on the value of property arising from improved public health. At the same time, an analysis that fails to incorporate the consequence of land use changes when accounting for costs will not capture the full effects of regulation.

3. Revealed Preference Methods

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, it may be feasible to determine accurately and precisely the monetary value needed for a rulemaking. There is a large and well-developed literature on revealed preference in the peer-reviewed, applied economics literature.

Although these methods are well grounded in economic theory, they are sometimes difficult to implement given the complexity of market transactions and the paucity of relevant data. When designing or evaluating a revealed preference study, the following principles should be considered:

- the market should be competitive. If the market isn't competitive (e.g., monopoly, oligopoly), then you should consider making adjustments such that the price reflects the true value to society (often called the "shadow price");
- the market should not exhibit a significant information gap or asymmetric information problem. If the market suffers from information problems, then you should discuss the divergence of the price from the underlying shadow price and consider possible adjustments to reflect the underlying shadow price;
- the market should not exhibit an externality. In this case, you should discuss the divergence of the price from the underlying shadow price and consider possible adjustments to reflect the underlying shadow price;
- the specific market participants being studied should be representative of the target

populations to be affected by the rulemaking under consideration;

- a valid research design and framework for analysis should be adopted. Examples include using data and/or model specifications that include the markets for substitute and complementary goods and services and using reasonably unrestricted functional forms. When specifying substitute and complementary goods, the analysis should preferably be based on data about the range of alternatives perceived by market participants. If such data are not available, you should adopt plausible assumptions and describe the limitations of the analysis.
- the statistical and econometric models employed should be appropriate for the application and the resulting estimates should be robust in response to plausible changes in model specification and estimation technique; and
- the results should be consistent with economic theory.

You should also determine whether there are multiple revealed-preference studies of the same good or service and whether anything can be learned by comparing the methods, data and findings from different studies. Professional judgment is required to determine whether a particular study is of sufficient quality to justify use in regulatory analysis. When studies are used in regulatory analysis despite their technical weaknesses (e.g., due to the absence of other evidence), the regulatory analysis should discuss any biases or uncertainties that are likely to arise due to those weaknesses. If a study has major weaknesses, the study should not be used in regulatory analysis.

a. Direct Uses of Market Data

Economists ordinarily consider market prices as the most accurate measure of the marginal value of goods and services to society. In some instances, however, market prices may not reflect the true value of goods and services due to market imperfections or government intervention. If a regulation involves changes to goods or services where the market price is not a good measure of the value to society, you should use an estimate that reflects the shadow price. Suppose a particular air pollutant damages crops. One of the benefits of controlling that pollutant is the value of the crop yield increase as a result of the controls. That value is typically measured by the price of the crop. However, if the price is held above the market price by a government program that affects supply, a value estimate based on this price may not reflect the true benefits of controlling the pollutant. In this case, you should calculate the value to society of the increase in crop yields by estimating the shadow price, which reflects the value to society of the marginal use of the crop. If the marginal use is for exports, you should use the world price. If the marginal use is to add to very large surplus stockpiles, you should use the value of the last units released from storage minus storage cost. If stockpiles are large and growing, the shadow price may be low or even negative.

Other goods whose market prices may not reflect their true value include those whose production or consumption results in substantial (1) positive or negative external effects or (2) transfer payments. For example, the observed market price of gasoline may not reflect marginal social value due to the inclusion of taxes, other government interventions, and negative externalities (e.g., pollution). This shadow price may also be needed for goods whose market price is substantially affected by existing regulations that do not maximize net benefits.

b. Indirect Uses of Market Data

Many goods or attributes of goods that are affected by regulation--such as preserving environmental or cultural amenities--are not traded directly in markets. The value for these goods or attributes arise both from use and non-use. Estimation of these values is difficult because of the absence of an organized market. However, overlooking or ignoring these values in your regulatory analysis may significantly understate the benefits and/or costs of regulatory action.

"Use values" arise where an individual derives satisfaction from using the resource, either now or in the future. Use values are associated with activities such as swimming, hunting, and hiking where the individual makes use of the natural environment.

"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. Non-use value includes bequest and existence values.

General altruism for the health and welfare of others is a closely related concept but may not be strictly considered a "non-use" value.[80] A general concern for the welfare of others should supplement benefits and costs equally; hence, it is not necessary to measure the size of general altruism in regulatory analysis. If there is evidence of selective altruism, it needs to be considered specifically in both benefits and costs.

Some goods and services are indirectly traded in markets, which means that their value is reflected in the prices of related goods and services that are directly traded in markets. Their use values are typically estimated through revealed preference methods. Examples include estimates of the values of environmental amenities derived from travel-cost studies, and hedonic price models that measure differences or changes in the value of real estate. It is important that you utilize revealed preference models that adhere to economic criteria that are consistent with utility maximizing behavior. Also, you should take particular care in designing protocols for reliably estimating the values of these attributes.

4. Stated Preference Methods

Stated Preference Methods (SPM) have been developed and used in the peer-reviewed literature to estimate both "use" and "non-use" values of goods and services. They have also been widely used in regulatory analyses by Federal agencies, in part, because these methods can be creatively employed to address a wide variety of goods and services that are not easy to study through revealed preference methods.

The distinguishing feature of these methods is that hypothetical questions about use or non-use values are posed to survey respondents in order to obtain willingness-to-pay estimates relevant to benefit or cost estimation. Some examples of SPM include contingent valuation, conjoint analysis and risk-tradeoff analysis. The surveys used to obtain the health-utility values

[80] See McConnell KE (1997), *Journal of Environmental Economics and Management*, *32*, 22-37.

used in CEA are similar to stated-preference surveys but do not entail monetary measurement of value. Nevertheless, the principles governing quality stated-preference research, with some obvious exceptions involving monetization, are also relevant in designing quality health-utility research.

When you are designing or evaluating a stated-preference study, the following principles should be considered:

- the good or service being evaluated should be explained to the respondent in a clear, complete and objective fashion, and the survey instrument should be pre-tested;
- willingness-to-pay questions should be designed to focus the respondent on the reality of budgetary limitations and alerted to the availability of substitute goods and alternative expenditure options;
- the survey instrument should be designed to probe beyond general attitudes (e.g., a "warm glow" effect for a particular use or non-use value) and focus on the magnitude of the respondent's economic valuation;
- the analytic results should be consistent with economic theory using both "internal" (within respondent) and "external" (between respondent) scope tests such as the willingness to pay is larger (smaller) when more (less) of a good is provided;
- the subjects being interviewed should be selected/sampled in a statistically appropriate manner. The sample frame should adequately cover the target population. The sample should be drawn using probability methods in order to generalize the results to the target population;
- response rates should be as high as reasonably possible. Best survey practices should be followed to achieve high response rates. Low response rates increase the potential for bias and raise concerns about the generalizability of the results. If response rates are not adequate, you should conduct an analysis of non-response bias or further study. Caution should be used in assessing the representativeness of the sample based solely on demographic profiles. Statistical adjustments to reduce non-response bias should be undertaken whenever feasible and appropriate;
- the mode of administration of surveys (in-person, phone, mail, computer, internet or multiple modes) should be appropriate in light of the nature of the questions being posed to respondents and the length and complexity of the instrument;
- documentation should be provided about the target population, the sampling frame used and its coverage of the target population, the design of the sample including any stratification or clustering, the cumulative response rate (including response rate at each stage of selection if applicable); the item non-response rate for critical questions; the exact wording and sequence of questions and other information provided to respondents; and the training of interviewers and techniques they employed (as appropriate);
- the statistical and econometric methods used to analyze the collected data should be transparent, well suited for the analysis, and applied with rigor and care.

Professional judgment is necessary to apply these criteria to one or more studies, and thus there is no mechanical formula that can be used to determine whether a particular study is of sufficient quality to justify use in regulatory analysis. When studies are used despite having weaknesses on one or more of these criteria, those weaknesses should be acknowledged in the

regulatory analysis, including any resulting biases or uncertainties that are likely to result. If a study has too many weaknesses with unknown consequences for the quality of the data, the study should not be used.

The challenge in designing quality stated-preference studies is arguably greater for non-use values and unfamiliar use values than for familiar goods or services that are traded (directly or indirectly) in market transactions. The good being valued may have little meaning to respondents, and respondents may be forming their valuations for the first time in response to the questions posed. Since these values are effectively constructed by the respondent during the elicitation, the instrument and mode of administration should be rigorously pre-tested to make sure that responses are not simply an artifact of specific features of instrument design and/or mode of administration.

Since SPM generate data from respondents in a hypothetical setting, often on complex and unfamiliar goods, special care is demanded in the design and execution of surveys, analysis of the results, and characterization of the uncertainties. A stated-preference study may be the only way to obtain quantitative information about non-use values, though a number based on a poor quality study is not necessarily superior to no number at all. Non-use values that are not quantified should be presented as an "intangible" benefit or cost.

If both revealed-preference and stated-preference studies that are directly applicable to regulatory analysis are available, you should consider both kinds of evidence and compare the findings. If the results diverge significantly, you should compare the overall size and quality of the two bodies of evidence. Other things equal, you should prefer revealed preference data over stated preference data because revealed preference data are based on actual decisions, where market participants enjoy or suffer the consequences of their decisions. This is not generally the case for respondents in stated preference surveys, where respondents may not have sufficient incentives to offer thoughtful responses that are more consistent with their preferences or may be inclined to bias their responses for one reason or another.

5. Benefit-Transfer Methods

It is often preferable to collect original data on revealed preference or stated preference to support regulatory analysis. Yet conducting an original study may not be feasible due to the time and expense involved. One alternative to conducting an original study is the use of "benefit transfer" methods. (The transfer may involve cost determination as well). The practice of "benefit transfer" began with transferring existing estimates obtained from indirect market and stated preference studies to new contexts (i.e., the context posed by the rulemaking). The principles that guide transferring estimates from indirect market and stated preference studies should apply to direct market studies as well.

Although benefit-transfer can provide a quick, low-cost approach for obtaining desired monetary values, the methods are often associated with uncertainties and potential biases of unknown magnitude. It should therefore be treated as a last-resort option and not used without explicit justification.

In conducting benefit transfer, the first step is to specify the value to be estimated for the rulemaking. You should identify the relevant measure of the policy change at this initial stage. For instance, you can derive the relevant willingness-to-pay measure by specifying an indirect utility function. This identification allows you to "zero in" on key aspects of the benefit transfer.

The next step is to identify appropriate studies to conduct benefit transfer. In selecting transfer studies for either point transfers or function transfers, you should base your choices on the following criteria:

- The selected studies should be based on adequate data, sound and defensible empirical methods and techniques.
- The selected studies should document parameter estimates of the valuation function.
- The study context and policy context should have similar populations (e.g., demographic characteristics). The market size (e.g., target population) between the study site and the policy site should be similar. For example, a study valuing water quality improvement in Rhode Island should not be used to value policy that will affect water quality throughout the United States.
- The good, and the magnitude of change in that good, should be similar in the study and policy contexts.
- The relevant characteristics of the study and the policy contexts should be similar. For example, the effects examined in the original study should be "reversible" or "irreversible" to a degree that is similar to the regulatory actions under consideration.
- The distribution of property rights should be similar so that the analysis uses the same welfare measure. If the property rights in the study context support the use of WTA measures while the rights in the rulemaking context support the use of WTP measures, benefit transfer is not appropriate.
- The availability of substitutes across study and policy contexts should be similar.

If you can choose between transferring a function or a point estimate, you should transfer the entire demand function (referred to as benefit function transfer) rather than adopting a single point estimate (referred to as benefit point transfer).[81]

Finally, you should not use benefit transfer in estimating benefits if:

- resources are unique or have unique attributes. For example, if a policy change affects snowmobile use in Yellowstone National Park, then a study valuing snowmobile use in the state of Michigan should not be used to value changes in snowmobile use in the Yellowstone National Park.
- If the study examines a resource that is unique or has unique attributes, you should not transfer benefit estimates or benefit functions to value a different resource and vice versa. For example, if a study values visibility improvements at the Grand Canyon, these results should not be used to value visibility improvements in urban areas.
- There are significant problems with applying an *"ex ante"* valuation estimate to an *"ex*

[81] See Loomis JB (1992), *Water Resources Research*, *28*(3), 701-705 and Kirchoff, S, Colby, BG, and LaFrance, JT (1997), *Journal of Environmental Economics and Management*, *33*, 75-93.

post" policy context. If a policy yields a significant change in the attributes of the good, you should not use the study estimates to value the change using a benefit transfer approach.

- You also should not use a value developed from a study involving, small marginal changes in a policy context involving large changes in the quantity of the good.

Clearly, all of these criteria are difficult to meet. However, you should attempt to satisfy as many as possible when choosing studies from the existing economic literature. Professional judgment is required in determining whether a particular transfer is too speculative to use in regulatory analysis.

6. Ancillary Benefits and Countervailing Risks

Your analysis should look beyond the direct benefits and direct costs of your rulemaking and consider any important ancillary benefits and countervailing risks. An ancillary benefit is a favorable impact of the rule that is typically unrelated or secondary to the statutory purpose of the rulemaking (e.g., reduced refinery emissions due to more stringent fuel economy standards for light trucks) while a countervailing risk is an adverse economic, health, safety, or environmental consequence that occurs due to a rule and is not already accounted for in the direct cost of the rule (e.g., adverse safety impacts from more stringent fuel-economy standards for light trucks).

You should begin by considering and perhaps listing the possible ancillary benefits and countervailing risks. However, highly speculative or minor consequences may not be worth further formal analysis. Analytic priority should be given to those ancillary benefits and countervailing risks that are important enough to potentially change the rank ordering of the main alternatives in the analysis. In some cases the mere consideration of these secondary effects may help in the generation of a superior regulatory alternative with strong ancillary benefits and fewer countervailing risks. For instance, a recent study suggested that weight-based, fuel-economy standards could achieve energy savings with fewer safety risks and employment losses than would occur under the current regulatory structure.

Like other benefits and costs, an effort should be made to quantify and monetize ancillary benefits and countervailing risks. If monetization is not feasible, quantification should be attempted through use of informative physical units. If both monetization and quantification are not feasible, then these issues should be presented as non-quantified benefits and costs. The same standards of information and analysis quality that apply to direct benefits and costs should be applied to ancillary benefits and countervailing risks.

One way to combine ancillary benefits and countervailing risks is to evaluate these effects separately and then put both of these effects on the benefits side, not on the cost side. Although it is theoretically appropriate to include disbenefits on the cost side, legal and programmatic considerations generally support subtracting the disbenefits from direct benefits.

7. Methods for Treating 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 understand the magnitudes of the effects of alternative actions. However, some important benefits and costs (e.g., privacy protection) may be inherently too difficult to quantify or monetize given current data and methods. You should carry out a careful evaluation of non-quantified benefits and costs. Some authorities[82] refer to these non-monetized and non-quantified effects as "intangible".

a. Benefits and Costs that are Difficult to Monetize

You should monetize quantitative estimates whenever possible. Use sound and defensible values or procedures to monetize benefits and costs, and ensure that key analytical assumptions are defensible. If monetization is impossible, explain why and present all available quantitative information. For example, if you can quantify but cannot monetize increases in water quality and fish populations resulting from water quality regulation, you can describe benefits in terms of stream miles of improved water quality for boaters and increases in game fish populations for anglers. You should describe the timing and likelihood of such effects and avoid double-counting of benefits when estimates of monetized and physical effects are mixed in the same analysis.

b. Benefits and Costs that are Difficult to Quantify

If you are not able to quantify the effects, you should present any relevant quantitative information along with a description of the unquantified effects, such as ecological gains, improvements in quality of life, and aesthetic beauty. You should provide a discussion of the strengths and limitations of the qualitative information. This should include information on the key reason(s) why they cannot be quantified. In one instance, you may know with certainty the magnitude of a risk to which a substantial, but unknown, number of individuals are exposed. In another instance, the existence of a risk may be based on highly speculative assumptions, and the magnitude of the risk may be unknown.

For cases in which the unquantified benefits or costs affect a policy choice, you 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. Also, please include a summary table that lists all the unquantified benefits and costs, and use your professional judgment to highlight (e.g., with categories or rank ordering) those that you believe are most important (e.g., by considering factors such as the degree of certainty, expected magnitude, and reversibility of effects).

While the focus is often placed on difficult to quantify benefits of regulatory action, some costs are difficult to quantify as well. Certain permitting requirements (e.g., EPA's New Source Review program) restrict the decisions of production facilities to shift to new products and adopt innovative methods of production. While these programs may impose substantial costs on the economy, it is very difficult to quantify and monetize these effects. Similarly, regulations that establish emission standards for recreational vehicles, like motor bikes, may adversely affect the

[82] Mishan EJ (1994), *Cost-Benefit Analysis*, fourth edition, Routledge, New York.

performance of the vehicles in terms of driveability and 0 to 60 miles per hour acceleration. Again, the cost associated with the loss of these attributes may be difficult to quantify and monetize. They need to be analyzed qualitatively.

8. Monetizing Health and Safety Benefits and Costs

We expect you to provide a benefit-cost analysis of major health and safety rulemakings in addition to a CEA. The BCA provides additional insight because (a) it provides some indication of what the public is willing to pay for improvements in health and safety and (b) it offers additional information on preferences for health using a different research design than is used in CEA. Since the health-preference methods used to support CEA and BCA have some different strengths and drawbacks, it is important that you provide decision makers with both perspectives.

In monetizing health benefits, a WTP measure is the conceptually appropriate measure as compared to other alternatives (e.g., cost of illness or lifetime earnings), in part because it attempts to capture pain and suffering and other quality-of-life effects. Using the WTP measure for health and safety allows you to directly compare your results to the other benefits and costs in your analysis, which will typically be based on WTP.

If well-conducted revealed-preference studies of relevant health and safety risks are available, you should consider using them in developing your monetary estimates. If appropriate revealed-preference data are not available, you should use valid and relevant data from stated-preference studies. You will need to use your professional judgment when you are faced with limited information on revealed preference studies and substantial information based on stated preference studies.

A key advantage of stated-preference and health-utility methods compared to revealed preference methods is that they can be tailored to address the ranges of probabilities, types of health risks and specific populations affected by your rule. In many rulemakings there will be no relevant information from revealed-preference studies. In this situation you should consider commissioning a stated-preference study or using values from published stated-preference studies. For the reasons discussed previously, you should be cautious about using values from stated-preference studies and describe in the analysis the drawbacks of this approach.

a. Nonfatal Health and Safety Risks

With regard to nonfatal health and safety risks, there is enormous diversity in the nature and severity of impaired health states. A traumatic injury that can be treated effectively in the emergency room without hospitalization or long-term care is different from a traumatic injury resulting in paraplegia. Severity differences are also important in evaluation of chronic diseases. A severe bout of bronchitis, though perhaps less frequent, is far more painful and debilitating than the more frequent bouts of mild bronchitis. The duration of an impaired health state, which can range from a day or two to several years or even a lifetime (e.g., birth defects inducing mental retardation), need to be considered carefully. Information on both the severity and

duration of an impaired health state is necessary before the task of monetization can be performed.

When monetizing nonfatal health effects, it is important to consider two components: (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 you use literature values to monetize nonfatal health and safety risks, it is important to make sure that the values you have selected are appropriate for the severity and duration of health effects to be addressed by your rule.

If data are not available to support monetization, you might consider an alternative approach that makes use of health-utility studies. Although the economics literature on the monetary valuation of impaired health states is growing, there is a much larger clinical literature on how patients, providers and community residents value diverse health states. This literature typically measures health utilities based on the standard gamble, the time tradeoff or the rating scale methods. This health utility information may be combined with known monetary values for well-defined health states to estimate monetary values for a wide range of health states of different severity and duration. If you use this approach, you should be careful to acknowledge your assumptions and the limitations of your estimates.

b. Fatality Risks

Since agencies often design health and safety regulation to reduce risks to life, evaluation of these benefits can be the key part of the analysis. A good analysis must present these benefits clearly and show their importance. Agencies may choose to monetize these benefits. The willingness-to-pay approach is the best methodology to use if reductions in fatality risk are monetized.

Some describe the monetized value of small changes in fatality risk as the "value of statistical life" (VSL) or, less precisely, the "value of a life." The latter phrase can be misleading because it suggests erroneously that the monetization exercise tries to place a “value” on individual lives. You should make clear that these terms refer to the measurement of willingness to pay for reductions in only small risks of premature death. They have no application to an identifiable individual or to very large reductions in individual risks. They do not suggest that any individual's life can be expressed in monetary terms. Their sole purpose is to help describe better the likely benefits of a regulatory action.

Confusion about the term "statistical life" is also widespread. This term refers to the sum of risk reductions expected in a population. For example, if the annual risk of death is reduced by one in a million for each of two million people, that is said to represent two "statistical lives" extended per year (2 million people x 1/1,000,000 = 2). If the annual risk of death is reduced by one in 10 million for each of 20 million people, that also represents two statistical lives extended.

The adoption of a value for the projected reduction in the risk of premature mortality is the subject of continuing discussion within the economic and public policy analysis community. A considerable body of academic literature is available on this subject. This literature involves either explicit or implicit valuation of fatality risks, and generally involves the use of estimates of VSL from studies on wage compensation for occupational hazards (which generally are in the range of 10^{-4} annually), on consumer product purchase and use decisions, or from an emerging literature using stated preference approaches. A substantial majority of the resulting estimates of VSL vary from roughly $1 million to $10 million per statistical life.[83]

There is a continuing debate within the economic and public policy analysis community on the merits of using a single VSL for all situations versus adjusting the VSL estimates to reflect the specific rule context. A variety of factors have been identified, including whether the mortality risk involves sudden death, the fear of cancer, and the extent to which the risk is voluntarily incurred.[84] The consensus of EPA's recent Science Advisory Board (SAB) review of this issue was that the available literature does not support adjustments of VSL for most of these factors. The panel did conclude that it was appropriate to adjust VSL to reflect changes in income and any time lag in the occurrence of adverse health effects.

The age of the affected population has also been identified as an important factor in the theoretical literature. However, the empirical evidence on age and VSL is mixed. In light of the continuing questions over the effect of age on VSL estimates, you should not use an age-adjustment factor in an analysis using VSL estimates.[85]

Another way that has been used 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 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. You should consider providing estimates of both VSL and VSLY, while recognizing the developing state of knowledge in this area.

Longevity may be only one of a number of relevant considerations pertaining to the rule. You should keep in mind that regulations with greater numbers of life-years extended are not necessarily better than regulations with fewer numbers of life-years extended. In any event, when you present estimates based on the VSLY method, you should adopt a larger VSLY

---

[83] See Viscusi WK and Aldy JE, *Journal of Risk and Uncertainty* (forthcoming) and Mrozek JR and Taylor LO (2002), *Journal of Policy Analysis and Management*, *21*(2), 253-270.

[84] Distinctions between "voluntary" and "involuntary" should be treated with care. Risks are best considered to fall within a continuum from "voluntary" to "involuntary" with very few risks at either end of this range. These terms are also related to differences in the cost of avoiding risks.

[85] Graham JD (2003), Memorandum to the President's Management Council, Benefit-Cost Methods and Lifesaving Rules. This memorandum can be found at http://www.whitehouse.gov/omb/inforeg/pmc_benefit_cost_memo.pdf

estimate for senior citizens because senior citizens face larger overall health risks from all causes and they may have accumulated savings to spend on their health and safety.[86]

The valuation of fatality risk reduction is an evolving area in both results and methodology. Hence, you should utilize valuation methods that you consider appropriate for the regulatory circumstances. Since the literature-based VSL estimates may not be entirely appropriate for the risk being evaluated (e.g., the use of occupational risk premia to value reductions in risks from environmental hazards), you should explain your selection of estimates and any adjustments of the estimates to reflect the nature of the risk being evaluated. You should present estimates based on alternative approaches, and if you monetize mortality risk reduction, you should do so on a consistent basis to the extent feasible. You should clearly indicate the methodology used and document your choice of a particular methodology. You should explain any significant deviations from the prevailing state of knowledge. If you use different methodologies in different rules, you should clearly disclose the fact and explain your choices.

c. Valuation of Reductions in Health and Safety Risks to Children

The valuation of health outcomes for children and infants poses special challenges. It is rarely feasible to measure a child's willingness to pay for health improvement and an adult's concern for his or her own health is not necessarily relevant to valuation of child health. For example, the wage premiums demanded by workers to accept hazardous jobs are not readily transferred to rules that accomplish health gains for children.

There are a few studies that examine parental willingness to pay to invest in health and safety for their children. Some of these studies suggest that parents may value children's health more strongly than their own health. Although this parental perspective is a promising research strategy, it may need to be expanded to include a societal interest in child health and safety.

Where the primary objective of a rule is to reduce the risk of injury, disease or mortality among children, you should conduct a cost-effectiveness analysis of the rule. You may also develop a benefit-cost analysis to the extent that valid monetary values can be assigned to the primary expected health outcomes. For rules where health gains are expected among both children and adults and you decide to perform a benefit-cost analysis, the monetary values for children should be at least as large as the values for adults (for the same probabilities and outcomes) unless there is specific and compelling evidence to suggest otherwise.[87]

Discount Rates

Benefits and costs do not always take place in the same time period. When they do not, it is incorrect simply to add all of the expected net benefits or costs without taking account of when the actually occur. If benefits or costs are delayed or otherwise separated in time from each other, the difference in timing should be reflected in your analysis.

[86] Office of Information and Regulatory Affairs, OMB, Memorandum to the President's Management Council, ibid.
[87] For more information, see Dockins C., Jenkins RR, Owens N, Simon NB, and Wiggins LB (2002), *Risk Analysis*, 22(2), 335-346.

As a first step, you should present the annual time stream of benefits and costs expected to result from the rule, clearly identifying when the benefits and costs are expected to occur. The beginning point for your stream of estimates should be the year in which the final rule will begin to have effects, even if that is expected to be some time in the future. The ending point should be far enough in the future to encompass all the significant benefits and costs likely to result from the rule.

In presenting the stream of benefits and costs, it is important to measure them in constant dollars to avoid the misleading effects of inflation in your estimates. If the benefits and costs are initially measured in prices reflecting expected future inflation, you can convert them to constant dollars by dividing through by an appropriate inflation index, one that corresponds to the inflation rate underlying the initial estimates of benefits or costs.

1. The Rationale for Discounting

Once these preliminaries are out of the way, you can begin to adjust your estimates for differences in timing. (This is a separate calculation from the adjustment needed to remove the effects of future inflation.) Benefits or costs that occur sooner are generally more valuable. The main rationales for the discounting of future impacts are:

(a) Resources that are invested will normally earn a positive return, so current consumption is more expensive than future consumption, since you are giving up that expected return on investment when you consume today.
(b) Postponed benefits also have a cost because people generally prefer present to future consumption. They are said to have positive time preference.
(c) Also, if consumption continues to increase over time, as it has for most of U.S. history, an increment of consumption will be less valuable in the future than it would be today, because the principle of diminishing marginal utility implies that as total consumption increases, the value of a marginal unit of consumption tends to decline.

There is wide agreement with point (a). Capital investment is productive, but that point is not sufficient by itself to explain positive interest rates and observed saving behavior. To understand these phenomena, points (b) and (c) are also necessary. If people are really indifferent between consumption now and later, then they should be willing to forgo current consumption in order to consume an equal or slightly greater amount in the future. That would cause saving rates and investment to rise until interest rates were driven to zero and capital was no longer productive. As long as we observe positive interest rates and saving rates below 100 percent, people must be placing a higher value on current consumption than on future consumption.

To reflect this preference, a discount factor should be used to adjust the estimated benefits and costs for differences in timing. The further in the future the benefits and costs are expected to occur, the more they should be discounted. The discount factor can be calculated given a discount rate. The formula is $1/ (1+ \text{the discount rate})^t$ where "t" measures the number of years in the future that the benefits or costs are expected to occur. Benefits or costs that have been adjusted in this way are called "discounted present values" or simply "present values".

When, and only when, the estimated benefits and costs have been discounted, they can be added to determine the overall value of net benefits.

2. Real Discount Rates of 3 Percent and 7 Percent

OMB's basic guidance on the discount rate is provided in OMB Circular A-94 (http://www.whitehouse.gov/omb/circulars/index.html). This Circular points out that the analytically preferred method of handling temporal differences between benefits and costs is to adjust all the benefits and costs to reflect their value in equivalent units of consumption and to discount them at the rate consumers and savers would normally use in discounting future consumption benefits. This is sometimes called the "shadow price" approach to discounting because doing such calculations requires you to value benefits and costs using shadow prices, especially for capital goods, to correct for market distortions. These shadow prices are not well established for the United States. Furthermore, the distribution of impacts from regulations on capital and consumption are not always well known. Consequently, any agency that wishes to tackle this challenging analytical task should check with OMB before proceeding.

As a default position, OMB Circular A-94 states that a real discount rate of 7 percent should be used as a base-case for regulatory analysis. The 7 percent rate is an estimate of the average before-tax rate of return to private capital in the U.S. economy. 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. OMB revised Circular A-94 in 1992 after extensive internal review and public comment. In a recent analysis, OMB found that the average rate of return to capital remains near the 7 percent rate estimated in 1992. Circular A-94 also recommends using other discount rates to show the sensitivity of the estimates to the discount rate assumption.

Economic distortions, including taxes on capital, create a divergence between the rate of return that savers earn and the private rate of return to capital. This divergence persists despite the tendency for capital to flow to where it can earn the highest rate of return. Although market forces will push after-tax rates of return in different sectors of the economy toward equality, that process will not equate pre-tax rates of return when there are differences in the tax treatment of investment. Corporate capital, in particular, pays an additional layer of taxation, the corporate income tax, which requires it to earn a higher pre-tax rate of return in order to provide investors with similar after-tax rates of return compared with non-corporate investments. The pre-tax rates of return better measure society's gains from investment. Since the rates of return on capital are higher in some sectors of the economy than others, the government needs to be sensitive to possible impacts of regulatory policy on capital allocation.

The effects of regulation do not always fall exclusively or primarily on the allocation of capital. When regulation primarily and directly affects private consumption (e.g., through higher consumer prices for goods and services), a lower discount rate is appropriate. The alternative most often used is sometimes called the "social rate of time preference." This simply means the rate at which "society" discounts future consumption flows to their present value. If we take the rate that the average saver uses to discount future consumption as our measure of the social rate

of time preference, then 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 terms on a pre-tax basis. For example, the yield on 10-year Treasury notes has averaged 8.1 percent since 1973 while the average annual rate of change in the CPI over this period has been 5.0 percent, implying a real 10-year rate of 3.1 percent.

For regulatory analysis, you should provide estimates of net benefits using both 3 percent and 7 percent. An example of this approach is EPA's analysis of its 1998 rule setting both effluent limits for wastewater discharges and air toxic emission limits for pulp and paper mills. In this analysis, EPA developed its present-value estimates using real discount rates of 3 and 7 percent applied to benefit and cost streams that extended forward for 30 years. You should present a similar analysis in your own work.

In some instances, if there is reason to expect that the regulation will cause resources to be reallocated away from private investment in the corporate sector, then the opportunity cost may lie outside the range of 3 to 7 percent. For example, the average real rate of return on corporate capital in the United States was approximately 10 percent in the 1990s, returning to the same level observed in the 1950s and 1960s. If you are uncertain about the nature of the opportunity cost, then you should present benefit and cost estimates using a higher discount rate as a further sensitivity analysis as well as using the 3 and 7 percent rates.

3. Time Preference for Health-Related Benefits and Costs

When future benefits or costs are health-related, some have questioned whether discounting is appropriate, since the rationale for discounting money may not appear to apply to health. It is true that lives saved today cannot be invested in a bank to save more lives in the future. But the resources that would have been used to save those lives can be invested to earn a higher payoff in future lives saved. People have been observed to prefer health gains that occur immediately to identical health gains that occur in the future. Also, if future health gains are not discounted while future costs are, then the following perverse result occurs: an attractive investment today in future health improvement can always be made more attractive by delaying the investment. For such reasons, there is a professional consensus that future health effects, including both benefits and costs, should be discounted at the same rate. This consensus applies to both BCA and CEA.

A common challenge in health-related analysis is to quantify the time lag between when a rule takes effect and when the resulting physical improvements in health status will be observed in the target population. In such situations, you must carefully consider the timing of health benefits before performing present-value calculations. It is not reasonable to assume that all of the benefits of reducing chronic diseases such as cancer and cardiovascular disease will occur immediately when the rule takes effect. For rules addressing traumatic injury, this lag period may be short. For chronic diseases it may take years or even decades for a rule to induce its full beneficial effects in the target population.

When a delay period between exposure to a toxin and increased probability of disease is likely (a so-called latency period), a lag between exposure reduction and reduced probability of

disease is also likely. This latter period has sometimes been referred to as a "cessation lag," and it may or may not be of the same duration as the latency period. As a general matter, cessation lags will only apply to populations with at least some high-level exposure (e.g., before the rule takes effect). For populations with no such prior exposure, such as those born after the rule takes effect, only the latency period will be relevant.

Ideally, your exposure-risk model would allow calculation of reduced risk for each year following exposure cessation, accounting for total cumulative exposure and age at the time of exposure reduction. The present-value benefits estimate could then reflect an appropriate discount factor for each year's risk reduction. Recent analyses of the cancer benefits stemming from reduction in public exposure to radon in drinking water have adopted this approach. They were supported by formal risk-assessment models that allowed estimates of the timing of lung cancer incidence and mortality to vary in response to different radon exposure levels.[88]

In many cases, you will not have the benefit of such detailed risk assessment modeling. You will need to use your professional judgment as to the average cessation lag for the chronic diseases affected by your rule. In situations where information exists on latency but not on cessation lags, it may be reasonable to use latency as a proxy for the cessation lag, unless there is reason to believe that the two are different. When the average lag time between exposures and disease is unknown, a range of plausible alternative values for the time lag should be used in your analysis.

4. Intergenerational Discounting

Special ethical 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 some consideration of their interest.

One way to do this would be to follow the same discounting techniques described above and supplement the analysis with an explicit discussion of the intergenerational concerns (how future generations will be affected by the regulatory decision). Policymakers would be provided with this additional information without changing the general approach to discounting.

Using the same discount rate across generations has the advantage of preventing time-inconsistency problems. For example, if one uses a lower discount rate for future generations, then the evaluation of a rule that has short-term costs and long-term benefits would become more favorable merely by waiting a year to do the analysis. Further, using the same discount rate across generations is attractive from an ethical standpoint. If one expects future generations to be better off, then giving them the advantage of a lower discount rate would in effect transfer resources from poorer people today to richer people tomorrow.

---

[88] Committee on Risk Assessment of Exposure to Radon in Drinking Water, Board on Radiation Effects Research, Commission on Life Sciences (1996), *Risk Assessment of Radon in Drinking Water*, National Research Council, National Academy Press, Washington, DC.

Some believe, however, that it is ethically impermissible to discount the utility of future generations. That is, government should treat all generations equally. Even under this approach, it would still be correct to discount future costs and consumption benefits generally (perhaps at a lower rate than for intragenerational analysis), due to the expectation that future generations will be wealthier and thus will value a marginal dollar of benefits or costs by less than those alive today. Therefore, it is appropriate to discount future benefits and costs relative to current benefits and costs, even if the welfare of future generations is not being discounted. Estimates of the appropriate discount rate appropriate in this case, from the 1990s, ranged from 1 to 3 percent per annum.[89]

A second reason for discounting the benefits and costs accruing to future generations at a lower rate is increased uncertainty about the appropriate value of the discount rate, the longer the horizon for the analysis. 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 explained by Martin Weitzman[90], in the limit for the deep future, the properly averaged certainty-equivalent discount factor (i.e., $1/[1+r]^t$) corresponds to the minimum discount rate having any substantial positive probability. From today's perspective, the only relevant limiting scenario is the one with the lowest discount rate – all of the other states at the far-distant time are relatively much less important because their expected present value is so severely reduced by the power of compounding at a higher rate.

If your rule will have important intergenerational benefits or costs you might consider a further sensitivity analysis using a lower but positive discount rate in addition to calculating net benefits using discount rates of 3 and 7 percent.

5. Time Preference for Non-Monetized Benefits and Costs

Differences in timing should be considered even for benefits and costs that are not expressed in monetary units, including health benefits. The timing differences can be handled through discounting. EPA estimated cost-effectiveness in its 1998 rule, "Control of Emissions from Nonroad Diesel Engines," by discounting both the monetary costs and the non-monetized emission reduction benefits over the expected useful life of the engines at the 7 percent real rate recommended in OMB Circular A-94.

Alternatively, it may be possible in some cases to avoid discounting non-monetized benefits. If the expected flow of benefits begins as soon as the cost is incurred and is expected to be constant over time, then annualizing the cost stream is sufficient, and further discounting of benefits is unnecessary. Such an analysis might produce an estimate of the annualized cost per ton of reduced emissions of a pollutant.

6. The Internal Rate of Return

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

The internal rate of return is the discount rate that sets the net present value of the discounted benefits and costs equal to zero. The internal rate of return does not generally provide an acceptable decision criterion, and regulations with the highest internal rate of return are not necessarily the most beneficial. Nevertheless, it does provide useful information and for many it will offer a meaningful indication of regulation's impact. You should consider including the internal rate of return implied by your regulatory analysis along with other information about discounted net present values.

Other Key Considerations

1. Other Benefit and Cost Considerations

You should include these effects in your analysis and provide estimates of their monetary values when they are significant:

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

Estimates of benefits and costs should be based on credible changes in technology over time. For example, retrospective studies may provide evidence that "learning" will likely reduce the cost of regulation in future years. The weight you give to a study of past rates of cost savings resulting from innovation (including "learning curve" effects) should depend on both its timeliness and direct relevance to the processes affected by the regulatory alternative under consideration. In addition, you should take into account cost-saving innovations that result from a shift to regulatory performance standards and incentive-based policies. On the other hand, significant costs may result from a slowing in the rate of innovation or of adoption of new technology due to delays in the regulatory approval process or the setting of more stringent standards for new facilities than existing ones. In some cases agencies are limited under statute to consider only technologies that have been demonstrated to be feasible. In these situations, it may be useful to estimate costs and cost savings assuming a wider range of technical possibilities.

When characterizing technology changes over time, you should assess the likely technology changes that would have occurred in the absence of the regulatory action (technology baseline). Technologies change over time in both reasonably functioning markets and imperfect markets. If you assume that technology will remain unchanged in the absence of regulation when technology changes are likely, then your analysis will over-state both the benefits and costs attributable to the regulation.

Occasionally, cost savings or other forms of benefits accrue to parties affected by a rule who also bear its costs. For example, a requirement that engine manufacturers reduce emissions from engines may lead to technologies that improve fuel economy. These fuel savings will

normally accrue to the engine purchasers, who also bear the costs of the technologies. There is no apparent market failure with regard to the market value of fuel saved because one would expect that consumers would be willing to pay for increased fuel economy that exceeded the cost of providing it. When these cost savings are substantial, and particularly when you estimate them to be greater than the cost associated with achieving them, you should examine and discuss why market forces would not accomplish these gains in the absence of regulation. As a general matter, any direct costs that are averted as a result of a regulatory action should be monetized wherever possible and either added to the benefits or subtracted from the costs of that alternative.

2. The Difference between Costs (or Benefits) and Transfer Payments

Distinguishing between real costs and transfer payments is an important, but sometimes difficult, problem in cost estimation. Benefit and cost estimates should reflect real resource use. Transfer payments are monetary payments from one group to another that do not affect total resources available to society. A regulation that restricts the supply of a good, causing its price to rise, produces a transfer from buyers to sellers. The net reduction in the total surplus (consumer plus producer) is a real cost to society, but the transfer from buyers to sellers resulting from a higher price is not a real cost since the net reduction automatically accounts for the transfer from buyers to sellers. However, transfers from the United States to other nations should be included as costs, and transfers from other nations to the United States as benefits, as long as the analysis is conducted from the United States perspective.

You should not include transfers in the estimates of the benefits and costs of a regulation. Instead, address them in a separate discussion of the regulation's distributional effects. Examples of transfer payments include the following:

- Scarcity rents and monopoly profits
- Insurance payments
- Indirect taxes and subsidies

Treatment of Uncertainty

The precise consequences (benefits and costs) of regulatory options are not always known for certain, but the probability of their occurrence can often be developed. The important uncertainties connected with your regulatory decisions need to be analyzed and presented as part of the overall regulatory analysis. You should begin your analysis of uncertainty at the earliest possible stage in developing your analysis. You should consider both the statistical variability of key elements underlying the estimates of benefits and costs (for example, the expected change in the distribution of automobile accidents that might result from a change in automobile safety standards) and the incomplete knowledge about the relevant relationships (for example, the uncertain knowledge of how some economic activities might affect future climate change).[91] By assessing the sources of uncertainty and the way in which benefit and cost estimates may be

[91] In some contexts, the word "variability" is used as a synonym for statistical variation that can be described by a theoretically valid distribution function, whereas "uncertainty" refers to a more fundamental lack of knowledge. Throughout this discussion, we use the term "uncertainty" to refer to both concepts.

affected under plausible assumptions, you can shape your analysis to inform decision makers and the public about the effects and the uncertainties of alternative regulatory actions.

The treatment of uncertainty must be guided by the same principles of full disclosure and transparency that apply to other elements of your regulatory analysis. Your analysis should be credible, objective, realistic, and scientifically balanced.[92] Any data and models that you use to analyze uncertainty should be fully identified. You should also discuss the quality of the available data used. Inferences and assumptions used in your analysis should be identified, and your analytical choices should be explicitly evaluated and adequately justified. In your presentation, you should delineate the strengths of your analysis along with any uncertainties about its conclusions. Your presentation should also explain how your analytical choices have affected your results.

In some cases, the level of scientific uncertainty may be so large that you can only present discrete alternative scenarios without assessing the relative likelihood of each scenario quantitatively. For instance, in assessing the potential outcomes of an environmental effect, there may be a limited number of scientific studies with strongly divergent results. In such cases, you might present results from a range of plausible scenarios, together with any available information that might help in qualitatively determining which scenario is most likely to occur.

When uncertainty has significant effects on the final conclusion about net benefits, your agency should consider additional research prior to rulemaking. The costs of being wrong may outweigh the benefits of a faster decision. This is true especially for cases with irreversible or large upfront investments. If your agency decides to proceed with rulemaking, you should explain why the costs of developing additional information—including any harm from delay in public protection—exceed the value of that information.

For example, when the uncertainty is due to a lack of data, you might consider deferring the decision, as an explicit regulatory alternative, pending further study to obtain sufficient data.[93] Delaying a decision will also have costs, as will further efforts at data gathering and analysis. You will need to weigh the benefits of delay against these costs in making your decision. Formal tools for assessing the value of additional information are now well developed in the applied decision sciences and can be used to help resolve this type of complex regulatory question.

"Real options" methods have also formalized the valuation of the added flexibility inherent in delaying a decision. As long as taking time will lower uncertainty, either passively or actively through an investment in information gathering, and some costs are irreversible, such as the potential costs of a sunk investment, a benefit can be assigned to the option to delay a decision. That benefit should be considered a cost of taking immediate action versus the alternative of delaying that action pending more information. However, the burdens of delay—including any harm to public health, safety, and the environment—need to be analyzed carefully.

---

[92] When disseminating information, agencies should follow their own information quality guidelines, issued in conformance with the OMB government-wide guidelines (67 FR 8452, February 22, 2002).

[93] Clemen RT (1996), *Making Hard Decisions: An Introduction to Decision Analysis*, second edition, Duxbury Press, Pacific Grove.

1. Quantitative Analysis of Uncertainty

Examples of quantitative analysis, broadly defined, would include formal estimates of the probabilities of environmental damage to soil or water, the possible loss of habitat, or risks to endangered species as well as probabilities of harm to human health and safety. There are also uncertainties associated with estimates of economic benefits and costs, such as the cost savings associated with increased energy efficiency. Thus, your analysis should include two fundamental components: a quantitative analysis characterizing the probabilities of the relevant outcomes and an assignment of economic value to the projected outcomes. It is essential that both parts be conceptually consistent. In particular, the quantitative analysis should be conducted in a way that permits it to be applied within a more general analytical framework, such as benefit-cost analysis. Similarly, the general framework needs to be flexible enough to incorporate the quantitative analysis without oversimplifying the results. For example, you should address explicitly the implications for benefits and costs of any probability distributions developed in your analysis.

As with other elements of regulatory analysis, you will need to balance thoroughness with the practical limits on your analytical capabilities. Your analysis does not have to be exhaustive, nor is it necessary to evaluate each alternative at every step. Attention should be devoted to first resolving or studying the uncertainties that have the largest potential effect on decision making. Many times these will be the largest sources of uncertainties. In the absence of adequate data, you will need to make assumptions. These should be clearly identified and consistent with the relevant science. Your analysis should provide sufficient information for decision makers to grasp the degree of scientific uncertainty and the robustness of estimated probabilities, benefits, and costs to changes in key assumptions.

For major rules involving annual economic effects of $1 billion or more, you should present a formal quantitative analysis of the relevant uncertainties about benefits and costs. In other words, you should try to provide some estimate of the probability distribution of regulatory benefits and costs. In summarizing the probability distributions, you should provide some estimates of the central tendency (e.g., mean and median) along with any other information you think will be useful such as ranges, variances, specified low-end and high-end percentile estimates, and other characteristics of the distribution.

Your estimates cannot be more precise than their most uncertain component. Thus, your analysis should report estimates in a way that reflects the degree of uncertainty and not create a false sense of precision. Worst-case or conservative analyses are not usually adequate because they do not convey the complete probability distribution of outcomes, and they do not permit calculation of an expected value of net benefits. In many health and safety rules, economists conducting benefit-cost analyses must rely on formal risk assessments that address a variety of risk management questions such as the baseline risk for the affected population, the safe level of exposure or, the amount of risk to be reduced by various interventions. Because the answers to some of these questions are directly used in benefits analyses, the risk assessment methodology must allow for the determination of expected benefits in order to be comparable to expected costs. This means that conservative assumptions and defaults (whether motivated by science

policy or by precautionary instincts), will be incompatible with benefit analyses as they will result in benefit estimates that exceed the expected value. Whenever it is possible to characterize quantitatively the probability distributions, some estimates of expected value (e.g., mean and median) must be provided in addition to ranges, variances, specified low-end and high-end percentile estimates, and other characteristics of the distribution.

Whenever possible, you should use appropriate statistical techniques to determine a probability distribution of the relevant outcomes. For rules that exceed the $1 billion annual threshold, a formal quantitative analysis of uncertainty is required. For rules with annual benefits and/or costs in the range from 100 million to $1 billion, you should seek to use more rigorous approaches with higher consequence rules. This is especially the case where net benefits are close to zero. More rigorous uncertainty analysis may not be necessary for rules in this category if simpler techniques are sufficient to show robustness. You may consider the following analytical approaches that entail increasing levels of complexity:

- Disclose qualitatively the main uncertainties in each important input to the calculation of benefits and costs. These disclosures should address the uncertainties in the data as well as in the analytical results. However, major rules above the $1 billion annual threshold require a formal treatment.
- Use a numerical sensitivity analysis to examine how the results of your analysis vary with plausible changes in assumptions, choices of input data, and alternative analytical approaches. Sensitivity analysis is especially valuable when the information is lacking to carry out a formal probabilistic simulation. Sensitivity analysis can be used to find "switch points" -- critical parameter values at which estimated net benefits change sign or the low cost alternative switches. Sensitivity analysis usually proceeds by changing one variable or assumption at a time, but it can also be done by varying a combination of variables simultaneously to learn more about the robustness of your results to widespread changes. Again, however, major rules above the $1 billion annual threshold require a formal treatment.
- Apply a formal probabilistic analysis of the relevant uncertainties – possibly using simulation models and/or expert judgment as revealed, for example, through Delphi methods.[94] Such a formal analytical approach is appropriate for complex rules where there are large, multiple uncertainties whose analysis raises technical challenges, or where the effects cascade; it is required for rules that exceed the $1 billion annual threshold. For example, in the analysis of regulations addressing air pollution, there is uncertainty about the effects of the rule on future emissions, uncertainty about how the change in emissions will affect air quality, uncertainty about how changes in air quality will affect health, and finally uncertainty about the economic and social value of the change in health outcomes. In formal probabilistic assessments, expert solicitation is a useful way to fill key gaps in your ability to assess uncertainty.[95] In general, experts can

[94] The purpose of Delphi methods is to generate suitable information for decision making by eliciting expect judgment. The elicitation is conducted through a survey process which eliminates the interactions between experts. See Morgan MG and Henrion M (1990), *Uncertainty: A Guide to Dealing with Uncertainty in Quantitative Riskand Policy Analysis*, Cambridge University Press.

[95] Cooke RM (1991), *Experts in Uncertainty: Opinion and Subjective Probability in Science*, Oxford University Press.

be used to quantify the probability distributions of key parameters and relationships. These solicitations, combined with other sources of data, can be combined in Monte Carlo simulations to derive a probability distribution of benefits and costs. You should pay attention to correlated inputs. Often times, the standard defaults in Monte Carlo and other similar simulation packages assume independence across distributions. Failing to correctly account for correlated distributions of inputs can cause the resultant output uncertainty intervals to be too large, although in many cases the overall effect is ambiguous. You should make a special effort to portray the probabilistic results—in graphs and/or tables—clearly and meaningfully.

New methods may become available in the future. This document is not intended to discourage or inhibit their use, but rather to encourage and stimulate their development.

2. Economic Values of Uncertain Outcomes

In developing benefit and cost estimates, you may find that there are probability distributions of values as well for each of the outcomes. Where this is the case, you will need to combine these probability distributions to provide estimated benefits and costs.

Where there is a distribution of outcomes, you will often find it useful to emphasize summary statistics or figures that can be readily understood and compared to achieve the broadest public understanding of your findings. It is a common practice to compare the "best estimates" of both benefits and costs with those of competing alternatives. These "best estimates" are usually the average or the expected value of benefits and costs. Emphasis on these expected values is appropriate as long as society is "risk neutral" with respect to the regulatory alternatives. While this may not always be the case, you should in general assume "risk neutrality" in your analysis. If you adopt a different assumption on risk preference, you should explain your reasons for doing so.

3. Alternative Assumptions

If benefit or cost estimates depend heavily on certain assumptions, you should make those assumptions explicit and carry out sensitivity analyses using plausible alternative assumptions. If the value of net benefits changes from positive to negative (or vice versa) or if the relative ranking of regulatory options changes with alternative plausible assumptions, you should conduct further analysis to determine which of the alternative assumptions is more appropriate. Because different estimation methods may have hidden assumptions, you should analyze estimation methods carefully to make any hidden assumptions explicit.

F. Specialized Analytical Requirements

In preparing analytical support for your rulemaking, you should be aware that there are a number of analytic requirements imposed by law and Executive Order. In addition to the regulatory analysis requirements of Executive Order 12866, you should also consider whether your rule will need specialized analysis of any of the following issues.

Impact on Small Businesses and Other Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. chapter 6), agencies must prepare a proposed and final "regulatory flexibility analysis" (RFA) if the rulemaking could "have a significant impact on a substantial number of small entities." You should consider posting your RFA on the internet so the public can review your findings.

Your agency should have guidelines on how to prepare an RFA and you are encouraged to consult with the Chief Counsel for Advocacy of the Small Business Administration on expectations concerning what is an adequate RFA. Executive Order 13272 (67 FR 53461, August 16, 2002) requires you to notify the Chief Counsel for Advocacy of any draft rules that might have a significant economic impact on a substantial number of small entities. Executive Order 13272 also directs agencies to give every appropriate consideration to any comments provided by the Advocacy Office. Under SBREFA, EPA and OSHA are required to consult with small business prior to developing a proposed rule that would have a significant effect on small businesses. OMB encourages other agencies to do so as well.

Analysis of Unfunded Mandates

Under the Unfunded Mandates Act (2 U.S.C. 1532), you must prepare a written statement about benefits and costs prior to issuing a proposed or final rule (for which your agency published a proposed rule) that may result in aggregate expenditure by State, local, and tribal governments, or by the private sector, of $100,000,000 or more in any one year (adjusted annually for inflation). Your analytical requirements under Executive Order 12866 are similar to the analytical requirements under this Act, and thus the same analysis may permit you to comply with both analytical requirements.

Information Collection, Paperwork, and Recordkeeping Burdens

Under the Paperwork Reduction Act (44 U.S.C. chapter 35), you will need to consider whether your rulemaking (or other actions) will create any additional information collection, paperwork or recordkeeping burdens. These burdens are permissible only if you can justify the practical utility of the information for the implementation of your rule. OMB approval will be required of any new requirements for a collection of information imposed on 10 or more persons and a valid OMB control number must be obtained for any covered paperwork. Your agency's CIO should be able to assist you in complying with the Paperwork Reduction Act.

Information Quality Guidelines

Under the Information Quality Law, agency guidelines, in conformance with the OMB government-wide guidelines (67 FR 8452, February 22, 2002), have established basic quality performance goals for all information disseminated by agencies, including information disseminated in support of proposed and final rules. The data and analysis that you use to support your rule must meet these agency and OMB quality standards. Your agency's CIO should be able to assist you in assessing information quality. The Statistical and Science Policy

Branch of OMB's Office of Information and Regulatory Affairs can provide you assistance. This circular defines OMB's minimum quality standards for regulatory analysis.

Environmental Impact Statements

The National Environmental Policy Act (42 U.S.C. 4321-4347) and related statutes and executive orders require agencies to consider the environmental impacts of agency decisions, including rulemakings. An environmental impact statement must be prepared for "major Federal actions significantly affecting the quality of the human environment." You must complete NEPA documentation before issuing a final rule. The White House Council on Environmental Quality has issued regulations (40 C.F.R. 1500-1508) and associated guidance for implementation of NEPA, available through CEQ's website (http://www.whitehouse/gov/ceq/).

Impacts on Children

Under Executive Order 13045, "Protection of Children from Environmental Health Risks and Safety Risks," each agency must, with respect to its rules, "to the extent permitted by law and appropriate, and consistent with the agency's mission," "address disproportionate risks to children that result from environmental health risks or safety risks." For any substantive rulemaking action that "is likely to result in" an economically significant rule that concerns "an environmental health risk or safety risk that an agency has reason to believe may disproportionately affect children," the agency must provide OMB/OIRA "an evaluation of the environmental health or safety effects of the planned regulation on children," as well as "an explanation of why the planned regulation is preferable to other potentially and reasonably feasible alternatives considered by the agency."

Energy Impacts

Under Executive Order 13211 (66 FR 28355, May 22, 2001), agencies are required to prepare and submit to OMB a Statement of Energy Effects for significant energy actions, to the extent permitted by law. This Statement is to include a detailed statement of "any adverse effects on energy supply, distribution, or use (including a shortfall in supply, price increases, and increased use of foreign supplies)" for the action and reasonable alternatives and their effects. You need to publish the Statement or a summary in the related NPRM and final rule. For further guidance, see OMB Memorandum 01-27 ("Guidance on Implementing Executive Order 13211", July 13, 2001), available on OMB's website.

G. Accounting Statement

You need to provide an accounting statement with tables reporting benefit and cost estimates for each major final rule for your agency. You should use the guidance outlined above to report these estimates. We have included a suggested format for your consideration.

Categories of Benefits and Costs

To the extent feasible, you should quantify all potential incremental benefits and costs. You should report benefit and cost estimates within the following three categories: monetized quantified, but not monetized; and qualitative, but not quantified or monetized.

These categories are mutually exclusive and exhaustive. Throughout the process of listing preliminary estimates of benefits and costs, agencies should avoid double-counting. This problem may arise if more than one way exists to express the same change in social welfare.

Quantifying and Monetizing Benefits and Costs

You should develop quantitative estimates and convert them to dollar amounts if possible. In many cases, quantified estimates are readily convertible, with a little effort, into dollar equivalents.

Qualitative Benefits and Costs

You should categorize or rank the qualitative effects in terms of their importance (e.g., certainty, likely magnitude, and reversibility). You 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.

Treatment of Benefits and Costs over Time

You should present undiscounted streams of benefit and cost estimates (monetized and net) for each year of the analytic time horizon. You should present annualized benefits and costs using real discount rates of 3 and 7 percent. The stream of annualized estimates should begin in the year in which the final rule will begin to have effects, even if the rule does not take effect immediately. Please report all monetized effects in 2001 dollars. You should convert dollars expressed in different years to 2001 dollars using the GDP deflator.

Treatment of Risk and Uncertainty

You should provide expected-value estimates as well as distributions about the estimates, where such information exists. When you provide only upper and lower bounds (in addition to best estimates), you should, if possible, use the 95 and 5 percent confidence bounds. Although we encourage you to develop estimates that capture the distribution of plausible outcomes for a particular alternative, detailed reporting of such distributions is not required, but should be available upon request.

The principles of full disclosure and transparency apply to the treatment of uncertainty. Where there is significant uncertainty and the resulting inferences and/or assumptions have a critical effect on the benefit and cost estimates, you should describe the benefits and costs under plausible alternative assumptions. You may add footnotes to the table as needed to provide documentation and references, or to express important warnings.

In a previous section, we identified some of the issues associated with developing estimates of the value of reductions in premature mortality risk. Based on this discussion, you should present alternative primary estimates where you use different estimates for valuing reductions in premature mortality risk.

Precision of Estimates

Reported estimates should reflect, to the extent feasible, the precision in the analysis. For example, an estimate of $220 million implies rounding to the nearest $10 million and thus a precision of +/-$5 million; similarly, an estimate of $222 million implies rounding to the nearest $1 million and thus, a precision of +/-$0.5 million.

Separate Reporting of Transfers

You should report transfers separately and avoid the misclassification of transfer payments as benefits or costs. Transfers occur when wealth or income is redistributed without any direct change in aggregate social welfare. To the extent that regulatory outputs reflect transfers rather than net welfare gains to society, you should identify them as transfers rather than benefits or costs. You should also distinguish transfers caused by Federal budget actions -- such as those stemming from a rule affecting Social Security payments -- from those that involve transfers between non-governmental parties -- such as monopoly rents a rule may confer on a private party. You should use as many categories as necessary to describe the major redistributive effects of a regulatory action. If transfers have significant efficiency effects in addition to distributional effects, you should report them.

Effects on State, Local, and Tribal Governments, Small Business, Wages and Economic Growth

You need to identity the portions of benefits, costs, and transfers received by State, local, and tribal governments. To the extent feasible, you also should identify the effects of the rule or program on small businesses, wages, and economic growth.[96] Note that rules with annual costs that are less than one billion dollars are likely to have a minimal effect on economic growth.

[96] The Regulatory Flexibility Act (5 U.S.C. 603(c), 604).

OMB #: **Agency/Program Office:**
Rule Title:
RIN#: **Date:**

Category	*Primary Estimate*	*Minimum Estimate*	*Maximum Estimate*	*Source Citation (RIA, preamble, etc.)*
BENEFITS				
Annualized monetized benefits				
Annualized quantified, but unmonetized, benefits				
Qualitative (unquantified) benefits				
COSTS				
Annualized monetized costs				
Annualized quantified, but unmonetized, costs				
Qualitative (unquantified) costs				
TRANSFERS				
Annualized monetized transfers: "on budget"				
from whom to whom?				
Annualized monetized transfers: "off-budget"				
From whom to whom?				
Category	*Effects*			*Source Citation (RIA, preamble, etc.)*
Effects on State, local, and/or tribal governments				
Effects on small businesses				
Effects on wages				
Effects on growth				

H. Effective Date

The effective date of this Circular is January 1, 2004 for regulatory analyses received by OMB in support of proposed rules, and January 1, 2005 for regulatory analyses received by OMB in support of final rules. In other words, this Circular applies to the regulatory analyses for draft proposed rules that are formally submitted to OIRA after December 31, 2003, and for draft final rules that are formally submitted to OIRA after December 31, 2004. (However, if the draft proposed rule is subject to the Circular, then the draft final rule will also be subject to the Circular, even if it is submitted prior to January 1, 2005.) To the extent practicable, agencies should comply earlier than these effective dates. Agencies may, on a case-by-case basis, seek a waiver from OMB if these effective dates are impractical.

APPENDIX E. RESPONSE TO COMMENTS ON THE DRAFT REGULATORY ANALYSIS GUIDELINES

The Circular published today provides OMB's guidance to Federal agencies on the development of regulatory analysis as required under Section 6(a)(3)(c) of Executive Order No. 12866, "Regulatory Planning and Review," and a variety of related authorities. (E.O.12866 was issued by President Clinton in 1993.) The Circular also provides guidance to agencies on the regulatory accounting statements that are required under the Regulatory Right-to-Know Act. This Circular refines OMB's "best practices" document of 1996 (http://www.whitehouse.gov/omb/inforeg/riaguide.html), which was issued as a guidance in 2000 (http://www.whitehouse.gov/omb/memoranda/m00-08.pdf), and reaffirmed in 2001 (http://www.whitehouse.gov/omb/memoranda/m01-23.html). It replaces both the 1996 "best practices" and the 2000 guidance. The final guidelines have been issued as OMB Circular A-4, Regulatory Analysis Guidelines, and this Circular is available on OMB's web site at http://www.whitehouse.gov/omb/circulars/index.html.

This Circular is designed to assist analysts in the regulatory agencies by defining good regulatory analysis—called either "regulatory analysis" or "analysis" for brevity—and standardizing the way benefits and costs of Federal regulatory actions are measured and reported. Executive Order 12866 requires agencies to conduct a regulatory analysis for economically significant regulatory actions as defined by Section 3(f) (1). This requirement applies to rulemakings that rescind or modify existing rules as well as to rulemakings that establish new requirements.

Regulatory analysis is a widely-accepted tool regulatory agencies use to anticipate and evaluate the likely consequences of rules. It provides a formal way of organizing the evidence on the key effects—good and bad—of the various alternatives that should be considered in developing regulations. The motivation is to (1) learn if the benefits of an action are likely to justify the costs or (2) discover which of various possible alternatives would be the most cost-effective.

A good regulatory analysis is designed to inform the public and other parts of the Government (as well as the agency conducting the analysis) of the effects of alternative actions. Regulatory analysis will sometimes show that a proposed action is misguided, but it can also demonstrate that well-conceived actions are reasonable and justified.

OMB subjected the draft guidelines to external peer review and public comment. Together, 360 comments were received. A large number of public comments were less than one-page in length and focused on one specific issue in benefit-cost analysis. By and large, the peer reviewers strongly supported the use of regulatory analysis in rulemaking and OMB's efforts to revise the regulatory analysis guidelines. OMB has made numerous changes to the draft guidelines in response to the peer review and public comments.

This chapter primarily summarizes and responds to the areas of regulatory analysis guidelines and the role of regulatory analysis in rulemaking that received most of the attention from commenters.

A. Benefit-Cost Analysis

Most commenters supported the need for OMB guidance on benefit-cost analysis (BCA), but there were a range of views on how OMB's current guidance should be modified. One key area of comment centered on the appropriate way to conduct and use BCA and cost-effectiveness analysis (CEA) in the development of health, safety, and environmental regulations.

Three commenters (236, 334, 335) expressed concern that the "net-benefit" test in BCA leads to an effort to reduce all benefits and costs to quantification and monetization. One (335) commented that any factor that "does not lend itself to quantification, and then monetization, tends to fall out of the equation entirely." Others (250, 333) expressed concern that OMB had placed BCA "at the heart of regulatory decision making" to the exclusion of other statutory criteria. OMB recognizes that some benefits and costs, including important ones such as protecting landscapes, preventing species extinction, protecting privacy, nurturing families, advancing fairness objectives, and encouraging innovation, cannot be fully quantified and/or expressed in monetary units.

The final guidance urges analysts to characterize the non-quantifiable benefits and costs and, where feasible, identify the most important of these factors. EO 12866 requires consideration of non-quantified factors per the "benefits justify costs" test in EO 12866. Moreover, OMB recognizes that the role of BCA in regulatory decision making will vary widely depending upon the statutory standards governing an agency's decision making (251, 350).

One commenter (236) questioned whether it is even appropriate to assign a dollar value to a variety of attributes associated with health, safety, and environmental regulation. OMB recognizes that monetizing some of the effects of regulation is difficult, and quantifying some effects may not even be feasible. In such cases, cost-effectiveness analysis provides a rigorous way to identify options that achieve the most effective use of resources available in terms of achieving the intended regulatory benefits.

One commenter (360) observed that monetary values for prevention of morbidity are often unavailable and that health-utility values, numeric ratings of health conditions, are more available than monetary values. OMB concurs with this observation, which is why the final guidance encourages agencies to consider analytic approaches for translating health-utility values into monetary values.

One commenter (360) expressed concern that the draft Guidance might permit agencies to compute benefits in BCA through a procedure that would translate quality-adjusted life years (QALYs) into dollars through a procedure based on current health care investments (e.g., using the cost-effectiveness ratios for heart disease or cancer treatment as a normative benchmark). The commenter described such a procedure as "problematic" since health care investments may not reflect individual preferences. If agencies translate QALYs into dollars for use in BCA, agencies should consider a procedure based on personal preference and willingness to pay.

One commenter (360), in discussing BCA, expressed concern about the theoretical relevance and validity of the traditional "cost-of-illness" (COI) values used by some agencies. COI values typically include only health care expenses and lost wages, ignoring pain and subjective concerns. BCA should be based on WTP rather than COI values. However, OMB notes that WTP values sometimes ignore the external costs of premature death and illness (e.g., public health care expenditures) and thus COI values, if properly computed, may have an appropriate role in supplementing WTP values. They also have a clearly defined role in CEA, as defined in the public health and medical literature.

One commenter (360) expressed the view that "models are reasonably well established for estimating WTP for health benefits of air quality improvements". Although EPA has made progress in this field, most of this modeling is based on application of "benefit-transfer" methods that are associated with substantial uncertainty. While the commenter (360) is correct that some transfer values used by agencies have been based on elaborate meta-analyses, the technique of meta-analysis is not designed to address the problem of irrelevant information. The final guidance encourages agencies to employ economic tools and data that are directly relevant to the specific regulatory context. On a related matter, the same commenter (360) stated that "it is widely accepted that the mortality effects dominate these (EPA particulate) analyses (based on WTP studies over the last decade)." The relative size of morbidity versus mortality benefits in BCA cannot be known with confidence until complete and relevant information are available for both morbidity and mortality effects.[97]

One commenter (299) urged OMB to insist that agencies present benefit and cost estimates on a regional and State basis as well as a national basis. Such information can be useful in certain situations. However, the burden on agencies of producing highly disaggregated benefit and cost information can be significant. The final OMB guidance provides discretion to agencies to determine, with OMB oversight, what level of disaggregation is appropriate.

Three commenters (236, 334, 335) asserted that BCA has an "ingrained tendency" to overestimate costs and underestimate benefits, particularly in environmental policy. The revised guidelines seek to ensure that analysts account for all important effects of regulations, regardless of the analysts' ability to quantify them. Analysts should strive to do their best to prepare complete and unbiased estimates of both expected benefits and costs during the rulemaking process.

One commenter (299) suggested that the guidance should instruct agencies to perform and take account of retrospective analysis of their benefit and cost estimates. Retrospective analysis of rules is valuable and is often most objectively performed by independent think tanks and universities. When agencies conduct such evaluations, the final OMB guidance is applicable; indeed, some of the specific provisions in the final guidelines are based on insights learned from previous retrospective evaluations (e.g., studies showing how learning curves reduce the marginal variable cost of production).

---

[97] Committee on Estimating the Health Risk-Reduction Benefits of Proposed Air Pollution Regulations, Board on Environmental Studies and Toxicology, National Research Council (2002), *Estimating the Public Health Benefits of Proposed Air Pollution Regulations*, National Academy Press, Washington, DC.

One commenter (326) urged OMB to prohibit the use of benefit assessments that treat "avoided costs" of regulatory alternatives as a benefit. Agencies should not use "avoided-cost" methods unless the agency can present a viable case that, in the absence of the preferred regulation, the costly alternatives will be adopted or can assess how likely it is that the costly alternatives will be adopted. In cases where the rulemaking agency itself has the discretion not to adopt the costly alternatives, the avoided cost should not be included as a benefit. The final guidelines include a specific warning on the use of "avoided costs" as a measure of benefits.

In contrast to the above comments, one commenter (348) emphasized that agency practices typically understate the costs of regulation because they focus on compliance cost to business rather than full social costs. The full costs include, for example, not just the tangible costs to producers of building more fuel-efficient vehicles but also any decrements in vehicle quality (e.g., performance or size) or safety that may result. Full social costs are often larger than strict compliance costs, and the final guidelines instruct agencies to identify and quantify whenever possible all potential incremental costs.

One commenter (335) requests that greater consideration be given to the role of technology in lowering the costs of regulation over time. This is a valid point that was acknowledged in OMB's draft guidelines and has been retained in the final guidelines. This point is already built into the standard cost-estimation methods used by Federal agencies such as the U.S. Environmental Protection Agency. More research is needed to refine and better quantify patterns in technological cost reduction that occur over time. At the same time, the promises of technology are sometimes overestimated, with actual effectiveness sometimes lower and operating costs sometimes higher than originally expected. Two commenters (340, 342) cautioned against excessive optimism about "technology-forcing" regulations due to concerns for practicality and affordability. In addition to this concern, there may be opportunity costs associated with technology-forcing regulations because the regulations may divert resources from one avenue of research to another. Agency analysts should carefully evaluate the claims made in favor of and against regulations that would promote new technologies.

For lifesaving rules, commenters differed on whether agencies should use the economic "value of statistical life" (VSL) and/or the economic "value of a statistical life year" (VSLY). In the BCA literature, the VSL method is more widely used. A common objection to VSL is that it does not take into account life expectancy (260, 332, 348). For the same individual, saving 40 years of life is more valuable than extending life by less than a year. VSLY is the only practical approach that has been developed and used to address this objection to the VSL approach. Yet several commenters (e.g., 344) argued that a simple VSLY method -- implying that VSL declines linearly with age and that each year of life is valued the same -- is not well grounded in economic theory or empirical research on personal preferences.

In the final guidelines, we continue to encourage use of both methods but have made two key changes: (1) an instruction to analysts to use the same VSL for people of all ages, and (2) an instruction to analysts to present results with larger values for VSLY when rules are aimed primarily or significantly at protection of senior citizens (because seniors face larger overall health risks from all causes and because they have accumulated savings and liquid assets to

expend on protection of their health and safety). The result is a premium on each life year saved among senior citizens, though there is uncertainty about how large this premium should be.

OMB received numerous comments (e.g., 346) objecting to use of an age-adjustment factor that reduces VSL for those over age 65. In a recent memorandum to the President's Management Council, OMB directed all agencies not to use such an age-adjusted factor in VSL analysis. The Circular incorporates this direction to the agencies.

OMB received a number of often conflicting public comments on the proper role of contingent valuation (CV) methods in regulatory analysis. CV methods quantify benefits through surveys of personal willingness to pay for goods and services. Some commenters (307, 314, 328, 341, 342, 350) argued that the OMB guidance is too permissive regarding CV methods, while others (227, 246, 291) argued that the quality standards for CV studies imposed by OMB were overly stringent or misdirected. CV has an appropriate role in regulatory analysis, but the hypothetical nature of the questions require that the analyst make sure such surveys are designed, conducted, analyzed, and reported in a rigorous way.

B. Cost-Effectiveness Analysis

In the draft guidelines, OMB proposed to expand the role of cost-effectiveness analysis (CEA) in regulatory analysis, in addition to maintaining the strong traditional role for BCA. Major health and safety rulemakings are to be supported by a CEA as well as a BCA. The vast majority of commenters favored the expanded role for CEA in regulatory analysis.

In discussing agency preparedness to conduct BCA and CEA, one commenter (360) cautioned that some "agency cultures are entrenched": "At EPA, for instance, standard procedures are for using BCA and there is likely to be a costly learning curve for using CEA. At some of the public health agencies the learning curve for monetization techniques is likewise high. . ." Although there may be some merit in this historical observation, OMB is encouraged that analysts at EPA and other public health agencies are already engaged in active discussions about how to improve the practice of regulatory analysis. The costs to agencies of using analytic tools and data that are already widely used in the peer-reviewed literature will be relatively small.

One commenter (360), while suggesting that OMB's guidance should be more prescriptive, also argued that "agencies should have the option of performing BCA and CEA in their preferred way as a supplement to meeting the OMB guidelines and to do so without the need of justification." OMB encourages agencies to present a variety of analytic perspectives in regulatory analysis; approaches that are inconsistent with OMB guidance will require justification.

This commenter (360), responding to the CEA and BCA requirements in the draft guidance, urged OMB to phase in the BCA/CEA requirements over several years. OMB is prepared to waive analytic requirements in the near term if agencies demonstrate that they are not equipped to comply but have a concrete plan for developing appropriate capabilities.

One commenter (347) argued that BCA should be employed when the agency has some choice over whether regulations should be issued at all, whereas CEA is only appropriate when the agency is limited to a choice over which regulatory method to adopt in order to achieve a mandated objective. In addition to this distinction, OMB believes that some decision makers may gain insight from both CEA and BCA when the agency has some choice about whether to regulate. In the health field, for example, CEA is much more widely conducted and used than BCA, even when a decision maker has broad discretion on how to proceed.

One commenter (284) supported the requirement for CEA but argued that BCA should generally be preferred, even for health and safety rulemakings. BCA does provide more information about economic efficiency than CEA but CEA offers a complementary perspective, particularly for health and safety rules.

One commenter (270) stated that OMB should not assume that a single metric of effectiveness can be selected for all rulemakings. Instead, this commenter advocated that agencies perform CEAs with several measures of effectiveness because the different measures may illuminate different aspects of regulation. OMB agrees with this comment. For example, OMB is not aware of any single measure that can combine both public health and ecological outcomes (unless they can both be quantified and expressed in dollar units, in a BCA). Thus, the final OMB guidance does not require a universal effectiveness metric for use in CEA**.**

In the draft guidance, OMB noted that health and safety agencies are using a variety of effectiveness measures in CEA: lives saved, "equivalent" lives saved, life-years saved, and quality-adjusted life years saved. Additional measures have been suggested in the academic literature. A range of views were expressed about which measures of effectiveness should be employed by health and safety agencies.

Specialists in public health and medicine (4, 291) have argued that the quality-adjusted life year (QALY) is currently the preferred measure of effectiveness in the peer-reviewed literature, and thus OMB should treat QALYs as the preferred measure. They pointed out that a key advantage of "QALYs saved" over "lives saved" and "life-years saved" is that QALYs account for the impact of nonfatal diseases and injuries on a person's quality of life. Another commenter (360) expressed concern that if lives saved or life-years saved are used as the measure of effectiveness, other health endpoints may be ignored. OMB will ask the Institute of Medicine to assemble a panel of specialists in CEA and bioethics to evaluate the advantages and disadvantages of different measures of effectiveness.

One commenter (292) raised a concern that the health framework is not based on personal willingness to pay, which is the foundation of BCA. Yet other commenters (4, 246, 336) raised concerns about private willingness to pay as a sole health-policy standard, based on ethical reasons (since it is tied to a person's ability to pay) and technical concerns (i.e., developing accurate, precise and robust measurements of willingness to pay for health gains has proven to be challenging). The CEA-QALY framework does depart from personal willingness to pay, but CEA is intended to supplement, not replace, BCA. Even proponents of CEA (4) in the health field believe it should be presented in conjunction with BCA.

CEA allows policymakers to consider how much investment in QALY gains is appropriate in different rulemaking contexts, without imposing an analytic determination of how much investment in safety is enough. A somewhat different view (246) is that "CEA using QALYs or similar metrics is best interpreted as an evaluation method that individuals might agree to, based on notions of fairness, even more so before knowing their own particular circumstances (i.e., behind a Rawlsian veil of ignorance)." Thus, CEA may be considered more sensitive to certain fairness concerns than BCA. It should be noted that in practice, some issues of "fairness" are also addressed in BCA (e.g., use of the same VSL for all lives saved).

Technical concerns were also raised about some of the simplifying, restrictive assumptions about individual preferences that underpin the QALY framework, but these commenters did not suggest a superior metric for use in CEA (359). As one specialist (4) noted, "In order to facilitate comparison of cost-effectiveness findings across programs, common denominators should be encouraged, and QALYs represent the best available health preference measure for that purpose". Another specialist (350) noted that the simplifying assumptions with QALYs are of most concern when the QALY measure is applied to widely different programs and populations.

Commenters raised concerns about the technical quality of some published QALY surveys (292). One commenter (360) notes that QALY surveys are often derived from small, specialized samples and that the survey techniques used to determine health-utility values need to examined rigorously for robustness and unbiasedness. These concerns have merit and thus agencies should review QALY surveys carefully before selecting numerical values for use in regulatory analysis. Just as contingent valuation surveys need to be scrutinized with care, surveys designed to assess health preferences and QALYs need to be scrutinized with care.

QALYs are the most commonly used measure in CEA, are based on simplifying assumptions, and more research is needed to improve the QALY measure and/or develop alternative or supplementary measures. It is not necessary to select a single effectiveness measure at this time, and the QALY measure needs further development to justify such exclusive status (259). Agencies should, when possible, develop and present cost-effectiveness ratios with one or more effectiveness measures that provide insight to regulators.

Some commenters (251, 253, 335, 336) expressed concern with some of the implications of the quality-adjusted life year (QALY) method in terms of the treatment of the elderly and those who have disabilities. Another commenter (341), while favoring use of the life-year metric, argued that it will be difficult to persuade the public that it should accept "quality adjustments".

Circular A-4 directs that CEA methods based on QALYs should be modified to address such concerns, especially when lifesaving rules are aimed at protecting the disabled. For the sake of both analytic simplicity and fairness, lifesaving gains achieved among groups with disabilities should be computed without penalizing these groups for their pre-existing conditions; this can be done by using life-expectancy information on the longevity of the non-disabled in the same age cohort, as measured in standard life tables. For rules that prevent or mitigate

disabilities, the QALY method is well designed to reflect the values of those who are at an increased risk of becoming disabled.

One commenter sought more clarity from OMB about the reasons for imposing a CEA requirement in addition to existing requirements (251). First, as explained above, CEA provides a different perspective for regulators by responding to some—though not all—of the technical and ethical limitations of BCA. Second, CEA—by its very nature—provides guidance on how to maximize public health gains across a specified set of regulatory options with available public health resources. By contrast, the focus of BCA is on whether a particular investment in health protection is efficient from a societal perspective given the many demands in our economy, including housing, transportation, and education.

C. Probabilistic Uncertainty Analysis

The draft guidelines included a requirement that agencies present a formal quantitative analysis of the relevant uncertainties within regulatory analyses for major rules involving economic effects of $1 billion or more. This analysis should present probability distributions for the estimated benefits and costs to provide decision makers with information on the degree of scientific uncertainty and the robustness of estimated probabilities, benefits, and costs. The majority of comments were favorable to this expanded requirement for formal probability analysis in regulatory analysis. Here we summarize and respond to some of the critical comments.

One commenter (3) acknowledged that formal probability analysis, based on expert judgment, has value in personal decision making (e.g., medical decision analysis) but is not appropriate for use in public decision making. The commenter's rationale was that, when subject to political pressures from various interests, experts may find it difficult to provide candid probability assessments for public policy. OMB acknowledges that this is a potential problem but it applies to all forms of expert judgement, not just those used to inform a formal probability analysis. By using multiple experts and peer review, agencies can reduce the influence of such pressures on probability assessments.

One commenter (335) urged that the requirement for probability analysis be dropped and replaced with a more limited approach to uncertainty analysis suggested in current EPA guidelines. However, it was EPA's limited approach that was recently evaluated by a panel of the National Research Council in its report, *Estimating the Public Health Benefits of Proposed Air Pollution Regulations* (September 2002). The panel concluded that "EPA should begin to move the assessment of uncertainties from its ancillary analyses into its primary analyses by conducting probabilistic, multiple-source uncertainty analyses. This shift will require specification of probability distributions for major sources of uncertainty. These distributions should be based on available data and expert judgement." The final OMB guidance is consistent with this recommendation.

One commenter (360) recommended that OMB guidance address "appropriate development of scenarios to fairly represent statistical and model uncertainties, given that Monte Carlo simulation will be used. . ." OMB considers scenario analysis and Monte Carlo simulation

to be only two of the available tools of formal probability analysis. Rather than present detailed guidance at this early stage, OMB intends to convene agency analysts to discuss their experiences in performing probability analysis. Over time, as agency experience is accumulated, it may be appropriate for OMB to issue supplemental guidance on this topic.

Another commenter (347) regards the use of "Delphi methods" -- panels of experts providing probability judgments -- as troubling and provides the following suggestions to safeguard against misuse of expert judgments: "Any resort to expert judgment should include full identification of the experts, their qualifications, their publications and testimony histories, and any contractual relationships with the agency or interested parties. Agency employees should not be used for this sort of validation, and the agency should avoid using the same experts repeatedly." OMB agrees that relevant expertise, public transparency, and independence from the agency are important facets of a major expert-judgment project. Agencies and OMB need to develop more experience with the expert-judgment approach to probability assessment before issuing detailed guidance.

The same commenter (347) urged OMB to include greater specificity in the guidance about the need for transparency in both data and modeling: ". . . the agency should disclose the models used to make the determination, the way data were gathered and handled, and the data themselves should be released to the public unless exempted in the same manner that information can be withheld under the Freedom of Information Act (FOIA). Only in that way can the analysis meet the data quality guidelines goal of reproducibility." OMB agrees that transparency about data and modeling are critical to achieve, as described in OMB's information-quality guidelines and cross-referenced in the final OMB Circular on regulatory analysis.

A number of commenters (257, 328, 347, 348, 350) believe that the $1 billion threshold for probability analysis should be lowered, and possibly be replaced by the $100 million threshold contained in EO 12866. Another commenter (339) argued that the $1 billion threshold should be accompanied by a "tiered" approach to uncertainty analysis for rules costing less than $1 billion but more than $100 million per year. But, as one commenter (347) also noted, the $1 billion threshold will focus this probability analysis on the small number of rules that have the largest impact on the economy. As agencies gain experience with formal probability analysis, it may be appropriate to apply this type of analysis to a larger number of rules in the future. OMB believes that the final guidance provides agencies and OMB the appropriate degree of discretion to define the amount of uncertainty analysis that is appropriate for specific rules.

One commenter (292) expressed concern about the emphasis on probability distributions instead of best estimates of risk, cost, and benefit. This commenter was concerned that risks should not be dismissed simply because they could not be proven based on tests of statistical significance. Another commenter (250) expressed concern that probability analysis might mean delay of regulation until there is certainty. However, OMB guidelines do not impose statistical significance or certainty as a requirement for regulatory intervention. OMB agrees with a statement by one commenter (292) that agencies should focus on "best" estimates of risk (i.e., the expected estimates of risk specified in the OMB information quality guidelines). OMB also agrees with this commenter that best estimates may require use of both "hard" and "soft" data, including judgmental probabilities. A probability distribution may be necessary or useful in

constructing "best estimates" of risk, cost, and benefit. Without such a probability distribution, it is not clear how an expected estimate would be derived.

Another commenter (227) objected to the practice of combining two or more assumptions to produce a low "alternative estimate" of benefits, citing the alternative benefit analysis in several recent EPA rulemakings A different commenter (254) objected to the practice of combining two or more assumptions to produce an implausibly large estimate of risk or benefit, citing the risk assessment practices in EPA's pesticides program. Yet both of these commenters appear to support OMB's step toward more formal probability analysis in primary estimates of risks, benefits, and costs.

One commenter (236) argued that complex probability analyses would make the rulemaking process less transparent for the ordinary citizens and the average reader. OMB's response is that tools have been developed to convey probability information to decision makers and the public. Federal agencies have a responsibility to develop and convey these probabilities of benefit and cost.

D. Time Preference and the Discounting of Future Benefits and Costs

Benefits and costs do not always occur in the same time period. If benefits and costs are separated in time, the difference in timing should be accounted for in the analysis. The main rationales for doing so include:

(a) Resources that are invested will normally earn a positive return, so current consumption is more expensive than future consumption, since you are giving up that expected return on investment when you consume today.
(b) Postponed benefits also have a cost because people generally prefer present to future consumption. They are said to have positive time preference.

To make this adjustment, analysts use a discount factor to reflect the differences in timing of benefit and cost estimates. The magnitude of this discount factor depends on the discount rate and the differences in timing of benefits and costs. The further in the future the benefits and costs are expected to occur, the greater the discount factor.

OMB proposed that BCA and CEA be conducted using two discount rates: 3 percent and 7 percent. The draft guidelines would also permit sensitivity analyses with rates higher than 7 percent and lower than 3 percent whenever a strong case could be made for rates outside the 3 to 7 percent range. A lower rate might be appropriate when a rule has very long run effects and significant intergenerational consequences, a higher rate when a rule is likely to have a large displacement effect on high return private capital. The commenters presented a wide range of views on how time preference and the analytic practice of discounting should be handled in regulatory analysis, although there was substantial support for the proposal to use two discounts rates: 3 percent and 7 percent.

At least two commenters (235, 246) urged OMB to be more specific about the time horizons to be employed in regulatory analysis. If the selected time horizon is too short,

important benefits and costs could be omitted. OMB has left this judgment to the agencies that conduct analysis because it believes that general guidance on this point is not possible. The time horizons relevant to various rulemakings vary enormously. A useful guidepost is that the time horizon should be long enough to encompass all important benefits and costs so that extending the horizon would not change the results of the analysis significantly, but this insight does not provide a numerical time frame.

One commenter (348) raised a concern that a range of 3 percent to 7 percent rate might not encompass all the appropriate discount rates. If the target population realizing benefits and costs is relatively poor, they may exhibit discount rates above 7 percent in their personal consumption decisions, while better-off households may exhibit lower rates of discount in their personal decision making. The final Guidance is designed with sufficient flexibility to permit agencies to present results with multiple rates, including rates above 7 percent, if a strong case for a higher rate has been made by the agency.

The same commenter (348) argued further that there should be at most a single "weak default" rate of 7 percent rather than a range of rates. OMB agrees that the discount rate should not be seen as a universal constant but also believes that agency analysts need some guidance on the range of rates that is appropriate to use in the absence of compelling evidence for one specific rate or another. Also, specification of discount rates assures comparability of analysis across agencies.

One commenter (4) stated that a 7 percent discount rate seems high, even as an upper bound. He argued that 7 percent may be high, both as an estimate of the long-term, historical pre-tax rate of return on private-sector investment or as a forecast of future rates of return on private investment. The reviewer's comments appear to be strongly influenced by the recent disappointing results in U.S. financial markets. As shown in Appendix F, OMB has developed evidence using data from the National Income and Product Accounts and other sources that on a long-term basis, the real rate of return to capital in the United States has been around 7 percent and even higher for the corporate sector. The commenter's recommended rate for regulatory analysis (2.5 percent - 3.0 percent) is close to the lower rate contained in OMB Circular A-4, but this low rate would not be appropriate for regulations that had a strong displacing effect on capital investment.

Another commenter (9) claimed that 7 percent was too high because it does not account for the negative externalities (e.g., pollution) that are associated with some forms of private investment. However, the commenter did not demonstrate that these externalities would significantly reduce the 7 percent rate. Another commenter (227) argued that the 7 percent rate was based on the outmoded opportunity-cost-of-private-capital approach and discounting for regulatory analysis instead should be based on the preferred "shadow-price of capital" approach. However, another (246) argued that the shadow-price approach is not yet sufficiently well developed to be applied in routine regulatory analysis. OMB agrees that, while in principle, the shadow-price approach is a more accurate approach, it is not yet sufficiently developed to specify as a general approach to discounting.

Several commenters (251, 259, 334, 335, 336, 346, and 350) acknowledged the need for discounting future streams of dollars, but argued that loss of life is a qualitative change for which discounting may not be appropriate. They argued further that life cannot be invested in a bank account, like money, to yield a higher value over time. Particular concern was expressed about how discounting reduces the computed value of preventing diseases and impairments that occur after a long latency period.

Upon close examination, however, the argument of some commenters that agency analysts should assign a zero discount rate to future health gains is not convincing. The discount rate is an analytic tool that enables policy makers to compare regulatory alternatives that yield benefits at different times and with different costs. Without discounting of future health gains, some very perverse results will occur.

First, consider the simple case in which the agency faces two regulatory alternatives: Option A will save 10,000 lives within 15 years and Option B will save 10,000 lives in 50 years. If a zero discount rate is applied to these health gains, the two options will be viewed as equivalent, which is counter to the common sense and technical view that it is preferable to save the 10,000 lives sooner rather than later. Although there may be exceptional cases where future health gains are preferred over near-term health gains, these should be treated as exceptions rather than the common practice.

Second, consider a slightly more complex case where Option A, which saves 10,000 lives at a low cost (e.g., $10 million or $1,000 per life saved) is being analyzed as to the proper effective date. If a lower discount rate is applied to future health gains than future costs, then it can be shown that Option A will look even better analytically if the effective date is delayed a year (because the future costs will be discounted more than the future lifesaving). This reflects the Keeler-Cretin paradox, named for analysts at the Rand Corporation, which states that any attempt to assign a lower rate of discount to future health gains than costs will produce the perverse result that an attractive lifesaving investment will always be made more attractive with delay of its effective date. In order to avoid this perversity, there is professional consensus that the same discount rate should be applied to future health gains and costs.

Finally, the discounting of future health gains (compared to near-term costs) does not even depend on the argument the saving lives is intrinsically more valuable today than in the future. As long as lifesaving is costly in the near term, the analyst needs to consider the opportunity costs of those investments, since there is a foregone investment opportunity from near term costs (e.g., the opportunity cost is that the same funds could be invested at a positive rate of return and expended later to save more lives or accomplish other valuable purposes). Analysts can account for this opportunity cost either (a) by increasing the costs to reflect the expected rate of return on investment or (b) discounting the future health gains at a rate equivalent to the expected rate of return on the required investment. Either procedure leads to the same analytic result.

A number of commenters (9, 334, and 335) suggested that a zero discount rate should be considered when evaluating rules with long-term, intergenerational impacts. They advanced a variety of practical and philosophical arguments for that position. However, another commenter

(336) pointed out that rules with indeterminate or indefinite long-term effects must be evaluated with a non-zero discount rate in order to avoid a perverse result: rules with benefits expected to continue over an open-ended or infinite time horizon would always be considered more worthwhile, and thus preferred, to rules with specified benefits for a finite time period. Without discounting, the infinite stream of benefits would have an infinite value. For rules with intergenerational impacts, the reviewer (336) favored presentation of results with a 1 percent discount rate. The draft guidelines allowed agencies to use such a low rate in this context. The commenter (336) noted that any discount rate for intergenerational benefits lasting beyond a few decades should not exceed 1 percent, since otherwise the time frames involved will automatically trivialize the future benefits out of recognition.

Some commenters (284, 292, 307, 340, 341, 348), however, raised concerns with OMB's proposed new approach to intergenerational discounting, which would permit agencies to use a rate of discount as low as 1 percent for analysis of regulations with long-term effects on future generations. One commenter (340) stated the view that market rates of return on investment are generally larger for longer time periods, but did not explain why the simple passage of time would be expected to increase rates of return. This commenter argued that the opportunity costs of investing now to protect future generations should be evaluated using a discount rate larger than the 3 percent and 7 percent rates used for more near-term horizons. Others (341), after quoting several prominent economists who believe that ethics and economics should inform policy toward social time preference, reject a role for ethics and instead urges OMB to base the intergenerational discount rate on market determinations. Another commenter (348) objected to intergenerational rates less than 3 percent because it would amount to a "transfer of wealth" from the current generation to future generations who are likely to be even better off.

These comments reveal that intergenerational time preference is a matter of both economics and fairness. The final guidelines permit agency analysts to present results for intergenerational rules using discount rates that are outside the 3 percent and 7 percent range required for all regulatory analysis.

One commenter (303) praised OMB for the new instruction for presentation of the annual time streams of benefits and costs in regulatory analysis. The reviewer went further and requested that these streams be summed and a sensitivity analysis be reported with a 0 percent discount rate. OMB believes that presenting the annual time streams is important for transparency, but that the discounting of future benefits and costs is necessary for meaningful intertemporal comparisons.

One commenter (340) asked if discount rates for longer periods of time should be larger than for shorter periods because interest earned in the market has an upwardly sloping supply curve for longer time periods. OMB believes this is a fair point, but there are reasons for not making this adjustment. First, it would add to the complication of the guidelines by requiring a different rate for different time periods. The guidelines do make an allowance for this when the time period is very long, as it is for intergenerational discounting, but within generations a simple process of discounting using only two rates is recommended for most analysis. More importantly, over the relevant time periods, say, 5 to 30 years, the yield curve has not been especially steep on average. The average difference between the five-year interest rate and the

thirty-year rate has only been about 1/2 percentage point over the last 25 years. This is not large enough to justify a separate discount rate for short versus long-term regulatory impacts.

E. Data: Collection, Access, and Quality

Several commenters made specific points about the need for quality, transparency, and public access to data used in regulatory analysis. Others expressed concern about whether OMB's regulatory analysis and data quality guidelines are too onerous for agencies. The major comments are summarized here.

One commenter (347) suggests that the draft OMB guidance gives insufficient direction about when data are insufficient to support a decision, either because they are so few in number, or they are gathered improperly. In cases where the data are inadequate, the commenter argues, the agencies should be required to gather additional data. Similarly, another commenter (326) argued that agencies sometimes initiate rulemakings without investing the effort to collect the valid data needed to inform the rulemaking process. OMB notes that data collection is costly and no data are of perfect quality. The costs and value of more data collection and quality control should be analyzed with the "value-of-information" framework promoted in the OMB guidelines.

One commenter (259) raised a concern that the combination of OMB's new regulatory analysis guidelines and OMB's new information quality guidelines might cause rejection of promising regulations. OMB believes that the requirements in the two sets of guidelines are compatible and, in both cases, agencies are provided discretion to tailor the investment in data quality and regulatory analysis to the importance of the rulemaking.

APPENDIX F: COMPUTING AVERAGE RATES OF RETURN TO PRIVATE CAPITAL IN THE UNITED STATES: 1947-2001

Between 1947 and 2001, the real rate of return to total private capital in the United States averaged around 7 percent. The corresponding estimate for the domestic corporate sector alone was around 9 percent over the same span of time. These estimates were derived from National Income and Product Accounts (NIPA) data, related data on stocks of physical capital from the Bureau of Economic Analysis (BEA), and other sources. The rates of return were calculated by dividing an estimate of capital income by the current value of the capital stock. Property and income taxes attributable to capital were included in the numerator along with investors' after-tax incomes. The capital stocks were valued at replacement cost or market value and computed as mid-year averages. The last complete year of available data was 2001.

A. Sources for the National Capital Stock Estimate

The total capital stock consisted of the sum of the value of structures, equipment, inventories, and land. U.S. citizens' holdings of foreign capital were added to the total, and foreign holdings of U.S. capital were subtracted. This definition of the capital stock aligns with the NIPA definition of national income, which includes U.S. citizen's earnings wherever earned and excludes foreign earnings made in the United States.

The estimated value of private structures and equipment came from "Current-Cost Net Stock of Fixed Assets and Consumer Durable Goods," Table 1.1 in BEA's set of standard fixed asset tables, last revised September 25, 2002. It can be found at http://www.bea.doc.gov/bea, BEA's web site. End-of-year values were converted to midyear values by averaging. The estimate included both residential and nonresidential assets.

The estimated value of private inventories was drawn from NIPA Table 5.12B "Private Inventories and Domestic Final Sales by Industry (Q)," also available on the BEA web site. The quarterly levels for the second and third quarters of each year were averaged to obtain the mid-year values.

Land values through 1994 were drawn from the estimated market value of private land reported in the Federal Reserve System's flow-of-funds balance sheet estimates. This series, however, has been discontinued. Since 1994, the estimated land values were a composite estimate. Data from the Federal Reserve's Flow-of-Funds data base were used to estimate landholdings of private households and corporations. The estimated land values for these sectors were calculated as the difference between total real estate values as reported in the flow-of-funds balance sheets and the estimated values of structures in each sector. The data can be found in Tables B-100 and B-102 of the Flow of Funds Accounts of the United States: Balance Sheets, and they can be accessed through the Federal Reserve website, http://www.federalreserve.gov. Agricultural land values were derived from Department of Agriculture estimates of the market value of farm real estate. The estimates were obtained from the following web site: http://www.ers.usda.gov/Briefing/FarmIncome/Data/Bs_t6.htm. BEA estimates for the net value of farm structures were subtracted from the total value of farm real estate to obtain an estimate of

the value of land. The landholdings of the economy's remaining sectors were not directly observable. Estimates of the missing values were computed based on the assumption that the share of this land in total landholdings approaches the average ratio for these sectors that prevailed from 1946 through 1994 -- about 32 percent.

Net holdings of foreign capital were added to the estimated total capital stock to align the estimate with the measure of capital income drawn from NIPA. The NIPA national income data include earnings of U.S. citizens on holdings of foreign capital while excluding foreigners' earnings from domestic capital. For recent years BEA's estimates of the U.S.-owned and foreign owned private assets with direct investment at market value were used for this adjustment, see Table 1 from U.S. Net International Investment Position at Yearend 2002, a BEA News Release. The historical data can be found at the BEA website.

B. Sources for the Estimate of Capital Income

Capital income was derived entirely from NIPA data. It includes corporate profits with inventory valuation and capital consumption adjustments net of the earnings of the Federal Reserve System, net interest, and rent, plus some further additions which are detailed below.

The most important of these further additions was an adjustment to reflect the capital share of proprietors' income. Proprietors' income consists of the income earned by unincorporated businesses and the self-employed. Much of this income is properly thought of as labor income, but the self employed and noncorporate business use physical capital, and thus part of proprietors' income consists of a return on that capital. To calculate the portion of proprietors' income due to capital, the share of capital income in national income excluding proprietors' income was computed and that same share was assumed to hold for proprietors' income. An alternative approach to the calculation produced a similar answer. On this approach, the labor component of proprietors' income was computed by imputing a wage to the workers in this sector and subtracting those imputed labor earnings from total proprietors' income with the remaining income attributed to noncorporate capital. The total rate of return was not significantly affected by whichever method was used. For example, the rate of return averaged 6.7 percent since 1947 on either approach.

Two further adjustments were made to arrive at total capital income. Property taxes were attributed entirely to capital income, while other indirect business taxes were distributed between labor and capital using the shares of labor and capital in national income excluding proprietors' income. A similar adjustment was made to business subsidies net of the surpluses of government enterprises. These subsidies were subtracted from capital income since they do not represent market determined income. Finally, business transfers were also added to total capital income.

C. The Corporate Sector

The corporate capital stock was measured as the sum of corporate equipment and structures, drawn from the BEA fixed capital data base, plus corporate land estimated using data from the Federal Reserve's flow-of-funds accounts, and an estimate of corporate inventories. Corporate inventories were computed using the ratio of corporate fixed capital to total capital. It

was assumed that the ratio of inventory to fixed capital was the same for corporate and noncorporate business.

Corporate capital income was measured as the sum of corporate profits with inventory valuation and capital consumption adjustments net of the earnings of the Federal Reserve System plus the net interest paid by the corporate sector with a minor adjustment to reflect indirect taxes, transfers and subsidies. The source for the estimates was NIPA Table 1.15, which can be located through the BEA web site. Capital income defined in this way is a broader concept than after-tax corporate profits. Corporations borrow to pay for some of their capital and the return on that borrowing is part of the total return on corporate capital, but it is not part of corporate profits. Also, indirect taxes on corporate output are partly borne by corporate capital stocks, and therefore are part of the total social return to corporate capital.

No adjustment was made for international holdings of capital because the capital income measure used for the corporate sector was domestic capital income which includes all earnings from U.S. capital stocks and excludes earnings on foreign capital.

The rate of return to corporate capital averaged 9.1 percent from 1947 through 2001, and 9.9 percent over the most recent 10-year period, 1992-2001. See Table 23.

Table 23. Average Rates of Return to Private Capital in the United States: 1947 – 2001

Year	Private Capital Stock ($ billion)	Total Capital Income ($ billion)	Average Rate of Return %	Corporate Capital Stock($ billion)	Corporate Capital Income ($ billion)	Average Rate of Return %
1947	756.1	48.3	6.4	279.7	25.1	9.0
1948	849.0	59.1	7.0	313.1	32.4	10.4
1949	893.1	56.6	6.3	323.3	30.3	9.4
1950	958.6	67.1	7.0	343.5	37.5	10.9
1951	1067.5	75.3	7.1	386.0	42.0	10.9
1952	1141.0	75.0	6.6	409.4	39.8	9.7
1953	1188.1	77.4	6.5	422.6	40.3	9.5
1954	1231.8	79.2	6.4	434.1	39.5	9.1
1955	1297.6	93.8	7.2	455.5	50.6	11.1
1956	1397.4	94.2	6.7	497.4	48.6	9.8
1957	1490.0	97.0	6.5	537.1	48.0	8.9
1958	1557.2	95.9	6.2	560.1	44.4	7.9
1959	1617.8	111.3	6.9	577.8	55.8	9.7
1960	1676.1	113.0	6.7	594.1	53.9	9.1
1961	1731.5	119.0	6.9	605.6	55.6	9.2
1962	1804.2	132.7	7.4	626.5	64.3	10.3
1963	1873.5	143.0	7.6	645.2	70.4	10.9
1964	1962.7	155.5	7.9	670.6	78.2	11.7
1965	2087.4	173.5	8.3	713.2	90.4	12.7
1966	2242.6	184.7	8.2	771.7	97.4	12.6
1967	2401.4	187.6	7.8	833.5	95.9	11.5

Table 23. Average Rates of Return to Private Capital in the United States: 1947 – 2001						
Year	**Private Capital Stock ($ billion)**	**Total Capital Income ($ billion)**	**Average Rate of Return %**	**Corporate Capital Stock($ billion)**	**Corporate Capital Income ($ billion)**	**Average Rate of Return %**
1968	2595.3	200.3	7.7	904.8	102.5	11.3
1969	2829.0	205.1	7.2	994.7	101.4	10.2
1970	3049.0	201.3	6.6	1092.4	91.0	8.3
1971	3303.3	227.5	6.9	1195.0	105.4	8.8
1972	3628.3	252.8	7.0	1304.8	118.8	9.1
1973	4120.7	283.9	6.9	1467.0	129.4	8.8
1974	4776.8	290.6	6.1	1727.0	121.5	7.0
1975	5386.7	323.9	6.0	1982.2	146.6	7.4
1976	6013.0	365.6	6.1	2187.2	168.2	7.7
1977	6793.0	421.1	6.2	2416.5	201.6	8.3
1978	7789.7	475.7	6.1	2733.7	231.1	8.5
1979	9072.3	517.5	5.7	3148.5	233.7	7.4
1980	10469.5	543.3	5.2	3611.0	223.5	6.2
1981	11711.0	633.1	5.4	4081.4	266.9	6.5
1982	12552.9	650.8	5.2	4425.0	250.7	5.7
1983	13165.3	728.9	5.5	4607.4	304.4	6.6
1984	13870.4	858.9	6.2	4848.1	378.3	7.8
1985	14584.6	903.7	6.2	5100.9	394.4	7.7
1986	15352.8	902.2	5.9	5323.5	372.8	7.0
1987	16222.0	988.6	6.1	5567.1	437.0	7.8
1988	17245.1	1107.8	6.4	5906.0	495.5	8.4
1989	18337.6	1166.9	6.4	6280.0	503.4	8.0
1990	18829.9	1213.0	6.4	6516.3	504.2	7.7
1991	18762.8	1236.9	6.6	6430.8	510.8	7.9
1992	18757.8	1257.5	6.7	6321.6	517.2	8.2
1993	19279.8	1337.6	6.9	6441.1	567.9	8.8
1994	20348.7	1448.2	7.1	6731.3	647.1	9.6
1995	21293.2	1580.8	7.4	7128.8	730.9	10.3
1996	22485.7	1702.6	7.6	7589.9	815.4	10.7
1997	23777.3	1846.5	7.8	8191.6	931.7	11.4
1998	25084.9	1905.5	7.6	8678.8	933.1	10.8
1999	26757.5	1980.7	7.4	9093.0	934.4	10.3
2000	28824.4	2060.3	7.1	9734.1	956.3	9.8
2001	30213.7	2037.4	6.7	10088.3	886.4	8.8
Average 1947 – 2001			6.7	Average 1947 – 2001		9.1
Average 1992 – 2001			7.2	Average 1992 – 2001		9.9

APPENDIX G. UPDATE ON RETURN AND PROMPT LETTERS

As OMB reported in the 2002 final report, the Bush Administration is again using the "return letter" as a tool to improve the quality of new rulemakings. The technical and policy rationales for OMB's returns are stated in letters to agency officials that are made public and posted on OMB's website. In 12 cases, after modifications and later submission for review under E.O. 12866, OMB concluded review of the rule.[98] Table 24 provides the status of the rules that OMB has returned to agencies during the 2001-03 period.

Table 24. Status of Draft Rules Returned for Reconsideration as of 7/22/03

Agency	Rule	Returned	Resubmitted	OMB Review Ended
USDA	Environment Enhancement for Nonhuman Primates	1/29/02	Not Resubmitted	–
HUD	Public Housing Capital Fund Program	11/21/01	5/15/03 (Final) 5/19/03 (NPRM)	7/8/03 (Final) NPRM Under Review
HUD	Establishment of a Demonstration Risk-Sharing Program	9/26/01	Not Resubmitted	–
DOT	Preference for U.S.-Flag Vessels in the Shipment of Cargoes on Ocean Vessels	6/13/03	Not Resubmitted	–
DOT	Tire Pressure Monitoring Systems	2/12/02	5/28/02	5/29/02
DOT	U.S. Locational Requirement for Dispatching the U.S. Rail Operations	9/20/01	11/13/01	11/20/01
DOT	Digital Flight Data Recorder Regulations	9/14/01	Not Resubmitted	–
DOT	Corrosion Prevention and Control Program	9/14/01	6/18/02	9/16/02
DOT	Aging Aircraft Safety	9/14/01	6/18/02	9/24/02
DOT	Certification of Pilots, Aircraft, and Repairmen for Light Sport Aircraft	8/8/01	12/17/01	1/3/02
DOT	Safety Requirements for External Product Piping on Cargo Tanks Transporting Flammable Liquid	8/8/01	Not Resubmitted	–
DOT	Part 145 Review: Repair Stations	7/20/01	7/20/01	7/30/01
VA	Evidence of Permanent and Total Disability	9/14/01	Not Resubmitted	–

[98] HUD's Public Housing Capital Fund Program regulation was split into two separate rules, one of which OMB cleared on July 8, 2003.

Table 24. Status of Draft Rules Returned for Reconsideration as of 7/22/03				
Agency	**Rule**	**Returned**	**Resubmitted**	**OMB Review Ended**
VA	Medical Care and Treatment for which VA Will Not Seek Reimbursement	10/3/01	Not Resubmitted	–
VA	Exclusions from Income	11/28/01	Not Resubmitted	–
VA	Availability of Vendee Financing for VA-Acquired Properties	10/8/02	Not Resubmitted	–
EPA	Water Quality Standards for Indian County	10/2/01	Not Resubmitted	–
OPM	Implementation of Additional Cost Principles in the Federal Employees Health Benefits Program	12/18/2002	Not Resubmitted	–
SBA	Small Business Size Standards: Economic Injury Disaster Loan Payment	2/11/02	5/15/02	5/23/02
SSA	Clarification of Rules	9/27/01	4/3/02	5/28/02
SSA	Filing Claims under the Federal Tort Claims Act and the Military Personnel and Civilian Employees Claims Act	9/27/01	9/22/02	12/13/02
SSA	Revised Medical Criteria for Evaluating Hematologic Disorders and Malignant Neoplastic Diseases	9/27/01	11/9/01	11/14/01
SSA	Representative Payment Under the Title II and Title XVI of the Social Security Act	9/27/01	6/20/03	Under Review
SSA	Ticket to Work and Self-Sufficiency Program	11/15/01	11/20/01	12/17/01

In addition to resurrecting the practice of returning rules to agencies for their reconsideration, OMB has taken a proactive role in suggesting regulatory priorities for agency consideration. The tool that OMB has developed to play this role constructively is the "prompt letter," which is intended to bring a policy matter to the attention of an agency.

Prompt letters do not have the mandatory implication of a Presidential directive. Unlike a "return letter," which is authorized by E.O. 12866, the prompt letter simply constitutes an OMB request that an agency elevate a matter in priority, recognizing that agencies have limited resources and many conflicting demands for priority attention. The ultimate decision about priority-setting remains in the hands of the regulatory agency.

An important feature of the prompt letter can be its public nature, aimed at stimulating agency, public and congressional interest in a potential regulatory or informational priority. Although prompt letters could be treated as confidential pre-decisional communications, OMB believes that it was wiser to make these prompt letters publicly available in order to focus congressional and public scrutiny on the important underlying issues. Table 25 provides a brief summary of agency responses to the ten prompt letters OMB has sent to agencies and related OMB and agency follow-up activities.

Table 25. Agency Responses to Prompt Letters as of 7/22/03

Agency	Prompt Letter Subject	Date	Agency Response
USDA	Dietary guidelines.	5/27/2003	The agency is developing a response to OMB's prompt letter.
USDA	Environmental incentives program.	11/18/2002	USDA has incorporated OMB's suggestions in a final rule that was issued on May 14, 2003.
Energy	National Energy Modeling System	2/24/2003	Energy and OMB are working together to implement the changes recommended in OMB's prompt letter.
DOL/OSHA	Promoting use of automated external defibrillators.	12/3/2001	OSHA has issued a technical information bulletin and BLS is conducting a survey.
HHS/FDA	Labeling for trans-fatty acids.	9/18/2001	FDA published a final rule in July 2003.
DOT/NHTSA	Modifying the frontal occupant protection standard by establishing a high-speed, frontal offset crash test.	12/7/2001	NHTSA plans to issue an NPRM in 2003.
EPA	Researching fine particulate matter.	12/4/2002	EPA is awaiting a report on this subject that NAS is preparing.
EPA	Improving the utility of the data available on the environmental performance of industrial facilities.	3/4/2002	EPA has completed its single facility ID project and has developed a central data exchange which it is starting to make available for reporting across programs. EPA is continuing to explore ways to speed up the release of TRI data while maintaining appropriate quality control.
EPA	Reducing pollution from non-road diesel engines.	6/7/2002	EPA issued an NPRM on 5/23/03.
OFHEO	Strengthening the corporate governance of Fannie Mae and Freddie Mac.	5/29/2002	OFHEO issued a final rule in April 2003 requiring disclosures of financial and other information by Fannie Mae and Freddie Mac.

APPENDIX H: NUMBER AND TIMING OF REGULATORY REVIEWS

OMB reviews significant regulatory actions to ensure consistency with applicable law, the President's priorities, the principles set forth in Executive Order 12866, and to ensure that regulatory actions do not conflict with the policies of another agency. Table 26 presents the number of regulatory reviews in the aggregate and by agency from 1998 through 2002. OMB reviewed nearly 600 rules in 2002.

Table 26. Status of Regulations Reviewed by Agency, 1998 – 2002

Agency	Rule Type	Total	2002	2001	2000	1999	1998
HHS	NES	404	70	66	89	88	91
	ES	138	37	28	26	22	25
USDA	NES	273	48	53	56	69	47
	ES	58	12	8	24	10	4
EPA	NES	232	31	52	51	42	56
	ES	67	11	9	18	15	14
DOT	NES	183	54	48	29	26	26
	ES	51	13	14	7	8	9
DOI	NES	197	55	32	63	28	19
	ES	20	4	3	6	4	3
DOC	NES	165	26	20	47	46	26
	ES	14	3	2	4	4	1
DOJ	NES	163	55	39	29	13	27
	ES	8	4	2	0	1	1
VA	NES	162	49	68	12	20	13
	ES	7	2	4	1	0	0
HUD	NES	158	32	35	29	36	26
	ES	8	2	0	2	3	1
OPM	NES	147	26	32	37	28	24
	ES	0	0	0	0	0	0
DOL	NES	100	33	9	29	17	12
	ES	24	8	1	8	3	4
ED	NES	75	17	0	29	23	6
	ES	1	0	0	0	1	0
Total NES		2259	496	454	500	436	373
Total ES		396	96	71	96	71	62
Unfunded Mandates		88	17	14	25	16	16
Totals		2655	592	525	596	507	435

Note: All rules were measured from February 1 of the stated year through January 31 of the following year. NES refers to rules that are not economically significant, and ES refers to rules that are economically significant.
Source: www.omb.gov

OMB is committed to performing its regulatory reviews within the 90-day period set out in E.O. 12866. As Table 27 reveals, OMB has already made substantial progress in reducing the number of reviews that consume more than the allotted 90 days.

OMB regards the 90-day review limit as a performance indicator for a strong regulatory gatekeeper. In previous Administrations, some OMB reviews consumed more than six months or even more than a year without any conclusion for the agency. OMB intends to provide agencies with prompt and explicit responses to their draft rulemaking actions.

Table 27. Timing of Regulatory Reviews, 1999 – 2003

Month	Year	Pending Over 90 Days	Total Pending	% Over 90 Days
January	1999	15	77	19.5%
April	1999	10	84	11.9%
July	1999	11	84	13.1%
October	1999	16	76	21.1%
January	2000	15	83	18.1%
April	2000	19	124	15.3%
July	2000	24	101	23.8%
October	2000	42	154	27.3%
January	2001	50	117	42.7%
April	2001	4	72	5.6%
July	2001	25	97	25.8%
October	2001	1	62	1.6%
January	2002	0	83	0.0%
April	2002	0	72	0.0%
July	2002	1	73	1.4%
October	2002	0	105	0%
January	2003	2	90	2.2%
April	2003	1	60	1.7%

Source: www.omb.gov

APPENDIX I: LIST OF PEER REVIEWERS AND PUBLIC COMMENTS

OMB appreciates all of the comments we received in response to the draft report. In particular, we would like to thank our invited peer reviewers: Cass Sunstein, University of Chicago; Lester Lave, Carnegie Mellon University; Milton C. Weinstein and James K. Hammitt of the Harvard School of Public Health; Kerry Smith, North Carolina State University; Paul Kleindorfer and Howard Kunreuther, University of Pennsylvania; Gordon Woo, Risk Management Solutions; Darius Lakdawalla, RAND; Jonathan Weiner, Duke University Law School; Douglas K. Owens, Stanford University; W. Kip Viscusi, Harvard Law School; Richard Wilson, Harvard University; Jane Gravelle, Congressional Research Service; and Barbara Fraumeni, Bureau of Economic Analysis (Department of Commerce). Below is a listing of all the written comments we have received (including from the peer reviewers), and the numbers we assigned to their comments. Some submitted multiple comments; in such cases more than one number was assigned.

1. Cass Sunstein, University of Chicago Law School
2. William A. Pizer, Resources for the Future
3. Lester Lave, Carnegie Mellon University
4. Milton C. Weinstein, Harvard School of Public Health
5. Kerry Smith, North Carolina State University
6. OMB Watch
7. Denise Johnson, Research and Special Programs Administration, Department of Transportation
8. John Loomis, Colorado State University
9. Mark Eads, U.S. EPA
10. Milton Weinstein, Harvard School of Public Health
11. Jim Tozzi, Center for Regulatory Effectiveness
12. Paul Kleindorfer and Howard Kunreuther, University of Pennsylvania
13. William L. Kovacs, U.S. Chamber of Commerce

13B. Phillip Lurie

14. Ralph L. Keeney
15. Gordon Woo, Risk Management Solutions
16. Darius Lakdawalla, RAND
17. Wahila Minshall
18. Thomas Windberg
19. George Greer
20. William L. Payne, Westinghouse Savannah River Company
21. Christina Milstein
22. Martha A. Williams
23. Susan Emge Miller
24. Claudia Slate
25. Gary Rost
26. Cory Golden
27. Mark O'Dell
28. Kari Kilgore
29. Daniel Barnett
30. Barbara Mills
31. Georgia Wagner
32. Carolyn Wilkerson
33. Kristofer Young
34. Zay Ogden
35. Tzipora Katz
36. Robert Bernhard
37. Analiese Miller
38. Harriet Cavalli
39. Beverly Ellingwood
40. Dawn Sajadea
41. Thomas Paulson
42. Yvonne McCallister

43. Mary Boersma
44. Dennis Sherman
45. Katherine Finn
46. Laura Lelievre
47. Marilyn Slater
48. Carole Wiles
49. Vicki Elson
50. Eric Miller
51. Sam Saltonstall
52. Carol Warren
53. Ingeborg Kelly
54. Riva Berleant
55. Margaret Minschein
56. Miriam Berg
57. Noreen McCluskey
58. A.J. Travland
59. Florence Vincent
60. Ryan Langemeyer
61. Len Carella
62. Bruce Hawkins
63. Janet Drake
64. Sandra Mardigian
65. Nancy Heistand
66. Jeff Poster
67. Mikasa Moss
68. Ernest Krause
69. Mary Delaney
70. Celena Cline
71. Alan Balkema
72. Gladis Rubio
73. Carol Strand
74. Shannon Capezzali
75. Derek B. Brett
76. George Dumun III
77. Paul Williams
78. Kimberly Scrader
79. Tricia Katz
80. Lawrence Schiber
81. Elaine Fischer
82. Virginia Storey-Welch
83. Elizabeth Bennett
84. Robert E. Rutkowski
85. Katie Olmstead
86. Laurie Kellogg
87. Nancy Haden
88. Larry D. Little
89. John H. Pratt
90. Nanna Bolling
91. Ravi Grover
92. Freda Shen
93. Cathleen Krahe
94. Glenys Spitze
95. Arlene Montemarano
96. Debra Rollins
97. Steve Tudisco
98. Julie Ford
99. Barbara J. Moore
100. Dan Mapes-Riordan
101. Sally Gibson
102. Mike Taylor
103. Rebecca Zimmerman
104. Penny and Robert Morris
105. Charles Chrurchman
106. Kim Kline
107. Larry Beede
108. Uri Neren
109. Frank Dina
110. Anthony Orkin
111. Ada J. Kidd
112. Doug Long
113. Gejoyces@aol.com
114. Charles Darnell
115. Joanne Lee
116. Deborah Carter Day
117. Pamela Nelson
118. Randi Perkins
119. Eleanor MacLellan
120. Chris Morrow
121. Clint Caughran
122. Susan Civitelli
123. Alan Papscun
124. Holly Szafranski
125. Stephanie Mertens
126. Judith Romell
127. Cassandra Lista
128. Roberta M. Burnes
129. Melanie J. Taormina
130. Jennifer Freeman and Dean Lobovits
131. Heidi Ripke
132.
133. William H. White
134. Tim Weiland

135. Ming Yuen-Schat
136. Sheryl and Jim Sussbauer
137. Dr. George W. Crawford
138. Richard Warren
139. Mary Murphy
140. I.A. Backer
141. Heather D. Quick
142. Nancy Fox
143. Rolfe McAfee
144. Nolan T. Jones
145. Kenneth F. Damro
146. Elaine Matthew
147. Kay Christopher
148. Loren L. Weiland
149. Robert E. Rutkowski
150. Edward Paul
151. David Anderson
152. Todd Heintz
153. James M. Nordlund
154. Katherine Cunningham-Eves
155. Sandra Schchat
156. Leona Bochantin
157. Nona Donahue
158. Jennifer Munch
159. Jonathan B. Weiner,
Duke University Law School
160. Susan M. Wald
161. Regina M. Holt
162. Daniel Piser
163. Ivan Greene
164. Jack Greene
165. Trinity Peacock-Broyles
166. Laurie Gawel
167. Jan Fernando
168. Phil Milgrom
169. Julia Mabry
170. James Peters
171. Beverly Zarin
172. Mary Caves
173. Mary Stadel
174. Stephen Wingeier
175. Dorothy A. Spencer
176. Keren M. Riegel
177. James E. Dunn and Penny Lynn
178. Lynda James
179. James McBride
180. Clara L. Young
181. John Neville
182. Christopher Hathaway
183. Robert Fehribach
184. Craig Havens
185. Michael John Mayo
186. Julie Cooley
187. Huck Rorick
188. Dr. Judith Schmidt
189. Marita M. Hardesty
190. William L. Webster
191. Joan Hebert
192. Robert C. Gibbons
193. Dr. Douglas E. Wingeier
194. Louis Paley
195. Frederick R. McKeehan
196. Eva Mecic
197. Diane Wills
198. Ellen Pearce
199. Phyllis Beallor
200. Ruth Stormo
201. Mary G. Caves
202. Burt Culver
203. Julie Pizzo
204. Nancy Fightlin
205. Dr. Lynn Stulberg
206. Rachel M. Jacobson
207. Lucille Nurkse
208. Cedar Barstow
209. Joseph Ancel
210. Steve Barnes
211. John Horejsi
212. Rohan Sabnis
213. Rudy Gartner
214. Stefanie Collins
215. Linda Wright Sheehan
216. Stanley L. Rose
217. Bev Jackson
218. Ellen Lougee
219. Beverly England Williams
220. Larry Zwolinski
221. Janet Hitt
222. Brian Topping
223. Ani St. Amand
224. Fred Koster
225. Alexandra Keith

226. Patricia J. Barry
227. A. Myrick Freeman III, Bowdoin College
228. Robert W. Hahn and Robert E. Litan, AEI-Brookings Joint Center
229. Ed Thomas, National Rural Water Association
230. Carl Hoefer
231. Roberta Beaumont
232. James T. Wood
233. Julie Huyler
234. Drew Markle
235. Ted Horbulyk, University of Calgary
236. Daniel Schwartz, Children's Environmental Health Network
237. Cynthia Wilson
238. Anne Pancella
239. Stephen Andrews
240. Jamie Stutzenburg
241. Jon Cecil
242. Felipe D. Garcia
243. Cassandra Howe
244. Marjory M Donn
245. Joan Keener
246. James K. Hammitt, Harvard School of Public Health
247. Raymond J. Sauvage, Tennessee Gas Pipeline
248. John S. Rogers, World City America
249. Robert J. Maxwell et al., beverage alcohol trade associations
250. Senator Richard J. Durbin
251. Lisa Heinzerling, Georgetown University Law Center
252. James Love, Consumer Project on Technology
253. Howard J. Fox, Earthjustice
254. George M. Gray, Harvard Center for Risk Analysis
255. Richard Solomanski
256. Wilson Knerr
257. Robert Strassburger, Alliance of Automobile Manufacturers
258. Joe F. Colvin, Nuclear Energy Institute
259. Senator Daniel K. Akaka
260. Thomas W. Curtis, American Water Works Association
261. Peter Maybarduk
262. Peter Elbow
263. Rebecca Barnes-Davies
264. David Shaw
265. Alicia Bakowski
266. Katherine F. Lindquist
267. Jackie Dale
268. Patricia Weiner
269. Jocelyn Groden
270. Jonathan Weiner, Duke University Law School
271. Richard Tanner
272. Andrea Armstrong
273. Dawn M. Martin
274. Peter Felsenthal
275. Seth Kaplan
276. John Langton
277. Nancy van Iderstine
278. John Brennan
279. Pamela Weiss
280. John Mahoney
281. Cornelius Dufallo
282. D. Rickard
283. Tommie Ferguson
284. Robert W. Hahn and Robert E. Litan, AEI-Brookings Joint Center
285. Shirine A. Hossaini
286. Stephanie Hinshaw
287. Michael Farnan
288. Carol Moore
289. Susan Woodruff
290. Beverly Ellingwood
291. Douglas K. Owens, Stanford University
292. W. Kip Viscusi, Harvard Law School
293. Jonathan P. Hausman
294. Warner North
295. Russ Kroncke

296. Ellen Kolasky
297. Marisa Bennett
298. John Marchese
299. Diane VanDe Hei,
Association of Metropolitan Water Agencies
300. Brian Lawrence
301. Carol Ann Goldstein
302. Lynne Aldrich
303. William Funk,
ABA Section on Administrative Law and Practice
304. Bruce Levinson,
Center for Regulatory Effectiveness
305. Fred H. Anderson
306. Miriam E. Chamberlain
307. Wendy L. Gramm and Susan E. Dudley,
Mercatus Center
308. Dennis Paustenbach,
Exponent
309. James W. Conrad
310. Jon Cecil
311. Bridget Riversmith
312. Margit Meissner
313. Francis J. Roberts
314. Thomas L. Jackson,
American Society of Civil Engineers
315. John Curle
316. Jeff Horejsi
317. John Mendeloff,
University of Pittsburgh
318. Matt Braynard
319. Dagmar Etkin,
Environmental Research Consulting
320. Mark Lewis,
National Park Visitors Alliance
321. Lynn Bergeson and Eileen Salathe Gernhard,
Rodenticide Registrants Task Force
322. Andrew Langer,
National Federation of Independent Business
323. Dick Hanneman,
The Salt Institute
324. David Fischer,
Chlorine Chemistry Council
325. Paul H. Dugard and W. Caffey Norman III,
Halogenated Solvents Industry Alliance
326. Kristy Bulleit, Lucinda Minton Langworthy, Michael Rossler, and Bob Stavins, for the Utility Water Act Group, Utility Air Regulatory Group, Edison Electric Institute
327. William L. Kovacs,
U.S. Chamber of Commerce
328. Howard J. Feldman,
American Petroleum Institute
329. Wendy Gramm and Susan Dudley,
Mercatus Center
330. Joe J. Mayhew,
American Chemistry Council
331. Fred L. Smith,
Competitive Enterprise Institute
332. Michael Whinihan,
General Motors Corporation
333. Reece Rushing,
OMB Watch
334. James K. Wyerman et al.,
(coalition of public interest groups)
335. Wesley Warren,
Natural Resources Defense Council
336. Karen Florini,
Environmental Defense
337. Robert N. Stavins, on behalf of USGen New England
338. Rebecca Barnes-Davies
339. David A. Lereah,
National Association of Realtors
340. Eileen Lee and Alex Hecht,
National Multi-Housing Council and National Apartment Association
341. Wendy Gramm and Susan Dudley,
Mercatus Center
342. R. Craig Silvertooth,
National Roofing Contractors Association
343. Edward Hudgins,
The Objectivist Center
344. Lauraine Chestnut,

Stratus Consulting
345. Anita Drummond, Associated Builders and Contractors
346. David Certner, AARP
347. Gerald Howard, National Association of Home Builders
348. Richard B. Belzer, Regulatory Checkbook
349. Lynn Dee
350. William L. Kovaks, U.S. Chamber of Commerce
351. Reece Rushing, OMB Watch
352. James K. Hammitt, Harvard School of Public Health
353. Jane Silverman
354. Lisa Manzi
355. Glenn Niblock, Vertex Associates
356. Richard Wilson, Harvard University
357. Tara Nelson
358. April A. Willis
359. Paul De Civita, Health Canada
360. Alan Krupnick, Resources for the Future
361. Ruth Swanson
362. Representative Doug Ose
363. Rhonda Mueller
364. Charles Fletcher
365. Cindy Gingrich-Baker
366. Judie Anders
367. Susanna de Fall

APPENDIX J: THE REGULATORY RIGHT-TO-KNOW ACT[99]

SEC. 624. (a) IN GENERAL.—For calendar year 2002 and each year thereafter, the Director of the Office of Management and Budget shall prepare and submit to Congress, with the budget submitted under section 1105 of title 31, United States Code, an accounting statement and associated report containing—

(1) an estimate of the total annual costs and benefits (including quantifiable and nonquantifiable effects) of Federal rules and paperwork, to the extent feasible—

(A) in the aggregate;

(B) by agency and agency program; and

(C) by major rule;

(2) an analysis of impacts of Federal regulation on State, local, and tribal government, small business, wages, and economic growth; and

(3) recommendations for reform.

(b) NOTICE.—The Director of the Office of Management and Budget shall provide public notice and an opportunity to comment on the statement and report under subsection (a) before the statement and report are submitted to Congress.

(c) GUIDELINES.—To implement this section, the Director of the Office of Management and Budget shall issue guidelines to agencies to standardize—

(1) measures of costs and benefits; and

(2) the format of accounting statements.

(d) PEER REVIEW.—The Director of the Office of Management and Budget shall provide for independent and external peer review of the guidelines and each accounting statement and associated report under this section. Such peer review shall not be subject to the Federal Advisory Committee Act (5 U.S.C. App.).

[99] Section 624 of the Treasury and General Government Appropriations Act, 2001, 31 U.S.C. § 1105 note, Pub. L. 106-554, §1(a)(3) [Title VI, § 624], Dec. 21, 2000, 114 Stat. 2763, 2763A-161.

Part 2: Eighth Annual Report to Congress on Agency Compliance with the Unfunded Mandates Reform Act

INTRODUCTION

This report represents OMB's eighth annual submission to Congress on agency compliance with the Unfunded Mandates Reform Act of 1995 (the Act). It details agency actions to involve State, local, and tribal governments in regulatory decisions that affect them, including expanded efforts to involve them in agency decision-making processes.

As has been done in recent years, this report is being included along with our annual report to Congress on the benefits and costs of Federal regulations. This was done because the two reports together address many of the same issues and both highlight the need for regulating in a responsible manner that accounts for the costs and benefits of rules and takes into consideration the interests of our intergovernmental partners. As OMB stated in previous reports, we intend to continue to publish these two reports together. This report on agency compliance with the Act covers the period of October of 2001 through September of 2002 (rules published before October of 2001 were described in last year's report.) The period covered by this year's report will correspond with the period covered by the cost-benefit report.

State and local governments have a vital constitutional responsibility to provide government services. They have the major role in providing domestic public services, such as public education, law enforcement, road building and maintenance, water supply, and sewage treatment. The Federal government contributes to that role by promoting a healthy economy and by providing grants, loans, and tax subsidies to State and local governments. However, over the past two decades, State, local, and tribal governments increasingly have expressed concerns about the difficulty of complying with Federal mandates without additional Federal resources. In response, Congress passed the Unfunded Mandates Reform Act of 1995 (the Act).

Title I of the Act focuses on the Legislative Branch, addressing the processes Congress should follow before enactment of any statutory unfunded mandates. Title II addresses the Executive Branch. It begins with a general directive for agencies to assess, unless otherwise prohibited by law, the effects of their rules on the other levels of government and on the private sector (Section 201). Title II also describes specific analyses and consultations that agencies must undertake for rules that may result in expenditures of over $100 million (adjusted annually for inflation) in any year by State, local, and tribal governments in the aggregate, or by the private sector. Specifically, Section 202 requires an agency to prepare a written statement for intergovernmental mandates that describes in detail the required analyses and consultations on the unfunded mandate. Section 205 requires that for all rules subject to Section 202, agencies must identify and consider a reasonable number of regulatory alternatives, and then generally select from among them the least costly, most cost-effective, or least burdensome option that achieves the objectives of the rule. Exceptions require the agency head to explain in the final rule why such a selection was not made or why such a selection would be inconsistent with law.

Title II requires agencies to "develop an effective process" for obtaining "meaningful and timely input" from State, local and tribal governments in developing rules that contain significant intergovernmental mandates (Section 204). Title II also singles out small governments for particular attention (Section 203). OMB's guidelines assist Federal agencies in complying with the Act and are based upon the following general principles:

- intergovernmental consultations should take place as early as possible, beginning before issuance of a proposed rule and continuing through the final rule stage, and be integrated explicitly into the rulemaking process;
- agencies should consult with a wide variety of State, local, and tribal officials;
- agencies should estimate direct costs and benefits to assist with these consultations;
- the scope of consultation should reflect the cost and significance of the mandate being considered;
- effective consultation requires trust and significant and sustained attention so that all who participate can enjoy frank discussion and focus on key priorities; and
- agencies should seek out State, local, and tribal views on costs, benefits, risks, and alternative methods of compliance, and whether the Federal rule will harmonize with and not duplicate similar laws in other levels of government.

The scope of consultation activities undertaken by Federal departments such as Education, Health and Human Services, and Agriculture demonstrate this Administration's commitment to building strong relationships with our intergovernmental partners based upon the constitutional principles of federalism embodied in Title II of the Act. Federal agencies have been actively consulting with States, localities, and tribal governments in order to ensure that regulatory activities were conducted consistent with the requirements of the Act. This year's report shows an increased level of engagement, as several agencies have begun major consultation initiatives. For example, Education has undertaken major consultation initiatives with State, local and tribal governments intended to implement the No Child Left Behind Act (NCLBA). The NCLBA, which reauthorized the Elementary and Secondary Education Act and incorporated the major education reforms proposed by President Bush in his No Child Left Behind initiative, focused on accountability and school improvement. To implement NCLBA, Education established a negotiated rulemaking process that included the participation of individuals representing parents, students and educators. In addition, Education held focus group sessions in Tampa, Florida; New Orleans, Louisiana; Washington, DC; and Denver, Colorado to consult with interested State, local and tribal governments and the public to obtain input in the development of its regulations. At these sessions and throughout the negotiated rulemaking process, Education raised questions regarding regulatory policy and asked for suggestions on how it could best implement the changes made by the NCLBA of 2001 to Title I of the Elementary and Secondary Education Act of 1965, as amended, with the least amount of burden to the entities affected by the changes. (May 6, 2002, 67 FR 30452) Education believes that the regulations were easier to implement because consensus was reached on issues in the draft regulations. (July 5, 2002, 67 FR 45038) The result was the development of regulations implementing NCLBA's provisions on academic standards and accountability. Negotiated rulemaking efforts have continued, as other portions of NCLBA are implemented.

Sections 206 and 208 of the Act direct OMB to send copies of required agency analyses to Congressional Budget Office (CBO), and to submit an annual report to Congress on agency compliance with Title II. Section 207 calls for the establishment of pilot programs for providing greater flexibility to small governments.

The remainder of this report discusses the results of agency actions in response to the Act between October 1, 2001 and September 30, 2002. Since not all agencies take many significant actions that affect other levels of government, this report focuses on the agencies that have regular and substantive interactions on regulatory matters that involve States, localities, and tribes, as well as the private sector. This report also lists and briefly discusses the regulations meeting the Title II threshold and the specific requirements of Sections 202 and 205 of the Act. Seven rules have met this threshold – none were intergovernmental mandates. The appendix to this report discusses agency consultation efforts. These include both those efforts required under the Act and the many actions conducted by agencies above and beyond these requirements, consistent with the spirit of the Act.

CHAPTER I: IMPACTS ON STATE, LOCAL, AND TRIBAL GOVERNMENTS

Over the past seven years, seven rules have imposed costs of more than $100 million per year (adjusted for inflation) on State, local, and tribal governments (and thus have been classified as public sector mandates under the Unfunded Mandates Act of 1995).[100]

- *EPA's Rule on Standards of Performance for Municipal Waste Combustors and Emissions Guidelines* (1995): This rule set standards of performance for new municipal waste combustor (MWC) units and emission guidelines for existing MWCs under sections 111 and 129 of the Clean Air Act [42 U.S.C. 7411, 42 U.S.C. 7429]. The standards and guidelines apply to MWC units at plants with combustion capacities greater than 35 mega grams per day (Mg/day) (approximately 40 tons per day) of municipal solid waste (MSW). The EPA standards require sources to achieve the maximum degree of reduction in emissions of air pollutants that the Administrator determined is achievable, taking into consideration the cost of achieving such emissions reduction, and any non-air quality health and environmental impacts and energy requirements.

  EPA estimated the annualized costs of the emissions standards and guidelines to be $320 million per year (in constant 1990 dollars) over existing regulations. While EPA estimated the cost of such standards for new sources to be $43 million per year, the cost to existing sources was estimated to be $277 million per year. The annual emissions reductions achieved through this regulatory action include, for example, 21,000 Mg. of sulfur dioxide; 2,800 Mg. of particulate matter (PM); 19,200 Mg of nitrogen oxides; 54 Mg. of mercury; and 41 Kg. of dioxins/furans.

- *EPA's Standards of Performance for New Stationary Sources and Guidelines for Control of Existing Sources: Municipal Solid Waste Landfills (1996):* This rule set performance standards for new municipal solid waste landfills and emission guidelines for existing municipal solid waste landfills under section 111 of the Clean Air Act. The rule addressed non-methane organic compounds (NMOC) and methane emissions. NMOC include volatile organic compounds (VOC), hazardous air pollutants (HAPs), and odorous compounds. Of the landfills required to install controls, about 30 percent of the existing landfills and 20 percent of the new landfills are privately owned. The remaining landfills are publicly owned. The total annualized costs for collection and control of air emissions from new and existing MSW landfills are estimated to be $100 million.

- *EPA's National Primary Drinking Water Regulations: Disinfectants and Disinfection Byproducts (1998):* This rule promulgates health-based maximum contaminant level

[100] We note that EPA's proposed rules setting air quality standards for ozone and particulate matter may ultimately lead to expenditures by State, local, or tribal governments of $100 million or more. However, Title II of the Unfunded Mandates Reform Act provides that agency statements of compliance with Section 202 must be conducted "unless otherwise prohibited by law". The conference report to this legislation indicates that this language means that the section "does not require the preparation of any estimate or analysis if the agency is prohibited by law from considering the estimate or analysis in adopting the rule." EPA has stated, and the courts have affirmed, that under the Clean Air Act, the primary air quality standards are health-based and EPA is not to consider costs. EPA issued all five of these rules, which are described here.

goals (MCLGs) and enforceable maximum contaminant levels (MCLs) for about a dozen disinfectants and byproducts that result from the interaction of these disinfectants with organic compounds in drinking water. The rule will require additional treatment at about 14,000 of the estimated 75,000 covered water systems nationwide. The costs of the rule are estimated at $700 million annually. The quantified benefits estimates range from zero to 9,300 avoided bladder cancer cases annually, with an estimated monetized value of $0 to $4 billion per year. Possible reductions in rectal and colon cancer and adverse reproductive and developmental effects were not quantified.

- *EPA's National Primary Drinking Water Regulations: Interim Enhanced Surface Water Treatment* (1998): This rule establishes new treatment and monitoring requirements (primarily related to filtration) for drinking water systems that use surface water as their source and serve more than 10,000 people. The purpose of the rule is to enhance health protection against potentially harmful microbial contaminants. EPA estimated that the rule will impose total annual costs of $300 million per year. The rule is expected to require treatment changes at about half of the 1,400 large surface water systems, at an annual cost of $190 million. Monitoring requirements add $96 million per year in additional costs. All systems will also have to perform enhanced monitoring of filter performance. The estimated benefits include average reductions of 110,000 to 338,000 cases of cryptosporidiosis annually, with an estimated monetized value of $0.5 to $1.5 billion, and possible reductions in the incidence of other waterborne diseases.

- *EPA's National Pollutant Discharge Elimination: System B Regulations for Revision of the Water Pollution Control Program Addressing Storm Water Discharges* (1999): This rule expands the existing National Pollutant Discharge Elimination System program for storm water control. It covers smaller municipal storm sewer systems and construction sites that disturb one to five acres. The rule allows for the exclusion of certain sources from the program based on a demonstration of the lack of impact on water quality. EPA estimates that the total cost of the rule on Federal and State levels of government, and on the private sector, is $803.1 million annually. EPA considered alternatives to the rule, including the option of not regulating, but found that the rule was the option that was "most cost effective or least burdensome, but also protective of the water quality."

- *EPA's National Primary Drinking Water Regulations; Arsenic and Clarifications to Compliance and New Source Contaminants Monitoring* (2001): This rule reduces the amount of arsenic that is allowed to be in drinking water from 50 ppb to 10 ppb. It also revises current monitoring requirements and requires non-transient, non-community water systems to come into compliance with the standard. This rule may affect either State, local or tribal governments or the private sector at an approximate annualized cost of $206 million. The monetized benefits of the rule range from $140 to $198 million per year. The EPA selected a standard of 10 ppb because it determined that this was the level that best maximizes health risk reduction benefits at a cost that is justified by the benefits, as required by the Safe Drinking Water Act.

- *EPA's Effluent Limitation Guidelines and New Source Performance Standards for the Construction and Development Category* (2002): This rule proposed three options to

address storm water discharges from construction sites. Option one proposed technology-based effluent limitation guidelines and standards (ELGs) for storm water discharges from construction sites required to obtain National Pollutant Discharge Elimination System (NPDES) permits. Option two proposed not to establish ELGs for storm water discharges from those sites, but to allow technology-based permit requirements to continue to be established based upon the best professional judgment of the permit authority. Option three would establish inspection and certification requirements that would be incorporated into the storm water permits issued by EPA and States, with other permit requirements based on the best professional judgment of the permit authority. EPA is considering each of the three options, and did not state a preferred option in the proposed rule. Options one and two would impose a mandate on the States, local, or tribal governments, in the aggregate, or private sector that would exceed $100 million per year. Option 3 would not impose a mandate with costs that exceed $100 million per year for the public or private sectors.

Although these seven EPA rules were the only ones over the past seven years to require expenditures by State, local, and tribal governments exceeding $100 million, they were not the only rules with impacts on other levels of governments. For example, 14 percent, 9 percent, and 6 percent of rules listed in the April 2001 Unified Regulatory Agenda cited some impact on State, local or tribal governments, respectively.

CHAPTER II: A REVIEW OF SIGNIFICANT REGULATORY MANDATES

In FY2002, Federal agencies issued five rules that were subject to Sections 202 and 205 of the Unfunded Mandates Reform Act because they require expenditures in any year by State, local or tribal governments, in the aggregate, or by the private sector, of at least $100 million in any one year (adjusted annually for inflation).[101] The Department of Energy issued one final rule; the Department of Transportation issued two proposed rules, and the Environmental Protection Agency issued two proposed rules. There were no rules for which agency analyses demonstrated expected expenditures in any year by State, local or tribal governments, in the aggregate, totaling more than $100 million. All of the rules discussed were covered by the Act because of anticipated expenditures by the private sector.

OMB worked with the agencies to ensure that the selection of the regulatory option for final rules fully complied with the requirements of Title II of the Act. For proposed rules, OMB often worked with the agency to ensure that they also solicited comment on alternatives. These were generally alternatives that could, in light of further public comment and additional analysis, be shown to be the least costly, most cost-effective, or least burdensome option at the final rule stage. Agency statements regarding compliance with the Act are included with the descriptions of the rules below.

DOE Energy Efficiency Standards for Central Air Conditioners and Heat Pumps (FINAL)

This rule finalized new energy conservation standards for central air conditioners and central air conditioning heat pumps to a level of 20 percent, which is the amount DOE determined was the maximum amount that was economically feasible. Consistent with this proposed determination, DOE proposes a Seasonal Energy Efficiency Rating of 12, with a corresponding Heating System Performance Factor of 7.4. These standards would apply to manufacturers in 2006.

DOE estimates that the standards would not result in the expenditure by the private sector of $100 million or more in a year, with the exception of one year in which industry expenditures could total approximately $110 million. DOE believes that this rule would establish energy conservation standards for central air conditioners and heat pumps that are designed to achieve the maximum improvement in energy efficiency that DOE determined to be both technologically feasible and economically justified.

DOT Salvage and Marine Firefighting Requirements; Vessel Response Plans for Oil (NPRM)

The Coast Guard proposes to revise the vessel response plan salvage and marine firefighting requirements for tank vessels carrying oil. These revisions will clarify the salvage and marine firefighting services that must be identified in vessel response plans. The proposed

[101] This listing includes only those rules meeting the Section 202 threshold published during the time period covered by this report (October 1, 2001 through September 30, 2002). Rules subject to Section 202 that were published after September 30, 2002, or that were withdrawn by the agency are not included in this report. Rules with unfunded mandates issued after September 30, 2002 will be addressed in next year's report.

changes will assure the appropriate salvage and marine firefighting resources are identified and available for responding to incidents up to and including the worst-case scenario. The proposed rulemaking will also set new response time requirements for each of the required salvage and marine firefighting services.

This rule is expected to cost more than $100 million in the first year the rule is in effect as salvage and firefighting companies invest in capital equipment. It will cost an estimated $127.9 million for the initial acquisition of salvage and firefighting equipment, $28.4 million for initial paperwork requirements, and $30.9 million each year for ongoing operations.

DOT Federal Motor Vehicle Improved Tires Safety Standards (NPRM)

The Transportation Recall Enhancement, Accountability, and Documentation Act of 2000 mandates a rulemaking to revise and update the safety performance requirements for tires. In response, the proposed rule establishes new and more stringent tire performance requirements in a new Federal motor vehicle safety standard that would apply to all new tires for use on vehicles with a gross vehicle weight rating of 10,000 pounds or less.

The proposal is expected to result in the expenditure by automobile manufacturers and/or tire manufacturers of approximately $282 million in annual costs, based on an estimated additional cost of $3.00 per tire.

EPA Effluent Limitation Guidelines and New Source Performance Standards for the Construction and Development Category (NPRM)

This rule proposed three options to address storm water discharges from construction sites. Option one proposed technology-based effluent limitation guidelines and standards (ELGs) for storm water discharges from construction sites required to obtain National Pollutant Discharge Elimination System (NPDES) permits. Option two proposed not to establish ELGs for storm water discharges from those sites, but to allow technology-based permit requirements to continue to be established based upon the best professional judgment of the permit authority. Option three would establish inspection and certification requirements that would be incorporated into the storm water permits issued by EPA and States, with other permit requirements based on the best professional judgment of the permit authority.

EPA is considering each of the three options, and did not state a preferred option in the proposed rule. Options one and two would impose a mandate on the States, local, or Tribal governments, in the aggregate, or private sector that would exceed $100 million per year. (Option one would cost $130 million per year and Option two would cost $505 million annually.) Option three represented a nonregulatory approach and therefore would not impose a mandate with costs that exceed $100 million per year for the public or private sectors.

EPA National Pollutant Discharge Elimination System; Proposed Regulations to Establish Requirements for Large Cooling Water Intake Structures at Existing Power Generating Facilities (NPRM)

This rule would establish national requirements applicable to the location, design, construction, and capacity of cooling water intake structures at these facilities and would be implemented through National Pollutant Discharge Elimination System (NPDES) permits. The rule provides facilities with several options for meeting the best technology available requirements under this proposed rule.

EPA estimated total annualized (post-tax) costs of compliance for the proposed rule to be $182 million. Of this total, $153 million would be incurred by the private sector and $19.6 million by State and local governments that offer in-scope facilities. EPA selected the approach taken in this proposed rule because it meets the requirement of the Clean Water Act that the chosen approach reflect the best technology available for minimizing adverse environmental impacts, and it is economically practicable.

APPENDIX: AGENCY CONSULTATION ACTIVITIES UNDER THE UNFUNDED MANDATES REFORM ACT OF 1995

Sections 203 and 204 of the Act require agencies to seek input from State, local and tribal governments on new Federal regulations imposing significant intergovernmental mandates. This appendix summarizes consultation activities by agencies whose actions significantly affect State, local, and tribal governments.

Nine agencies (the Departments of Agriculture, Commerce, Education, Health and Human Services, Housing and Urban Development, Interior, Justice, and Transportation, and the Environmental Protection Agency) have involved State, local, and tribal governments not only in their regulatory processes, but also in their program planning and implementation phases. These agencies have worked to enhance the regulatory environment by improving the way in which the Federal government relates to its intergovernmental partners. In general, the Departments not listed here (e.g., State, Defense) do not often impose mandates upon States, localities, or tribes and so have fewer occasions to consult with other levels of domestic government.

As the following descriptions indicate, Federal agencies are generally complying with both the letter and spirit of the Act by conducting a wide range of consultations. Agency consultations sometimes involve multiple levels of government, depending on the agency's understanding of the scope and impact of the rule. OMB continues to work with agencies to ensure that consultation occurs with the appropriate level of government.

Department of Agriculture

Food and Nutrition Service (FNS)

1. The Food Stamp Program High Performance Bonuses

The Farm Bill provided $48 million in bonuses for State agencies that demonstrate high or improved performance in administering the Food Stamp Program (FSP). On September 30, 2002, the Food and Nutrition Service (FNS) advised State agencies regarding the performance measures upon which it will base the bonuses for fiscal year (FY) 2003.

Holding multiple meetings concerning implementation of the Farm Bill, FNS consulted representatives of State agencies to get their input on the performance measures for the high performance bonuses. Meeting participants identified four performance measures that reflect FSP priorities and have available data: payment accuracy, negative error rates, participant access rates, and application timeliness. FNS subsequently adopted performance measures in each of the categories identified during the consultation process.

2. Eligibility and Certification Provisions of the Farm Security and Rural Investment Act of 2002

This proposed rulemaking amends Food Stamp Program regulations to implement 11 provisions of the Farm Security and Rural Investment Act of 2002 (FSRIA). The FSIRA established new eligibility and certification requirements for the receipt of food stamps.

Prior to drafting the proposed rule, FNS consulted with State and local agencies that administer the Food Stamp Program. FNS held three conferences with representatives of State and local human services agencies specifically to discuss the provisions of FSIA being implemented through this rule. The questions and comments made by the State and local agency representatives at the conferences give rise to many policy clarifications that were included in the rule.

3. Nationwide EBT Implementation and Ongoing Operations

In 1996, the Personal Responsibility and Work Opportunity Reconciliation Act mandated statewide Electronic Benefits Transfer (EBT) systems in all States by October 1, 2002. By the end of FFY 2002, over 89 percent of all households received food stamp benefits electronically in the 48 States that operate an EBT system. 46 of these systems were operating Statewide.

The importance of having State agencies share their experience amongst all States has become especially important as States work towards EBT implementation and reprocurement. The following is a list of activities FNS participated in to facilitate the sharing of best practices, new ideas, issues, and alternatives between EBT stakeholders and the agency. States participated in a workgroup that suggested model RFP and contract language that State agencies can use to facilitate RFP development. An extranet site was developed exclusively for State EBT partners as a way to better share information between States and FNS. Information on the website includes information on policies and regulations, standard RFP language, State RFPs that have been recently issued, State EBT profiles, and State contact information.

4. WIC Policy Memorandum 98-9, Revision 6: Nutrition Risk Criteria

This policy, issued in February 2002, addresses the determination of nutrition risk as part of the WIC eligibility determination process, particularly those nutrition risk conditions and/or factors that are allowable for use by State and local WIC agencies.

Prior to issuing the policy memo, FNS consulted with the Risk Identification and Selection Collaborative (RISC), a Federal/State partnership established to achieve consistency in the nutrition risk criteria used to determine WIC Program eligibility.
FNS also participated in regular conference calls to discuss the revisions to the WIC nutrition risk. There was State and local agency input at every step in the process of reviewing the scientific evidence and recommending approval/disapproval of all new or revised risk criteria. The revised WIC Nutrition Risk criteria in Revision 6 developed as a result of this process addressed the assessment of women applicants.

5. WIC Policy Memorandum 2001-7, Immunization Screening and Referral in WIC

This policy, issued in August 2001 and supplemented in December 2002, is intended to assure that children served by WIC are screened for immunization status and, if needed, are referred for immunizations.

The policy memo and associated training materials were developed by the National WIC-Immunization Working Group, which included FNS, the Centers for Disease Control and Prevention, the National WIC Association, the American Academy of Pediatrics, the Association of Immunization Managers, the Association of State and Territorial Health Officials, and Every Child By Two. Prior to issuing the final policy memo, FNS issued a draft version of the policy to all WIC State agencies for their review and comment. The final WIC policy memo on Immunization was issued on August 30, 2002; supplemental training materials, identified as critical during the consultation process, were provided to all WIC State agencies in December 2002.

6. Commodity Supplemental Food Program (CSFP)

FNS was concerned whether it should issue tentative caseload allocations pending enactment of the fiscal year 2003 full appropriations. State and Local CSFP Program Administrators and CSFP participants were affected by this policy, so FNS consulted with States and locals via conference calls with the board members of the National CSFP Association.

State and local CSFP Administrators were concerned that a further delay in enactment of fiscal year 2003 appropriations would jeopardize States' ability to utilize additional caseload slots. As a result of consultations with the National CSFP Association, on January 22, 2003, FNS issued tentative caseload allocations pending the enactment of fiscal year 2003 full appropriations

7. Promoting Summer Feeding: Nationwide Expansion of the Seamless Summer Feeding Waiver

The Seamless Summer Feeding Waiver streamlines program management and operations normally associated in feeding low-income children in the summer and during other times when school is not in session by allowing school districts to operate under procedures that combine aspects of the Summer Food Service Program (SFSP) and the National School Lunch Program (NSLP) and the School Breakfast Program (SBP).

Consultations that resulted in the FY 2002 expansion of the seamless waiver primarily occurred through normal channels of communications from State education agencies through FNS Regional Offices, including regional meetings held by FNS with State agencies. In addition, USDA officials, including the Under Secretary for Food and Consumer Services, discussed the seamless waiver and promoted its expansion with advocates, State and local food program operators, and school officials at numerous conferences, including two held in Washington, DC in February and March of 2002. Thus, in October 2001, FNS expanded the seamless waiver to any eligible SFA. The expansion resulted in over 500 SFAs providing more than 13 million meals to children under the waiver in over 3,800 sites during the summer of 2002.

8. Promoting Summer Feeding: Eliminating the SFSP budget submission requirement for eligible sponsors participating in the 14-State Pilot Project

Under this policy, the 14 States participating in the pilot project to eliminate cost accounting have the authority to waive the budget requirement for eligible sponsors. Normally, SFSP regulations require that sponsors must submit a budget as part of the application process each year. The purpose of this policy is to provide administrative relief to school sponsors in the pilot States, thereby allowing the schools to operate the SFSP in a manner similar to their operation of the NSLP during the school year.

Several State agencies questioned the need for budget submission by the sponsors participating in the pilot project based on their interpretation of the statutory language authorizing the pilot project. In addition, there was considerable interest in reducing paperwork burdens where possible, especially for schools, as an inducement to sponsor the SFSP. As a result of discussions with State agency staff and in view of a positive assessment of operations in FY 2001 by sponsors in pilot States, FNS issued policy guidance addressing these issues in February 2002.

9. Promoting Summer Feeding: Permitting More Flexibility in Meal Service Times

This policy permits State agencies to grant exceptions to SFSP sponsors to program regulations that stipulate specific time intervals between meals. The purpose of this policy is to remove barriers that some sponsors have experienced in providing meal services to SFSP participants. State agencies are responsible for approving requests for exemptions to required time intervals between meals.

State agencies requested greater flexibility in the timing of meal service and intervals between meals at numerous regional and national meetings. During these occasions, State agencies, sponsors and advocates encouraged flexibility, expressing concern to FNS that requiring rigid time intervals may impose barriers to participation for some sites serving meals to children. As a result of learning about the problems this caused some SFSP sites, FNS issued policy guidance in January 2002 that provides State agencies with the authority to waive the regulations at section 225.16(c) on a case-by-case basis.

10. Promoting Summer Feeding: Allowing Alaska to Waive Pre-Approval Visits for Several School Food Authorities (SFAs)

This policy permits the Alaska State agency to exempt the requirement at section 225.7(d)(1) for pre-approval visits to for two SFAs. The Alaska State agency requested this exemption because of the prohibitive cost in traveling to these locations. In addition, the State agency pointed out that both SFAs were successful sponsors of the National School Lunch Program (NSLP); no problems were found during the last CRE reviews of NSLP operations at either school district.

As the result of these consultations, in May 2002 FNS agreed to allow Alaska to waive pre-approval visits at these two SFAs. Instead of the pre-approval visits, the State agency was directed (1) to provide technical assistance over the phone, (2) to request documentation of production records, the meal counting and claiming system, and menus prior to operation, and (3) to conduct a full review within the first three weeks of the start of program operations.

11. Promoting summer feeding: Allowing Closed Enrolled SFSP Sites To Qualify for Participation Based on Area Eligibility Data

This policy exempts closed enrolled sites located in eligible areas operated by the New York City Board of Education from the requirement to qualify for SFSP participation based on the income eligibility of the individual participants at each site. Instead, these closed enrolled sites may use area eligibility data for the location of each site to qualify for SFSP participation.

The New York City Board of Education requested this policy as a way of reducing paperwork and encouraging the participation of more sites. It communicated its request to the New York SFSP State agency, which consulted with FNS. As a result of the request submitted by the New York State agency, FNS issued a waiver for the New York City Board of Education in May 2002.

12. Child and Adult Care Food Program (CACFP): Rule to Strengthen Program Integrity: Simplifying Appeal Rights Process for Day Care Homes

This interim rule (67 FR 43448) was published June 27, 2002, incorporated changes mandated by the Agricultural Risk Protection Act of 2000 and the Grain Standards and Warehouse Improvement Act of 2000. Several policies in the interim final rule reflect recommendations made by CACFP State agencies, sponsoring organizations, and advocates on a number of occasions at regional and national meetings. In addition, these groups and other members of the public encouraged adoption of these policies at nine listening sessions held by USDA around the country in the spring of 2002 on reauthorization issues affecting child nutrition programs.

Changes in the law required the provision of appeal rights to seriously deficient homes prior to their disqualification from program participation. FNS simplified the requirements for the appeal process for day care homes as a result of consultations with sponsoring organizations and State agencies. In order to make the system workable for sponsoring organizations, which must initiate action against seriously deficient providers, the new rules guarantee appeal rights for providers through administrative review (conducted either by the State agency or the sponsor).

13. CACFP: Interim Rule to Strengthen Program Integrity: Give State agencies authority to disregard insignificant errors

Under the new serious deficiency process outlined in the interim final rule, State agencies must be able to distinguish between errors in program management by CACFP institutions and problems that trigger initiation of the serious deficiency process. The process relies on a State

agency's ability to make these distinctions. The interim rule provides guidance to State agencies in making these determinations about the relative seriousness of an administrative problem by listing serious deficiencies for new, renewing, and participating institutions.

Consultations included State agencies, sponsoring organizations, and program advocates. State agency and sponsoring organizations asked for FNS to clarify the definition of serious deficiency and to identify a complete list of actions that must be treated as serious deficiencies. As a result of the feedback from State agencies and sponsors on this issue, the interim rule lists serious deficiencies for institutions at different phases of their participation in the CACFP.

14. CACFP: Interim Rule to Strengthen Program Integrity: Develop an On-line Database List of Disqualified Institutions and Daycare Home Providers

To facilitate the national feature of the new integrity provisions, the list of disqualified institutions and homes will be available online so that all State agencies and sponsoring organizations can have access to the list. An online system permits frequent updates.

Consultations included State agencies, sponsoring organizations, and program advocates. State agency and sponsoring organization administrators encouraged FNS to develop an online system to make the national list of disqualified institutions and home providers instantly accessible to them. As a result of the feedback from State agencies and sponsors on this issue, an online database of disqualified institutions and providers is in development by FNS.

15. Fruit and Vegetable Pilot Program

The Farm Security and Rural Investment Act of 2002 amended section 18 of the Richard B. Russell National School Lunch Act to require that fresh and dried fruits and fresh vegetables be made available to 25 elementary or secondary schools in four States and elementary or secondary schools on one Indian reservation (called the Fruit and Vegetable Pilot Program). FNS consulted the affected State agencies, the National Cancer Institute, Produce for Better Health Foundation, and the American School Food Service Association. During the consultation process, the need for flexible guidance was discussed, along with the need for rapid response to issues due to short time frame of project.

As a result of the consultation, criteria were developed for schools' participation, methods of reaching potential participants were developed, along with criteria how to expend funds. In addition, our guidance was modified to allow additional funds to be used towards administrative costs that allowed schools additional flexibility in meeting the pilot project goals.

Animal and Plant Health Inspection Service (APHIS)

1. APHIS' Plant Protection and Quarantine (PPQ) Program

This program carries out numerous activities to detect and contain, and in some cases, to manage or eradicate plant pests damaging to agricultural and environmental resources of the United States. These programs are conducted cooperatively with State agencies, which share

the costs with APHIS. In cases where APHIS regulations affect Native American tribes, those tribes are included in consultations. Concerns arise over the effects of APHIS regulations and policy on States, who are often largely responsible for enforcing the regulations under cooperative agreements. Points of concern may include availability of resources, practical obstacles to program success, coordinated national approach, and balancing the interests of stakeholders affected by quarantine actions with those who could be adversely affected by spread of the pest of concern.

APHIS reports the following results of our extensive consultations:
Phytophthora ramorum and Emerald Ash Borer: Through consultations with the States of California and Oregon (P. ramorum) and Ohio and Michigan (Emerald Ash Borer), we were able to devise regulatory strategies that protects against the interstate spread of these pests while being practical to enforce given the affected industries.

Through consultations with States that produce citrus, we were able to devise protocols to facilitate the movement of Mexican fruit fly host crops while protecting against the spread of the pest to unaffected areas.

Through consultations with States, we were able to devise a national certification program that facilitates the continued interstate movement of seed potatoes while protecting against the spread of Mop Top Virus.

2. National Low Pathogenic Avian Influenza (LPAI) Program

The program's goal is the elimination of LPAI subtypes H5 and H7 in the United States. State veterinary officials and the State commissioners of agriculture were consulted individually and as part of the U.S. Animal Health Organization's Transmissible Diseases of Poultry Committee (referred to below as the Committee), which includes USDA, State, industry, and academic representatives. The Committee developed and presented to APHIS a model plan that includes recommendations regarding live bird markets, commercial surveillance, and vaccine use. APHIS is currently in consultation with the Committee regarding its recommended model program.

Additionally, in 2002, there were outbreaks of LPAI in several States, most extensively and severely in Virginia. State representatives in the affected States raised the issues of the limits and scope of indemnity payments for poultry and materials destroyed because of LPAI, trade ramifications of the outbreaks, and the severe State liability in the event of the Virginia outbreak (i.e, the State confiscated and destroyed poultry and materials but lacked sufficient funds to compensate for the destroyed poultry and materials). APHIS compensated owners and growers of poultry for losses suffered due to an LPAI outbreak in Virginia. In 2002, APHIS worked closely with State officials in Virginia and surrounding States to control and eliminate the LPAI outbreak. To assist the State in compensating for poultry and materials destroyed, APHIS secured over $52 million from the Commodity Credit Corporation to pay owners and growers of poultry for losses suffered due to the outbreak.

3. Prevention of the Spread of Brucellosis from Bison in Yellowstone National Park to Domestic Livestock

APHIS worked closely with affected parties, including producers of domestic livestock, State governments, and Federal agencies. Each of these entities is represented on the Greater Yellowstone Interagency Brucellosis Committee. Governmental representatives to the committee include the States of Wyoming, Montana, and Idaho, as well as APHIS, the Forest Service, the National Parks Service, and the Department of the Interior.

The committee made recommendations for research and ranked the recommended research in priority order. APHIS is providing funds for the research in the order recommended by the Committee.

4. Program to Eradicate Bovine Tuberculosis

Livestock owners, dairy owners, and States are affected by this program. Consultations were conducted with State Departments of Agriculture and the U.S. Animal Health Association's Government Relations Group, which includes representatives of State Departments of Agriculture. State representatives provide information to APHIS to allow USDA to accurately classify each State with regard to tuberculosis risk. A State's classification determines what conditions must be met before cattle, bison, and captive cervids may be moved interstate from that State.

In 2002, based on information supplied by California, Texas, and Michigan, APHIS initiated rulemaking to downgrade the tuberculosis status of California and Texas and to upgrade that of Michigan. Based on consultation with States and on comments received during a rulemaking process, APHIS initiated rulemaking to modify certain provisions of the domestic tuberculosis regulations. Also, in response to comments jointly submitted by State Veterinarians in Arizona, California, New Mexico, Oklahoma, and Texas, APHIS is modifying an interim rule that revised testing requirements for cattle imported into the United States. The modification will strengthen requirements regarding certification of herd testing.

5. Programs to Prevent Diseases and Predation of Livestock on Native American Tribal Lands

APHIS consults regularly with Native American tribes and participates in national meetings of the Intertribal Agriculture Council, Native American Fish and Wildlife Society, and the National Congress of American Indians (NCAI). The issues raised by tribal governments in 2002 included protection of livestock from predators, identification and eradication of foreign animal diseases that might be introduced into the United States, and employment in careers in agriculture.

Actions taken by APHIS in 2002 include the following: Presentation of information to tribal governments regarding protection of livestock from predators, including information on services available from APHIS's Wildlife Services program; work with the Montana/Wyoming Indian Livestock Growers to develop cooperative agreements, funding agreements, and work

plans to protect livestock on reservations from foreign animal diseases; coordination of tribal efforts to initiate rabies vaccine programs; identification of tribes in Alaska involved in sheep production in preparation for potential funding of scrapie testing; and participation in outreach programs and job fairs sponsored by Native American schools and professional organizations.

Agricultural Marketing Service (AMS)

1. Recordkeeping Requirements for Certified Applicators of Federally Restricted Use Pesticides

These requirements are commonly known as the Federal Pesticide Recordkeeping Program, which was mandated in the 1990 Farm Bill. The regulations require certified private pesticide applicators to maintain records of their federally restricted use pesticide applications for a period of two years. The Agency has consulted with the State agencies that have authority to regulate pesticides in their respective States. The consultations include State agencies that have State statutes comparable to the Federal regulations and are recognized by the Agency. The Agency also works closely with the State Cooperative Extension Services that deliver educational programs to the certified private applicators. State cooperators have requested more flexibility in how the random selection of applicators to be inspected is made each year to better utilize their limited staff resources.

As a result of the request for additional recordkeeping tools the Agency produced and distributed 20,000 Federal recordkeeping books, which are provided free to certified private applicators. The Agency worked with its State Cooperators to identify how selections of private certified applicators could be conducted on a random basis and minimize the amount of travel and time being used by State personnel. States were allowed to customize the selections to best suit the needs of each State.

National Rural Development Partnership (NRDP)

1. California Rural Development Council (CRDC)

CRDC assisted the Hoopa Tribe in Northern California with developing a means of facilitating Native American tribes' access to government grants and funding opportunities. Tribal communities face significant shortages of non-government, community organizations that can assist in providing economic vitality and independence to rural areas.

By providing the Tribes with information about funding opportunities, the Council encouraged the development of nonprofit organizations within tribal communities. As a result of information gained through CRDC's network, the Hoopa Tribe has created an independent, nonprofit organization, and is now able to apply for funding while still maintaining their sovereignty. The organization, established under the new Hoopa nonprofit code, is the Tribe's first step toward gaining access to community-revitalizing government grants.

2. Kansas Rural Development Council (KRDC)

KRDC recently developed a Community Resource Team to assist Leoti, Kansas, the State's only Enterprise (EZ/EC) Community. Leoti had already made considerable progress towards completing an excellent strategic plan, but found itself bogged down with the prioritization and implementation of development projects. KRDC adapted and developed the Community Resource Team program to meet the particular needs of this EZ/EC community. KRDC commissioned the team, met with the community to examine the obstacles to success, and developed a final report. KRDC and the Community Resource Team provided the community with a detailed methodology on how to work with and develop volunteers without overburdening them. KRDC also extended the training and resources to the local school and hospital boards.

As a result of the KRDC's efforts to collaborate with local communities, Leoti is now able to more fully maximize the contributions of its local volunteers.

Department of Commerce

National Oceanic and Atmospheric Administration (NOAA)

1. Coastal Impact Assistance Program (CIAP)

NOAA consulted extensively with representatives of State and Local governments in the development of guidelines related to the Coastal Impact Assistance Program. The 2001 amendments to the Outer Continental Shelf Lands Act created the CIAP, which recognizes that impacts from Outer Continental Shelf oil and gas activities fall disproportionately on the coastal States and localities nearest to where the activities occur, and where the associated facilities are located. Accordingly, the CIAP legislation appropriated money to the Secretary of Commerce to disburse it to eligible States and coastal political subdivisions. In order to guide eligible States and local governments on how to participate in the CIAP, NOAA developed guidance providing necessary information. Pursuant to the legislation, seven States are eligible to participate in the CIAP: Alabama, Alaska, California, Florida, Louisiana, and Mississippi. Counties, parishes or equivalent units of government within those States lying all or in part within the coastal zone (as defined by the Coastal Zone Management Act) are also eligible for CIAP funding. In developing the CIAP Guidelines, NOAA frequently and consistently enlisted the advice of the eligible States and local jurisdictions. The guidelines were circulated in draft form with the express purpose of providing affected parties with an opportunity to suggest changes and improvements. The States and local governments who elected to participate in the consultation process raised numerous issues about the guidelines. For example, it was disputed whether the grants would be distributed directly to the local governments, or if they would have to use the appropriate State agency as a conduit. Additionally, the issue of whether the grant money could be placed in interest-bearing trust funds was raised.

As a result of the collaborative process among Federal officials, the affected States, and eligible local governments, the Department of Commerce was able to publish a Notice of Availability of Final Guidance for the Coastal Impact Assistance Program. As a result of input from interested State and local governments, several key issues were clarified. For example, as a direct result of discussions with affected parties, it was decided that grants could go directly to State or local governments, rather than using a State agency as a conduit. Additionally, in the

spirit of compromise, it was determined that grant monies could be placed in a trust fund, but that the State and/or local governments would not be able to retain the interest. Subsequent to the publication of the guidelines, consultation between NOAA and its intergovernmental partners continued. The States and local communities sought to amend or revise their plans for spending their grant money, and continue to work closely with NOAA to find appropriate methods of doing so without compromising the letter or the spirit of the CIAP.

Department of Education

Federal Student Aid Programs

1. Federal Perkins Loan Program

Under this program, institutions of higher education provide their students with loans to pay the costs of attendance. The loans are made from a fund maintained by the institution that includes both federally provided funds and institutional funds. Once the borrower enters repayment, the institution is required to take steps to collect on the loan. Many of the institutions participating in this Program are State institutions. Many of these institutions asked for more discretion in determining how to maintain documents relating to the loans and on when to stop collecting on low balance loans. The Department met with representatives of State institutions of higher education and conducted a formal negotiated rulemaking process that included representatives of these institutions.

The State institutions of higher education asked the Department to increase the level at which an institution could write off a loan from the current level of $5 to $25 or more. The Department agreed to raise the limit to $25. These same institutions also asked the Department to give them more discretion for deciding when to file suit against a borrower and how often to review cases for purposes of litigation. The draft and final regulations were modified to give the schools more discretion in this area. The institutions also asked for certain reductions in requirements relating to promissory notes and other records used in the Perkins Loan Program. The Department largely agreed to make these changes.

2. Higher Education Act

Under this program, a student loan borrower who has defaulted on a student loan may regain eligibility for more student aid by making 12 consecutive reasonable and affordable monthly payments. This is referred to as "rehabilitation." In the past, the Department of Education's regulations have allowed borrowers who are subject to a judgment for the defaulted loan to have the opportunity for "rehabilitation." A number of institutions of higher education that make loans under the Federal Perkins Loan Program argued that offering these borrowers rehabilitation was not in the best interests of the program because of the significant costs of litigating these cases in the first place and because these borrowers remain likely to not pay their loans even after rehabilitation. Also, representatives of some State institutions of higher education and State guaranty agencies wanted to maintain some discretion to offer borrowers against whom they have judgments many of the benefits of rehabilitation even if these borrowers would not be entitled to rehabilitation. Representatives of institutions of higher education that

make loans under the Federal Perkins Loan Program, including State institutions, participated in the Department's negotiated rulemaking process. Additionally, State Attorneys General offices that represent State institutions of higher education provided comments on the proposals through the representatives of the institutions.

Based on consultations with State institutions of higher education and State guaranty agencies, the regulations were modified to provide that borrowers who are subject to a judgment for defaulted loans are no longer entitled to rehabilitation. The regulations were also amended to specifically provide that institutions and guaranty agencies have the authority to offer borrowers against whom they have judgments many of the benefits of rehabilitation.

3. Federal Family Education Loan Program

Guaranty agencies in the Federal Family Education Loan Program, which are either State agencies or non-profit agencies, are required to take appropriate action to try to recover student loans that are due if the borrower files for bankruptcy. To get a loan discharged in bankruptcy, the borrower must file an adversary action against the holder of the loan. However, many courts have held that a State guaranty agency may assert its right to sovereign immunity to avoid such adversary actions. The Department of Education's regulations needed to be revised to avoid restrictions on the State agency's authority to assert sovereign immunity. State guaranty agencies were the party most affected by the regulations and Education addressed the issue through a negotiated rulemaking process that included representatives from organizations representing guaranty agencies. State agencies asked the Department to modify the regulations to ensure that actions by lenders would not preclude the assertion of sovereign immunity.

Based on these consultation activities, the regulations were modified to authorize State guaranty agencies that hold loans affected by bankruptcy filings to instruct lenders not to file a proof of claim in the bankruptcy. This will protect the State guaranty agency's ability to assert sovereign immunity.

4. Higher Education Act

Under the Higher Education Act of 1965, as amended (HEA), institutions that participate in the Federal student financial aid programs are required to return unearned funds on behalf of students that withdraw within 30 days after the institution knows the student left. Many of the institutions participating in the HEA Program are State institutions. Many of these institutions asked for more lenient timeframes for returning funds due to the complexities and delays present in the State government payment systems. The Department met with representatives of State institutions of higher education and conducted a formal negotiated rulemaking process that included representatives of these institutions. The State institutions of higher education asked the Department to increase the timeframes for returning unearned student funds from the current 30 day period, particularly for funds that were returned by mailing checks rather than using an electronic funds transfer. Some State representatives suggested that, as an alternative standard, the Department consider using the date when the payment request was initiated by the institution, rather than the date when the funds were actually returned.

As a result of the consultation process, the Department kept the 30-day requirement for returning unearned student funds, but added a new provision that allows a timely issued check to clear within 45 days after the institution knew the student left. An appeal process was also added that permits an institution to demonstrate that a failure to make the required timely payments was due to exceptional circumstances.

5. Designing State Academic Assessment Systems

This regulation permits a State considerable flexibility in designing its State assessment system required by Title I of the Elementary and Secondary Education Act, as amended by the No Child Left Behind Act of 2001. For example, a State may include in its assessment system either or both criterion-referenced assessments and assessments that yield national norms. The State may also use a combination of State and local assessments, provided its system has a rational and coherent design. Prior to negotiated rulemaking, the Department solicited advice and recommendations from the public, including representatives of State and local educational agencies, parents, teachers, paraprofessionals, members of local boards of education, and other organizations involved with the implementation and operation of Title I programs. To obtain additional advice and recommendations, the Department invited a broad spectrum of individuals and organizations, including representatives of State and local educational agencies, to participate in one of 7 focus groups held in Tampa, FL; New Orleans, LA; Washington, DC; and Denver, CO. The Department then conducted negotiated rulemaking, which consisted of five sessions over a two-week period. Of the team of 22 members, 11 were representatives of State or local educational agencies.

State educational agencies, in particular, were very concerned that the regulations afford them maximum flexibility to design their State assessment systems to best meet their individual needs. Some States, for example, already have assessments in place in grades 3-8 as required by the No Child Left Behind Act of 2001 and wanted to be able to continue to use those assessments. Other States argued for flexibility to combine criterion-referenced assessments in some grades with norm-referenced assessments in other grades. Still other States lobbied for flexibility to combine State-level assessments in some grades with locally developed assessments in other grades. The final regulations accommodate each of these approaches, but with sufficient caveats to ensure that the resulting design is rational and coherent and produces valid and reliable results that can be used to hold schools and districts accountable for student achievement.

6. Funding for Choice-related Transportation and Supplemental Educational Services

This regulation implements ambiguous and conflicting statutory provisions concerning a local educational agency's responsibility to make funds available to provide choice-related transportation and supplemental educational services. The Department consulted with State and other entities. Many local educational agencies worried that the statute could be interpreted to place an unlimited obligation on them to provide choice-related transportation to any student attending a school in need of improvement who wished to transfer schools. Large city districts, in particular, expressed serious concerns that an unlimited obligation went well beyond their responsibilities under the Federal Title I program and could potentially bankrupt them.

Based on State and other input from a number of early consultation opportunities, the Department produced both proposed and final regulations that make clear that a local educational agency's responsibility to provide choice-related transportation and supplemental educational services as required under Title I is limited to an amount equal to 20 percent of the agency's Title I allocation.

7. Disaggregation of Data

Under NCLB, a State must use data disaggregated by race/ethnicity, poverty, English language proficiency, and disability to hold schools and school districts accountable for the performance of students in those subgroups. Prior to negotiated rulemaking, the Department solicited advice and recommendations from the public, including representatives of State and local educational agencies, parents, teachers, paraprofessionals, members of local boards of education, and other organizations involved with the implementation and operation of Title I programs. Some commenters urged the Department to establish a minimum number in the regulations that would apply to all States. State educational agencies, however, expressed the desire for maximum flexibility on this issue in order to select a minimum number that was most appropriate for their circumstances.

Based on the results of the consultation, the regulations permit each State to set its own number, based on circumstances specific to that State. A State may determine the minimum number of students who constitute a sufficient number to make the results reliable for accountability and reporting purposes. This minimum number may vary among States as well as among purposes within a State. For example, a State may set a different number for reporting purposes than for determining adequate yearly progress. Similarly, it may be appropriate for a sparsely populated State to set a smaller minimum number than a densely populated State that generally has larger schools.

Department of Health and Human Services

Centers for Medicare and Medicaid Services

1. Independence Plus

Independence Plus is an initiative designed to promote family or individual independence and choices regarding the selection of long-term care supports and services provided in the home. The intent of the Independence Plus initiative is to expedite the ability of States to offer families with a member who requires long-term supports and services, or individuals who require long-term supports and services, greater opportunities to take care of their own health and direct their own services. Families and individuals exercise greater choice, control and responsibility for their services within cost neutral standards. In developing the proposal and draft templates, CMS consulted with States, advocates, participants and national organizations representing the needs of participants. States are required to consult with the Tribes as part of the public notice process used in development of 1115 demonstrations.

As a part of the Independence Plus initiative, CMS is requiring that States establish specific criteria in order to protect the health and welfare of program participants. These criteria include emergency backup systems, criminal background checks and incident management systems. States have raised concerns regarding CMS' authority to impose these criteria. As a result of the consultation process, CMS is working to revise the draft waiver templates and is also developing additional guidance to States regarding completing the templates and program development/implementation in the form of template instructions and resource materials.

2. Health Insurance Flexibility and Accountability (HIFA) Initiative

In August 2001 the President announced a new section 1115 approach called the Health Insurance Flexibility and Accountability (HIFA) initiative, which makes it easier for States to expand coverage to the uninsured. The HIFA initiative enables States to use Medicaid and unspent State Children's Health Insurance Program (SCHIP) funds in concert with private insurance options to expand coverage to low-income uninsured individuals. The goal of the HIFA initiative is to create a Federal framework that encourages State innovation to improve health insurance options. CMS works primarily with State agencies on the HIFA initiative, although CMS requires States to consult with the public (including Tribes) in the development of HIFA proposals.

There are currently 8 approved HIFA initiatives. Through consultation and technical assistance provided throughout the approval process, States have been able to administer their Medicaid/SCHIP programs in more flexible ways to better meet the needs of their citizens. Through consultation and technical assistance, CMS has worked to expedite the review process and reach closure in a timely way about HIFA concepts and proposals.

3. Pharmacy Plus

As part of the 2003 Budget, the Administration introduced the Pharmacy Plus initiative, through which States can extend Medicaid drug-only coverage to certain low-income elderly and disabled individuals. The initiative includes a template to facilitate State applications. The template outlines the major parameters of Pharmacy Plus, including use of private-sector benefit management techniques and eligibility for people below 200 percent of the Federal poverty level. Like all Section 1115 waivers, Pharmacy Plus demonstrations must be budget neutral to the Federal government. CMS works primarily with States on Pharmacy Plus, but CMS requires States to consult with the public (including Tribes) in the development of Pharmacy Plus proposals.

4. Program for All-Inclusive Care for the Elderly (PACE)

PACE is a prepaid, capitated plan that provides comprehensive health care services to frail, older adults in the community, who are eligible for nursing home care according to State standards. In order for a demonstration program to be transitioned to a permanent provider, the State must complete a State Plan Amendment to elect PACE as a State Plan option. The State, CMS and the provider enter into a three-party agreement to authorize the organization as a permanent provider.

CMS worked closely with States to approve the State Plan amendments and process applications for transitioning demonstrations to permanent providers by the required statutory timeframe. As a result of these consultation efforts, thirteen demonstration programs have been approved as permanent providers in FY 2002. There were eight State Plan Amendments approved which enabled the States to enter into the program agreements.

5. Trade Act-consultation with States

The Trade Adjustment Assistance Reform Act of 2002 appropriated $20 million for seed grants to States to create qualified high risk health insurance pools and $80 million for operation grants to States with existing qualified high risk pool to fund losses incurred in the operation of the pools. State high-risk health insurance pools are, in most cases, operated under the jurisdiction of the State Department of Insurance. Accordingly, the State Departments of Insurance apply for the grants. Consultations have occurred with officials from State Departments of Insurance, with officials from the National Association of State Comprehensive Health Insurance Plans (NASCHIP), with high-risk pool administrators, State legislative officials, staff from State congressional delegations and with several non-profit agencies interested in health insurance issues. States expressed concern about the timing and eligibility requirements of the grants.

Through the consultation process, CMS was educated by States about the operation of their high-risk pools and was able to announce the grant application procedures for the seed grant program on November 26, 2002. The procedures for the operation of the larger high-risk grant program were published in the Federal Register on April 25, 2003.

6. HHS Internal Tribal Communication and Coordination Project

This project was designed to enhance the education of HHS staff to better employ tribal consultation activities with American Indian, Alaska Native and Indian organizations compliant with Executive Order 13175 and HHS Tribal Consultation Policy. 300 HHS regional staff participated and benefited from 10 regional sessions conducted by the Office of Intergovernmental Affairs to assist them in understanding the basis for consultation requirements with tribal intergovernmental partners. The underlying assumption being that improved communication and coordination would lead to better consultation processes, and access to programs and improved services. The education intervention aimed at bringing HHS staff together as "One HHS," improve the understanding of the basis of HHS policy regarding tribes, identify the priorities and needs of tribes, and the ability of HHS to address those needs. The team collected specific recommendations to improve the HHS consultation, communication and coordination process for it Native American groups and individuals.

All five recommendations stemming from the consultation are being implemented. Regional Directors and IHS Area Directors are coordinating information to/from tribal organizations. On April 3, 2003, HHS Regional Directors and IHS Area Directors conducted the first-ever joint meeting to collaborate on issues and prepare for the first of annual regional tribal consultation sessions beginning in June 2003. Public Affairs staff are collaborating on HHS

public relations activities to improve communication and coordination with tribal organizations. The Office of Intergovernmental Affairs is enhancing its WEB page to include more information regarding HHS consultation activities and links to improve communication and coordination throughout the Department. All 10 regions have formed regional based *"Tribal Issues Workgroups"* which meet regularly to discuss tribal issues and areas of common interest and concern.

7. Reactivation – Intradepartmental Council on Native American Affairs (ICNAA)

HHS revitalized the Intradepartmental Council for Native American Affairs (ICNAA). The Council was authorized under the Native American Programs Act of 1974, as amended. However it remained mostly dormant for well over a decade. This Council serves as an advisory body to the Secretary and has the responsibility to assure Native American policy guidance and budget formulation is implemented across all Divisions. The Council intergovernmental partners include American Indians, Alaska Natives, Native Hawaiians, and other Pacific Islanders (including Samoans).

A profound impact of this Council is the revised premise within HHS that all Agencies bear responsibility for the government's responsibility and obligation to the Native people of this country. The "One HHS" Initiative has been of benefit to HHS as well as the American Indian, Alaska Native and Native American constituents of the Department in addressing HHS consultation requirements. One action item of the Council is the formation of a workgroup that is assigned to review the Department's current tribal consultation policy and make recommendations to improve and enhance the Department's consultation process consistent with E.O. 13175 and in conjunction with an external consultation process underway to solicit tribal input on the policy as well.

8. Title VI Tribal Self-Governance Feasibility Study

The Indian Self-Determination and Education Assistance Act required a determination of whether the Tribal Self-Governance Program administered by the Indian Health Service could be expanded to other programs within the Department. A tribal advisory group and HHS staff carried out consultations jointly during the entire two-year study period. Stakeholders were consulted on key study issues such as what HHS programs should be included in a demonstration, the impact of a demonstration on beneficiaries, and the design of a demonstration. The process was used to try to reach a consensus, to the extent possible, on the recommendations contained in the final report. Tribal, State, local and nongovernmental partners raised issues such as: contract support costs, programs consolidation, appeals, types of programs for inclusion, program implementation and other programmatic needs, number of demonstration project participants, eligibility and selection process and evaluation requirements.

Based on the information gained through these consultations, the Department submitted a report to the Congress and determined that a demonstration project was feasible for 11 of its programs and identified potential costs and other requirements for implementation of a demonstration project.

9. Electronic Laboratory Exchange Network (eLEXNET)

eLEXNET is an intergovernmental project that draws on the expertise of Federal, State and local officials to ensure safe food for consumers and improve the response when food emergencies or outbreaks of food borne illness occur. This pilot project is an Internet-based system that shares information on E. coli 0157:H7 among participating laboratories. This pilot project, funded by FDA and FSIS, started with 8 participating labs. eLEXNET serves as the first integrated food safety system for laboratory food samples and test result data. Currently, there are 53 labs in 37 States involved in the eLEXNET project. A consensus was reached that there was a need to integrate food safety activities at all levels of government. A vision of a successful food safety system was formed, obstacles to developing that system were identified, and proposed action items were assigned.

As part of the eLEXNET project, in addition to the extraordinary ability to exchange laboratory data among Federal, State, and local food safety agencies, a common format for data sharing has been developed. This includes standardization of how results will be reported, use of food product identification codes, and use of common methodology. This provides invaluable information in the coordination of multi-State outbreaks of foodborne illness.

10. Mammography Quality Standards Act

The Mammography Quality Standards Act (MQSA) required Federal certification of US mammography facilities. Under MQSA, FDA faced the task of inspecting and accrediting approximately 10,000 mammography providers throughout the country. Therefore, FDA contracted with the States. The MQSA inspection program is part of one of FDA's major State collaborations. Under these contracts, FDA trains, audits, and provides technical expertise to State inspectors. These State inspectors are certified by FDA to perform a regulatory function.

This collaboration works well because FDA often has the greater concentration of technical expertise and scientific resources, but States are closer to the source of any problem and can respond to public health emergencies quickly. The results of the MQSA FDA-State collaboration have shown that there is a 34 percent improvement in image quality of mammograms, and a 20 percent decrease in the amount of radiation required to provide a quality image. This is consistent with the program's goal of reducing unnecessary public radiation exposure.

Department of Housing and Urban Development

1. Working with Public Housing Agencies (PHAs) and Residents on Revisions to the Public Housing Assessment System (PHAS)

On February 6, 2003 (68 FR 6272), HUD published a proposed rule for public comment proposing to make several significant changes to the PHAS. Through the PHAS, HUD measures the performance of PHAs on four aspects of their operations: physical condition, financial condition, management operations, and resident service and satisfaction. The goals of the PHAS are to improve the delivery of services in public housing and enhance trust in the public

housing system among PHAs, public housing residents, HUD, and the general public. The February 6, 2003 proposed rule was the direct result of HUD's efforts during Fiscal Year 2002 to consult with PHAs, residents of public housing, and other stakeholders in the PHAS process. Consultations were held with public housing residents and with the four main national organizations representing PHAs: the Public Housing Authorities Directors Association (PHADA); the Council of Large Public Housing Authorities (CLPHA); the National Association of Housing and Redevelopment Officials (NAHRO); and the National Organization of African Americans in Housing (NOAAH).

Several issues, questions, and concerns were raised during HUD's consultation process. These questions and issues covered a variety of topics relating to the assessment and scoring of PHAs. Other topics raised by the public housing stakeholders were questions regarding the impact of resident-caused damages, and the details of the PHAS physical condition indicator. The proposed rule includes changes to specific PHAS components in response to concerns raised during the consultation process. For example, three components of the Management Assessment Sub-System have been removed as a result of the concerns expressed by stakeholders.

2. Working with Stakeholders to Streamline and Improve the Consolidated Plan Process

During Fiscal Year 2002, HUD, in response to the President's Management Agenda, began with its partners a consideration of ways to streamline the Consolidated Planning process. Communities develop five-year Consolidated Plans to guide their use of Community Development Block Grant (CDBG), HOME, Emergency Shelter, and Housing Opportunities for People With AIDs (HOPWA) grants. The Consolidated Plan is a strategic plan describing how grantees plan to use community development funds to meet their priorities. The President's Management Agenda directed HUD to work with local stakeholders to streamline the Consolidated Plan, making it more results-oriented and useful to communities in assessing their own progress toward addressing the problems of low-income areas. As part of its consultation process, HUD worked with States, counties and cities. Issues addressed included: reduction in compliance burden, better use of technology, streamlined planning, pilots of alternative planning procedures and legislative and/or regulatory changes to implement reformed, results-oriented planning and reporting systems nationally.

A report outlining the efforts of the working groups and steering committee is being prepared. Pilots are being designed to test some of the recommendations offered during consultations. In addition, HUD has posted background information, meeting summaries, and reports regarding this initiative on its website and is soliciting public comment on the efforts to streamline the Consolidated Plan.

Department of the Interior

Minerals Management Service

Interior's Minerals Revenue Management program (MRM) collects, verifies, and distributes mineral revenues from Federal and Indian lands. The program conducted a variety of consultation initiatives, discussed below.

1. State and Tribal Royalty Audit Committee

One means of consultation is the State and Tribal Royalty Audit Committee, comprised of State and Tribal audit managers who have cooperative audit agreements with MMS under the Federal Oil and Gas Royalty Management Act. The Committee meets at least quarterly, and subgroups of the committee may meet more often.

This Committee has achieved results in a number of areas:

- State and Tribal auditors from Colorado, North Dakota, and Oklahoma helped design various tools used in the new compliance system and will help train system users.
- Representatives from Colorado, Utah, Wyoming, and the Northern and Southern Ute Tribes helped design the compliance process for onshore oil and gas.
- Representative from States and Tribes work together on the Coal Subcommittee resolving a variety of coal related issues.

2. Work with State and Tribal auditors

MMS works on a continuing basis with State and tribal auditors to:

- Improve the language and content of orders sent to companies for royalty underpayment;
- Resolve valuation issues for royalty purposes involving Federal leases in their State or Indian leases on their Indian reservations; and
- Resolve complicated royalty disputes through negotiation.

MMS also negotiated an Intergovernmental Personnel Act (IPA) Fellowship Program with the Chippewa Cree Tribe. This IPA began May 2002.

Department of Justice

Community Oriented Policing Services (COPS)

1. The application of community policing principles to homeland security

State, local and tribal law enforcement agencies are all affected by the new demands being placed on them with regard to homeland security and were consulted in the process of developing this initiative. Since its inception in 1994 through the Violent Crime Control Act, COPS has consulted regularly with professional law enforcement organizations. COPS also maintains regular contact with intergovernmental organizations such as the U.S. Conference of Mayors, the National League of Cities, and the National Association of Counties, which provides the perspective of local government on law enforcement issues. COPS has conducted research and evaluations with local police departments to identify barriers and challenges to their implementation of community policing.

COPS' consultation with State and local government is reflected in the training provided through the Regional Community Policing Institutes, best practices publications, and targeted initiatives. The COPS Office convened a working session of its national network of Regional Community Policing Institutes (RCPIs). The RCPIs work closely with State, local and tribal agencies to create curricula and provide training. This session gave them the opportunity to discuss law enforcement's community policing needs post 9/11. The primary concerns raised at this working session were balancing the new responsibilities of homeland security with the continuing responsibilities of traditional law enforcement. This working session resulted in the COPS Office charging the RCPIs with creating a curriculum to address community policing in a post 9/11 world.

2. The timely and appropriate acquisition and implementation of law enforcement related technology

All COPS technology grantees from State, local, and tribal agencies were consulted for problem identification and resolution. The majority of consultations on this issue took place informally at various COPS funded or attended law enforcement conferences and workshops. Additionally, consultations have taken place over the phone with proactive grantees that sought solutions to the technology implementation problems they were facing.

The issues raised were similar in nature. Agencies were granted funding for technology implementation, but many did not know how to proceed in acquiring, integrating and implementing for optimal use. In response to these issues, the COPS Office enhanced its technology training and funded the development of a comprehensive publication entitled *Law enforcement Tech Guide -- How to plan, purchase and manage technology (successfully!)*.

Office of Justice Programs: Office on Violence against Women

1. The STOP Violence Against Women Formula Grant Program

This grant program was authorized by the Violence Against Women Act to develop and strengthen effective law enforcement and prosecution strategies to combat violent crimes against women, and to develop and strengthen victim services in cases involving violent crimes against women. This program provides grants to States. The Office on Violence Against Women (OVW) regularly consults with the State administrators of the STOP Program. Throughout the year, State administrators have raised concerns, which included: insufficient administrative funds, burdensome planning process, need for increased emphasis on sexual assault, and a desire for more resources available on the web.

In response to concerns expressed during the consultation process, States are now allowed ten percent of their STOP funds for their administrative costs, States now need to submit a comprehensive implementation plan only once every three years, as opposed to annually, conferences devoted to sexual assault, additional forms and information available on the OVW website.

Office of Justice Programs: Bureau of Justice Assistance

1. Byrne Formula Grant Program

The issue involved streamlining the administration of the Edward Byrne Memorial State and Local Law Enforcement Assistance Grant Program (Byrne Formula Grant Program). This program is a partnership among Federal, State, and local governments designed to create safer communities. BJA provides grants to States for use by States and units of local government to improve the functioning of the criminal justice system – with emphasis on violent crime and serious offenders – and enforce State and local laws that establish offenses similar to those in the Federal Controlled Substances Act. State Administering Agencies (SAAs) were consulted. SAAs are appointed by governors and are responsible for the planning, management, and sub-granting of the Federal funds. The SAAs were contacted via email for input on how BJA could simplify the application and award process under the Byrne Formula Grant Program. The National Criminal Justice Agency (NCJA) contacted the SAAs and compiled the suggestions. NCJA represents State, tribal, and local governments on crime prevention and crime control issues.

As a result of these consultations, the Byrne Formula Grant Program application will be on-line to simplify the application process. In addition, the requirements of the strategic plan have been reduced in scope to include only Byrne-funded programs and projects. BJA will continue, however, to request some broader questions, such as coordination issues, but only those required by the statute. A four-year grant cycle will be allowable. The planning updates required in the strategic planning off-years will be provided in a level of detail deemed appropriate by the grantee (e.g., a grantee may submit a brief letter noting that there has been no significant change to the plan). In addition, Byrne Formula Grant programs are now on four-year funding cycles.

2. Residential Substance Abuse Treatment Program

The issue involved steps to streamline the administration of the Residential Substance Abuse Treatment for State Prisoners (RSAT) Formula Grant Program, which assists States and units of local government in developing and implementing residential substance abuse treatment programs within State and local correctional and detention facilities. State Administering Agencies (SAAs) were consulted. Issues raised included: the 25% cash match requirement was financially burdensome; the three-year grant cycle was too short to make most effective use of funding; and the RSAT and Byrne Formula Grant programs have different grant cycles making program integration more difficult.

As a result of the consultative process, grantees and subgrantees may now satisfy the match requirement through cash, in-kind contributions, or a combination thereof. The RSAT grant period has been extended to four years. The RSAT and Byrne Formula Grant Programs are both on four-year funding cycles.

3. Southwest Border Prosecution Program

The Southwest Border Prosecution Program provides funds to the four southwest border States (Arizona, California, New Mexico, and Texas) and their respective counties for the handling of any federally-initiated and declined-referred criminal case that was prosecuted by a State or county prosecutor. Jurisdictions providing pre-trial detention for eligible case defendants are also eligible for funds. BJA consulted with prosecutors, judicial officials of county and State governments, and State criminal justice officials. The intergovernmental consultative process involved the development of the program's scope, format, and web-based application design.

Results from various consultations indicated that the best method for application delivery and management was through a centralized website that would be common and accessible to all participants at the county and State levels; that all counties in the four States should be eligible to participate, as opposed to just those along the border; that the application process be streamlined and simplified, since previous programs of this nature had been overly cumbersome to administer and request payments; and that the States have only minimal influence and comment over the applications submitted by their respective county jurisdictions.

Environment and Natural Resources Division (ENRD)

1. Joint State/Federal Civil Environmental Enforcement

In the past two years, ENRD has joined with nearly every State to bring enforcement cases. ENRD worked with States that were interested in strengthening their wetlands protection programs, in light of a Supreme Court ruling in 2001 that decreased Federal protection over certain isolated wetlands. Two Federal agencies and four State associations joined with DOJ as "cooperative parties" in organizing and bringing the conference. The State associations were: National Governors Association (Center for Best Practices), National Conference of State Legislatures, NAAG and Association of State Wetland Managers.

In fiscal year 2002, States were awarded, through settlement or judgment, more than $27 million as the result of joint civil environmental enforcement actions with ENRD. States increasingly participate in ENRD's most prominent cases. In fiscal year 2002, ENRD obtained a total of $3.6 billion in environmental protection work through injunctive relief. States participated as co-plaintiffs in cases that yielded $3.3 of the $3.6 billion in environmental protection work. Examples of recent cooperative civil enforcement actions include the following:

- ENRD joined with 11 States and 3 county air authorities in obtaining a proposed Clean Air Act consent decree with a major grain company. The settlement requires the company to implement sweeping environmental improvements at 52 plants in 16 States to reduce air pollution by 63,000 tons per year. The estimated cost of the work is $340 million over 10 years. The settlement includes a civil penalty of $4.6 million and supplemental environmental projects of $6.3 million. U.S. v. Archer Daniels Midland Co. (C.D. Ill.)

- ENRD joined with the State of Arkansas in obtaining a Clean Air Act consent decree with an oil company. The company will install environmental improvements at its petroleum

refinery at an estimated cost of $17 million and pay a civil penalty of $348,000. U.S. and State of Arkansas v. Lion Oil Co. (W.D. Ark.)

- ENRD joined with the States of Delaware and Louisiana, and a regional air pollution control agency in Washington State, in reaching a Clean Air Act agreement with companies operating nine petroleum refineries. The consent decree will reduce air emissions by over 60,000 tons per year. The companies also will collectively pay a $9.5 million civil penalty and spend about $5.5 million on environmental projects in communities affected by the refineries' pollution. United States v. Motiva Enterprises Limited Partnership, et al. (S.D. Tex.)

- ENRD joined with the States of Alabama, Arkansas, Nebraska, Utah, South Carolina and Texas in reaching agreements with a steel manufacturer under three environmental statutes - the Clean Air Act, Clean Water Act and the Resource Conservation and Recovery Act ("RCRA"). The consent decree requires operation of pollution control equipment for nitrogen oxide emissions, remediation of areas of contamination and improvements in waste management. The company will pay a civil penalty of $9 million, and spend $4 million on supplemental environmental projects. United States v. Nucor Steel, Inc. (D. S.C.)

2. Federal, State and Local Task Forces for Criminal Environmental Enforcement

Almost all Federal environmental statutes provide for delegation of programs to the States and recognize State enforcement authorities. Therefore, since the inception of the Federal environmental criminal program, it has been essential to work closely with State and local agencies. Information and other assistance is sought and obtained from State and local law enforcement and regulatory agencies. ENRD attorneys frequently serve as faculty for State and local training programs. ENRD solicits State and local prosecutors to participate in Federal training courses. More importantly, however, such efforts are now going far beyond the solicitation of information and cross training, to the formation of task forces and other means of cooperation and coordination. These task forces have been formed in many districts to address environmental crimes and related enforcement concerns. The Division's attorneys act as members of the task forces as they work jointly with Assistant United States Attorneys on cases in the district. They also provide information, general assistance, and support to all such task forces as called upon.

An example of a closely coordinated criminal environmental prosecution was recently brought against a petroleum refinery operator in Texas for covering up violations under the Clean Air Act and for submitting false statements. The plea agreement requires payment of a criminal penalty of $20 million, with $10 million paid in criminal fines and $10 million in special projects to improve the environment in Corpus Christi. The case was investigated by the Texas Environmental Enforcement Task Force, which includes State and Federal investigators. See *United States v. Koch Petroleum Group* (S.D. Tex.)

3. Indian Resources

The Indian Resources Section represents the United States in its capacity as trustee for American Indian tribes. To this end, the Section litigates cases in order to establish and protect the following: treaty hunting and fishing rights; tribal water rights; tribal lands and natural resources; and tribal jurisdiction and authority. The Section also defends actions by the Secretary of the Interior and Congress intended to further tribal sovereignty and Indian rights. This litigation is of vital importance to Indian tribes and Indian people.

Although the Indian Resources Section represents the interests of the United States and particularly the interests of the Interior Department, these interests are often aligned with the interests of Indian tribes. We therefore work both informally and formally with tribes in pursuing litigation and negotiating settlements. In the past several years we have had remarkable success in working with tribes, States, and private parties to settle disputes. For example, last year we engaged in settlement negotiations to resolve Zuni Pueblo claims to water rights in Arizona, working closely with representatives of the Tribe, the State and community water districts to reach a settlement that the interested groups jointly could support before Congress. Other examples of recent water rights settlements include working with the Shivwits Band of the Paiute Indian Tribe of Utah, the State of Utah, and area irrigation districts to secure enactment of the Shivwits Band of the Paiute Indian Tribe of Utah Water Rights Settlement Act and working with the Chippewa Cree Tribe of the Rocky Boy's Reservation and the State of Montana to settle the Chippewa Cree Tribe of the Rocky Boy's Reservation's water rights. With regard to treaty fishing rights, we worked closely with five Michigan tribes and the State of Michigan to negotiate a consent decree in *United States v. Michigan,* regarding treaty-fishing rights in Lake Michigan. Finally, we also played a role in negotiating and drafting a legislative settlement of three tribes' long-standing claims to the bed of the Arkansas River in Oklahoma. Congress enacted the legislation at the close of the 107th term.

Department of Transportation

Federal Motor Carrier Safety Administration

1. Hours of Service Regulations

The FMCSA's hours-of-service regulations regulate the maximum driving hours and minimum off-duty time of commercial motor vehicle (CMV) drivers. The States are required to adopt and enforce hours-of-service regulations consistent with the Federal standards in order to remain eligible for Motor Carrier Safety Assistance Program (MCSAP) grants. Many States participated directly in FMCSA's recently completed revision of the hours-of-service regulations, and all of them were represented indirectly through the Commercial Vehicle Safety Alliance (CVSA), which commented extensively on the agency's proposals. The States and CVSA argued that the proposed rules were excessively complex, would require a great deal of re-training of enforcement officers, and were virtually unenforceable at roadside. Motor carriers and CMV drivers argued that the rules were disruptive of trucking operations, excessively complex, far more expensive than the agency recognized, and ultimately self-defeating because the rules would require more drivers and trucks on the road in peak traffic periods, thus producing more – not fewer – accidents.

The proposed hours-of-service rules were fundamentally revised. The final regulation is simpler and cheaper, easier to enforce, and more compatible with current motor carrier operations.

Research and Special Programs Administration

1. Notice of Proposed Rulemaking on Pipeline Integrity Management for Gas Transmission Pipelines in High Consequence Areas

This rule proposed to require the identification of high consequence areas that could be affected by a pipeline failure and the establishment of integrity management programs to provide additional safety measures to better protect for persons in those high consequence areas. State pipeline safety programs will share inspection and enforcement responsibilities for the integrity management regulation. State pipeline safety officials have been consulted. State pipeline safety officials have expressed concern that the proposed rule is sufficiently clear to enable them to enforce it and that there needs to be training for State inspectors.

The agency has planned an approach to enforcement that will include the extensive use of protocols for inspectors (both Federal and State) to use for compliance inspections and for training in the use of these protocols. The agency does not charge States tuition for pipeline safety training.

Environmental Protection Agency

1. National Environmental Performance Partnership System (NEPPS)

EPA consults with States through the Environmental Council of the States (ECOS), whose objective is State participation in Agency activities, particularly those affecting State-implemented programs. Committees consisting of both State and EPA members perform most of this work through forums that are open to other stakeholders. EPA and the ECOS have an active joint work group to address continuing implementation issues and work to identify and remove remaining barriers to effective implementation of NEPPS.

ECOS has also launched several other projects with EPA consultation including work on children's health issues, a partnership to build locally and nationally accessible environmental systems, and development of core performance measures.

2. Office of Pollution Prevention and Toxics (OPPT)

EPA has several continuing outreach mechanisms related to its mission that allow OPPT to routinely secure State and tribal insights and advice. These institutionalized processes are therefore to some extent independent of specific rulemaking. Established in early 1990s, OPPT created the Forum on State Tribal Toxics Action (FOSTTA) as a vehicle to encourage State and tribal involvement in OPPT decision making. OPPT also uses the State Federal FIFRA Issues Research and Evaluation Group (SFIREG), established in 1974 by cooperative agreement between EPA and the American Association of Pesticide Control Officials, the association that

represents State level pesticide regulatory officials. SFIREG identifies, analyzes and provides State comment on pesticide regulatory issues and provides a mechanism for ongoing exchange of information about EPA and State pesticide programs.

Some specific examples of results from consulting with SFIREG include the formation of joint EPA-State workgroups to deal with a number of issues/projects. The SFIREG aids in developing guidance documents for use by EPA Regions and State agencies to define Quality Management and Quality Assurance procedures for State pesticide programs (completed in 2000). The Group also works on improving or clarifying several pesticide labeling issues, including products used in public health mosquito control programs, restricted reentry intervals for agricultural workers, label precautions to protect bees and other pollinators, and new requirements for the safe handling and use of phosphine gas fumigants (these are on-going now). EPA has used SFIREG to provide State input on labeling policy in general through comments on revisions to the Label Review Manual used by EPA staff.

3. Office of Policy, Economics, and Innovation (OEPI)

EPA, through the Office of Policy, Economics, and Innovation (OPEI), has many continuing mechanisms for consultation with State and local governments on regulatory issues. OPEI consults with State governments and through them with local governments to promote regulatory efficiency and improved environmental results. Some of these mechanisms include the *Joint EPA/State Agreement to Pursue Regulatory Innovation* signed in 1998 by EPA and the Environmental Council of the States (ECOS). The latter organization enables EPA and a number of States to consult regularly on nearly 35 active innovation projects. The ECOS Cross-Media Committee also invites EPA to attend its meetings and we extend a similar invitation for representatives from the Committee to attend the meetings of the EPA Innovation Action Council. States use these venues to identify issues relevant to regulatory innovation and to collaborate on demonstrations and evaluations.

OPEI also sponsors a State Innovation Grant Program, designed to provide resources to States to promote innovation in their regulatory programs through a competitive solicitation process. EPA recently completed a process designed to gather comment by State agencies on the design of this year's solicitation. Historically, EPA has consulted regularly with States as our co-regulators on regulatory innovation projects under Project XL and Project XL for communities. OPEI and its predecessor organizations also collaborated with States and communities in supporting a community-based environmental protection initiative. OPEI supports several State initiatives for innovation in environmental regulation, and consults frequently with individual States on specific projects.

4. Local Government Environmental Assistance Network (LGEAN)

EPA helps support this Internet-based information service (that has parallel toll-free voice and fax-back options). LGEAN provides a first stop for local government officials with questions about environmental compliance. The site contains information from EPA and eight participating nongovernmental organizations. Users can ask questions of experts, consult with their peers, review and comment on developing regulations, and find the full text or summaries

of State and Federal environmental statutes. LGEAN alerts users to hot topics and new developments in environmental compliance, tells them where to find technical and financial support, and provides them with a grant writing tutorial.

5. RCRA Burden Reduction Initiative

The RCRA Burden Reduction Initiative rulemaking will streamline or remove a third of the RCRA reporting and recordkeeping requirements. Many changes will affect State hazardous waste programs. Individual States and the States' national organization, the Association of State and Territorial Solid Waste Management Officials (ASTSWMO), responded to our proposed changes. They often raised issues that the agency would have otherwise been unaware of, and identified benefits of proposed changes that had not been considered.

EPA engaged ASTSWMO in a productive dialogue to fully understand their concerns. This dialogue resulted in compromises suiting the needs of the States while allowing us to achieve EPA's objective of significantly reducing burden associated with RCRA reporting and recordkeeping.

6. Hazardous Waste Identification Rule

EPA worked closely with the States in developing the revisions to the mixture and derived-from rules that were finalized in the 2001 Hazardous Waste Identification Rule (HWIR). Seven States participated on the EPA rulemaking workgroup (California, Colorado, Missouri, Oklahoma, Oregon, Virginia, and Washington), offering comments on early drafts of the proposed and final rules, particularly on implementation issues. For example, State input was key in developing proposed options on how much data should be included in the HWIR exemption notification package.

EPA also attended at least four national meetings of States (three hosted by ATSWMO and one hosted by the Northeast Waste Management Officials' Association.) In those meetings, EPA presented updates on the HWIR rulemaking and answered States' questions on the proposal. The States' input was especially key in contingent management, as they requested options for a "clean break" from hazardous waste regulation for these wastes. Records of those meetings are available in the HWIR docket.

7. State and Local Government Input on EPA's Public Involvement Policy

In June 2003, EPA released the new Public Involvement Policy, "A Framework for Implementing EPA's Public Involvement Policy", and "EPA's Response to Public Comments on Draft 2000 Public Involvement Policy." The final 2003 Policy highlights the unique roles that these governmental units play as well as the importance of partnerships with delegated programs. The Policy reaffirms our commitment to early and meaningful public involvement. EPA received comments from 26 State agencies, 12 local governments, and four tribal governments on the draft Policy and made the appropriate changes. States expressed strong interest in partnering on public involvement activities, and in using the tools (training, evaluation, and sharing information) that EPA is creating to improve public involvement in decisions. EPA also invited

States and tribes to aid informally in developing the Policy's implementation plan. Information is available at http://www.epa.gov/publicinvolvement/policy2003/index.htm.

EPA includes government officials from States, localities, and tribes in developing regulations, policies, and guidance that affects them. The agency continues to use various policies, advisory boards, newsletters, and reference handbooks to help State, local, and tribal officials learn about federal regulatory plans and to let them know how they can engage in the rule development process.