

**DRAFT 2006 REPORT TO CONGRESS
ON THE COSTS AND BENEFITS OF FEDERAL REGULATIONS**

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EXECUTIVE SUMMARY

This draft Report to Congress on the Costs and Benefits of Federal Regulations was prepared to implement Section 624 of the Treasury and General Government Appropriations Act of 2001 (Pub. L. No. 106-554, 31 U.S.C. § 1105 note), commonly known as the Regulatory Right-to-Know Act. The report will be published in its final form later this year, after revisions to this draft are made based on public comment, external peer review, and interagency review.

A key feature of this report is the estimates of the total costs and benefits of regulations reviewed by the Office of Management and Budget (OMB). Similar to previous reports, the report includes a 10-year look-back of major Federal regulations reviewed by OMB to examine their quantified and monetized benefits and costs:

- The estimated annual benefits of major Federal regulations reviewed by OMB from October 1, 1995 to September 30, 2005 range from \$94 billion to \$449 billion, while the estimated annual costs range from \$37 billion to \$44 billion. The substantial increase in aggregate benefits since last year is attributable to the addition of the Environmental Protection Agency's Clean Air Interstate Rule.
- During the past year, 13 "major" final rules with quantified and monetized benefits and costs were adopted. These rules added \$28 billion to \$178 billion in annual benefits compared to \$4.3 billion to \$6.6 billion in annual costs.
- There were an additional eight final "major" rules that did not have quantified and monetized estimates of both benefits and costs. Two of these eight rules implemented homeland security programs where the benefits of improved security are very difficult to quantify and monetize.

In addition, we report the latest results of our ongoing historical examination of the trends in Federal regulatory activity. Last year's report included preliminary estimates of the overall costs of major rules issued by Federal agencies each year from 1981 to 2004, and suggested that a better measure of the overall impact of regulation on the economy would be net benefits; that is, benefits minus costs. This report presents preliminary net benefit estimates for the years 1992 to 2005. The cost estimates are extended back to 1981, the beginning of the regulatory review program at OMB. Based on a preliminary review, the data reveal that:

- The average yearly cost of the major regulations issued during the Bush (43) Administration is about 54% less than over the previous 20 years.
- The average yearly benefit of the major regulations issued during the Bush (43) Administration is over double the yearly average for the previous eight years.
- Over the last 25 years, the major regulations reviewed by OMB have added at least \$123 billion to the overall yearly costs of regulations on the public.

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- The benefits of major regulations issued from 1992 to 2005 exceed the costs by over three fold.

The draft report also provides an update on various initiatives to improve regulatory cooperation internationally. While we have focused on U.S. engagement with the European Union, other efforts to promote cooperation are underway with key trading partners, including Canada and Mexico.

CHAPTER I: THE COSTS AND BENEFITS OF FEDERAL REGULATIONS

Section 624 of the Treasury and General Government Appropriations Act of 2001, often called the “Regulatory Right-to-Know Act,” (Pub. L. No. 106-554, 31 U.S.C. § 1105 note) calls for the Office of Management and Budget (OMB) to submit “an accounting statement and associated report” including:

(A) an estimate of the total annual costs and benefits (including quantifiable and nonquantifiable effects) of Federal rules and paperwork, to the extent feasible:

- (1) in the aggregate;
- (2) by agency and agency program; and
- (3) by major rule;

(B) an analysis of impacts of Federal regulation on State, local, and tribal government, small business, wages, and economic growth; and

(C) recommendations for reform.

Since the statutory language does not further define “major,” for the purposes of this Report, we were broadly inclusive in defining “major” rules. We have included all final rules promulgated by an Executive branch agency that meet any one of the following three measures:

- Rules designated as “major” under 5 U.S.C. § 804(2);¹
- Rules designated as meeting the analysis threshold under 2 U.S.C. § 1532;² and
- Rules designated as “economically significant” under section 3(f)(1) of Executive Order 12866.³

This chapter consists of two parts: the accounting statement, and a brief report on regulatory impacts on State, local, and tribal governments, small business, wages, and economic growth. Part A revises the benefit-cost estimates in last year’s Report by updating the estimates to the end of fiscal year 2005 (September 30, 2005). Like the 2005 Report, this chapter uses a 10-year look-back: estimates are based on the major regulations reviewed by OMB from

¹A “major rule” is defined in Subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996: Congressional Review of Agency Rulemaking (5 U.S.C. 804(2)) as a rule that is likely to result in: “(A) an annual effect on the economy of \$100,000,000 or more; (B) a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or (C) significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic and export markets.”

²A written statement containing a qualitative and quantitative assessment of the anticipated costs and benefits of the Federal mandate is required under the Section 202(a) of the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1532(a)) for all rules that may result in: “the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted annually for inflation) in any 1 year.”

³A regulatory action is considered “economically significant” under Executive Order 12866 3(f)(1) if it is likely to result in a rule that may have: “an annual effect on the economy of \$100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities.”

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October 1, 1995 to September 30, 2005.⁴ This means that five rules reviewed from October 1, 1994 to September 30, 1995 were included in the totals for the 2005 Report but are not included in the draft 2006 Report. A list of these rules can be found in Appendix C (see Table C-1). Appendix C also includes a summary of eight rules included in the 2004 Report but not included in the 2005 Report (see Table C-2), and a summary of 33 rules included in the 2003 Report but not included in the 2004 Report (see Table C-3).

All of the estimates presented in this chapter are based on agency information or transparent modifications of agency information performed by OMB.⁵ We also include in this chapter a discussion of major rules issued by “independent” regulatory agencies, although OMB does not review these rules under Executive Order 12866.⁶ This discussion is based on data provided by these agencies to the Government Accountability Office (GAO) under the Congressional Review Act.

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

Table 1-1 presents an estimate of the total costs and benefits of 95 regulations reviewed by OMB over the ten-year period from October 1, 1995 to September 30, 2005 that met two conditions.⁷ Each rule generated costs or benefits of at least \$100 million in any one year, 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.⁸ As discussed in previous Reports, 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. The estimates of the costs and benefits of Federal regulations over the period October 1, 1995 to September 30, 2005 are based on agency analyses subject to public notice and comments and OMB review under E.O. 12866.

⁴All previous Reports are available at: http://www.whitehouse.gov/omb/inforeg/regpol-reports_congress.html.

⁵OMB used agency estimates where available. If an agency quantified but did not monetize estimates, we used standard assumptions to monetize them, as explained in Appendix A. Inflation adjustments are performed using the latest available GDP deflator and all amortizations are performed using a discount rate of 7%, unless the agency has already presented annualized, monetized results using a different explicit discount rate.

⁶Section 3(b) of Executive Order 12866 excludes "independent regulatory agencies as defined in 44 U.S.C. 3502(10)".

⁷OMB discusses, in this report and in previous reports the difficulty of estimating and aggregating the costs and benefits of different regulations over long time periods and across many agencies using different methodologies. Any aggregation involves the assemblage of benefit and cost estimates that are not strictly comparable. In part to address this issue, the 2003 Report included OMB's new regulatory analysis guidance, OMB Circular A-4, which took effect on January 1, 2004 for proposed rules and January 1, 2005 for final rules. The guidance recommends what OMB defines as “best practice” in regulatory analysis, with a goal of strengthening the role of science, engineering, and economics in rulemaking. The overall goal of this guidance is a more competent and credible regulatory process and a more consistent regulatory environment. OMB expects that as more agencies adopt our recommended best practices, the costs and benefits we present in future reports will become more comparable across agencies and programs. OMB is working with the agencies to ensure that their impact analyses follow the new guidance.

⁸In many instances, agencies were unable to quantify all benefits and costs. We have conveyed the essence of these unquantified effects on a rule-by-rule basis in the columns titled “Other Information” in Appendix A of this and previous Reports. The monetized estimates we present necessarily exclude these unquantified effects.

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The aggregate benefits reported and costs in Table 1-1 are substantially larger than the aggregate presented in the 2005 Report. The increase in benefits is due primarily to the addition of an Environmental Protection Agency (EPA) rulemaking: The Clean Air Interstate Rule, which primarily requires 28 states and the District of Columbia to revise their air quality State Implementation Plans to include control measures to reduce emissions of sulfur dioxide and nitrogen oxides. This rule generates estimated average yearly benefits of \$50 billion to \$60 billion. The increase in costs is due primarily to this Clean Air Interstate rule (about \$1.8 billion in annual costs) and the Department of Transportation's (DOT) Tire Pressure Monitoring System rule (about \$1 to \$2 billion in annual costs). As can be seen in Tables 1-1 and 1-2, EPA rules continue to be responsible for the majority of costs and benefits generated by Federal regulation during this time period.

Table 1-1: Estimates of the Total Annual Benefits and Costs of Major Federal Rules, October 1, 1995 to September 30, 2005 (millions of 2001 dollars)

Agency	Number of Rules	Benefits	Costs
Department of Agriculture	7	3,530-6,747	2,215-2,346
Department of Education	1	633-786	349-589
Department of Energy	6	5,194-5,260	2,958
Department of Health and Human Services	19	21,313-33,268	3,853-4,029
Department of Homeland Security (Coast Guard)	1	44	305
Department of Housing and Urban Development	1	190	150
Department of Justice	1	275	108-118
Department of Labor	4	1,138-3,440	349
Department of Transportation	13	2,913-4,948	3,212-6,622
Environmental Protection Agency	42	58,670-394,454	23,572-26,200
Total	95	93,899-449,412	37,071-43,665

Table 1-2 provides additional information on aggregate benefits and costs for specific agency programs. In order for a program to be included in Table 1-2, the program needed to have finalized three or more rules in the last 10 years with monetized costs and benefits.

The ranges of costs and benefits presented in Tables 1-1 and 1-2 are not necessarily correlated. In other words, when interpreting the meaning of these ranges, the reader should not assume that low benefits are associated with low costs and that high benefits are associated with high costs. Thus, for example, it is possible that the net benefits of EPA's water programs, taken together, could range from negative \$2.1 billion to positive \$6.8 billion per year.

Table 1-2: Estimates of Annual Benefits and Costs of Major Federal Rules: Selected Programs and Agencies, October 1, 1995-September 30, 2005 (millions of 2001 dollars)

Agency	Number of Rules	Benefits	Costs
Department of Energy			
Energy Efficiency and Renewable Energy	6	5,194-5,260	2,958
Department of Health and Human Services			
Food and Drug Administration	13	3,435-14,948	1,015-1,190
Center for Medicare and Medicaid Services	4	16,634	2,544
Department of Labor			
Occupational Safety and Health Administration	4	1,138-3,440	349
Department of Transportation			
National Highway Traffic Safety Administration	8	2,070-4,105	2,123-5,532
Environmental Protection Agency			
Office of Air	30	55,321-376,686	17,534-19,797
Office of Water	9	1,425-10,066	3,203-3,568

Based on the information contained in this and 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) may be significantly larger than the sum of the costs and benefits reported in Table 1-1. More research is necessary to provide a stronger analytic foundation for comprehensive estimates of total costs and benefits by agency and program.

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 data. 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 rates of time preference, different treatments of uncertainty—these differences remain embedded in Tables 1-1 and 1-2. 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 benefit and cost estimates.

Many of these major rules have important non-quantified benefits and costs, which may have been a key factor in an agency’s decision to promulgate a rulemaking. These qualitative issues are discussed in the agency rulemaking documents, in previous versions of this Report, and in Table A-1 in Appendix A of this Report.

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The majority of the large estimated benefits of EPA rules are attributable to the reduction in public exposure to a single air pollutant: fine particulate matter. Thus, the favorable benefit-cost results for EPA regulation should not be generalized to all types of EPA rules or even to all types of clean-air rules. In addition, the ranges of costs and benefits presented in Tables 1-2 need to be treated with some caution. To the extent that the reasons for uncertainty differ across individual rules, aggregating high- and low-end estimates can result in totals that are extremely unlikely. In the case of the EPA rules reported here, however, a substantial portion of the uncertainty is similar across several rules: uncertainty in the reduction of premature deaths associated with reduction in particulate matter and the monetary value of reducing mortality risk. We continue to work with EPA to revise these ranges to more fully reflect the uncertainty in these estimates.

As Table 1-2 indicates, the degree of uncertainty in benefit estimates for clean air rules is large. In addition, the wide range of benefits estimates for particle control does not capture the full extent of the scientific uncertainty. The five key assumptions in the benefits estimates are as follows:

- Inhalation of fine particles is causally associated with a risk of 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.
- All fine particles, regardless of their chemical composition, are equally potent in causing premature mortality. This is an important assumption, because fine particles formed from power plant SO₂ and NO_x emissions are chemically different from fine particles emitted directly from both mobile sources and other industrial facilities, but no clear scientific grounds exist for supporting differential effects by particle type.
- 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.
- The forecasts for future emissions and associated air quality modeling are valid.
- The valuation of the estimated reduction in mortality risk is largely taken from studies of the tradeoff associated with the willingness to accept risk in the labor market.

In response to recommendations from a committee of the National Research Council/National Academy of Sciences, EPA is working with OMB to improve methods to quantify the degree of technical uncertainty in benefits estimates.⁹

⁹For more information on this study, please see *Estimating the Public Health Benefits of Proposed Air Pollution Regulations*, National Academy of Sciences, 2003. Available at <http://books.nap.edu/catalog/10511.html>.

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

In this section, we examine in detail the benefits and costs of the 45 major final rules for which OMB concluded review during the 12-month period beginning October 1, 2004, and ending September 30, 2005. These major rules represent approximately 15 percent of the 292 final rules reviewed by OMB during this period, and approximately one percent of the 3,980 final rules published in the *Federal Register* during this period. OMB believes, however, that the costs and benefits of major rules capture the vast majority of the total costs and benefits of all rules subject to OMB review.¹⁰

Of the 45 rules, 21 regulations were “social regulations,” which may require substantial additional private expenditures as well as provide new social benefits.¹¹ Of the 21 “social regulations,” we are able to present estimates of both monetized costs and benefits for 13 rules. The estimates are aggregated by agency in Table 1-3, and each rule is summarized in Table 1-4. Two of the rules for which we were not able to present estimates of both costs and benefits implemented homeland security programs where the benefits of improved security are very difficult to quantify and monetize.¹² Both of these rules did estimate costs, and these costs, as well as the available information on benefits, are summarized in Table 1-5. The six other final rules did not include monetized or quantified estimates for both costs and benefits, thus we did not include those rules in the totals in Tables 1-1 through 1-3. We attempt to summarize the available information on the impact of these rules in the “other information” column of Table A-1.

The remaining 24 regulations implemented Federal budgetary programs, which primarily caused income transfers, usually from taxpayers to program beneficiaries. Although rules that facilitate Federal budget programs are subject to E.O. 12866 and OMB Circular A-4, and are fully reviewed by OMB, this Report is focused on regulations that impose costs primarily through private sector mandates.

¹⁰We discuss the relative contribution of major rules to the total impact of Federal regulation in detail in the “response-to-comments” section on pages 26-27 of the 2004 Report. In summary, our evaluation of a few representative agencies found that major rules represented the vast majority of the costs and benefits of all rules promulgated by these agencies and reviewed by OMB.

¹¹The *Federal Register* citations for these major rules are found in Table A-1 in Appendix A.

¹²See Chapter 4 in the 2003 Report (pp 64-80) for a more detailed discussion of this issue.

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Social Regulation

Of the 45 economically significant rules reviewed by OMB, 21 regulations require substantial private expenditures or provide new social benefits. We are able to present monetized costs and benefits for about 70 percent (13 of 19) of the non-homeland security-related rules. Since OMB began to compile this report, this is among the highest percentage of economically significant rules presenting both monetized costs and monetized benefits. Table 1-3 presents total benefits and costs by agency of these major rules reviewed by OMB over the past year and Table 1-4 provides a summary of each regulation. These tables are the basis for the totals in the accounting statement in Section A of this chapter.

In assembling these tables of estimates of benefits and costs, OMB has 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 has monetized quantitative estimates where the agency has not done so. For example, we have converted 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 in Appendices A and B. Table A-1 in Appendix A also reports the available impact information, as reported by the agencies, on all 21 of the social regulations reviewed by OMB in the time period covered by this Report.

Table 1-3: Estimates of the Total Annual Benefits and Costs of Major Federal Rules, October 01, 2004 to September 30, 2005 (millions of 2001 dollars)

Agency	Number of Rules	Benefits	Costs
United States Department of Agriculture	2	693-823	628-737
Department of Health and Human Services	2	11,087-13,554	37
Department of Justice	1	275	108-118
Department of Transportation	4	1,330-1,709	948-2,332
Environmental Protection Agency	4	14,512-161,708	2,609-3,373
Total	13	27,896-178,070	4,329-6,597

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Table 1-4: Estimates of the Total Annual Benefits and Costs of Major Rules Issued Between October 1, 2004 to September 30, 2005 (millions of 2001 dollars per year)

Rule	Agency	Benefits	Costs	Explanation of OMB Calculations
Bovine Spongiform Encephalopathy: Minimal Risk Regions and Importation of Commodities	USDA-APHIS	572-639	557-623	
Mexican Hass Avocado Import Program	USDA-APHIS	122-184	71-114	
Amendments to the Performance Standard for Diagnostic X-Ray Systems and Their Major Components	HHS/FDA	87-2,549	30	
Immunization Standard for Long Term Care Facilities	HHS/CMS	11,000	6	
Electronic Orders for Schedule I and II Controlled Substances	DOJ/DEA	275	108-118	
Hours of Service of Drivers, 2005	DOT/FMCSA	19	-235	The baseline for the costs and benefits of the 2005 rule is the 2003 final Hours of Service rule, which is also included in the totals presented in Tables 1-1 and 1-2. The negative costs represent the relaxed requirements, relative to the 2003 rule, for short haul trucking. The positive benefits are due to the elimination of the 2003 rule's allowance of split resting periods in the truck's sleeper berth.
Tire Pressure Monitoring Systems	DOT/NHTSA	1,012-1,316	938-2,282	
Rear Center Lap/Shoulder Belt Requirement--Standard 208	DOT/NHTSA	188-236	162-202	
Upgrade of Head Restraints	DOT/NHTSA	111-139	83	
Clean Air Interstate Rule Formerly Titled: Interstate Air Quality Rule	EPA/Air	11,947-151,769	1,716-1,894	EPA reported results in 2010 and 2015. We interpolated the impact for the transition period and annualized at 7% and 3% from 2006 through 2015. We also calculated an uncertainty interval using a method explained in Appendix B.

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Rule	Agency	Benefits	Costs	Explanation of OMB Calculations
Clean Air Visibility Rule	EPA/ Air	2,302- 8,153	314-846	The low value of the range for costs and benefits is based on EPA Scenario 1. The “high” values of the range for cost and benefits was computed by combining the estimated NOx and SO2 Electricity Generating Units (EGU) emissions reductions from EPA’s Scenario 2 with the estimated non-EGU emission reductions using a cost per ton value of \$2,000 for reducing NOx and SO2. Cost estimates for the high value were estimated directly by EPA in the final impact analysis. Benefits estimates for the high value were derived by multiplying the combined emission reductions with OMB’s high estimate of the benefits per ton from stationary sources for each pollutant presented in Appendix B.
Clean Air Mercury Rule--Electric Utility Steam Generating Units	EPA/ Air	1-2	500	EPA reported results in 2010 and 2018. We interpolated the impact for the transition period and annualized at 7% and 3% from 2010 through 2020.
National Primary Drinking Water Regulations: Long Term 2 Enhanced Surface Water Treatment Rule	EPA/ Water	262-1,785	80-132	The uncertainty ranges are based on the highest and lowest mean impacts across 12 scenarios EPA reported. They varied the discount rate, the cost-of-illness based monetization approach, and the datasets used for the analysis across these 12 scenarios.
Total		27,899- 178,070	4,329- 6,597	

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Homeland Security Regulations

Table 1-5 presents the available impact information on the two major homeland security regulations adopted in the past year by DHS and HHS. Because the benefits of homeland security regulations are a function of the likelihood and severity of a hypothetical future terrorist attack, they are very difficult to forecast, quantify, and monetize. For the purposes of Table 1-5, we have annualized and converted the cost estimates to 2001 dollars in a manner similar to Table 1-4. We have also summarized the available information on how the agencies feel each of the rules will improve security or otherwise prevent or mitigate the consequences of a terrorist attack.

OMB has also compiled the total impact of all major, economically significant homeland security rules that have been finalized since the creation of the DHS and that contain monetized costs. Since DHS was created, they have finalized 9 major homeland security regulations that impose a total cost on the economy of between \$2.1 billion to \$3.9 billion a year.

Table 1-5: Estimates of the Total Annual Benefits and Costs of Major Federal Rules: Major Homeland Security Regulation, October 1, 2004-September 30, 2005 (millions of 2001 dollars)

Rule	Agency	Benefits	Costs	Other Information
Electronic Transmission of Passenger and Crew Manifests for Vessels and Aircraft	DHS-BCBP	Submission of manifest information is a necessary component of the nation's continuing program of ensuring aviation and vessel safety and protecting national security. The required information also will assist in the efficient inspection and control of passengers and crew members and thus will facilitate the effective enforcement of the customs, immigration, and transportation security laws.	127	No adjustment to agency estimate
Establishment and Maintenance of Records Pursuant to the Public Health Security and Bioterrorism Preparedness and Response Act of 2002	HHS-FDA	The final rule will help reduce the number of people who become ill during accidental or deliberate foodborne outbreaks by reducing the time required for preventive action. Furthermore, the final rule will eliminate the recurrence of outbreaks that may have been prevented had poor records quality not resulted in prematurely terminating the initial traceback investigation.	121-134	No adjustment to agency estimate
Total			248 – 261	

C. Regulations Implementing Federal Budgetary Programs

Of the 45 economically significant rules reviewed by OMB, Table 1-6 lists the 24 that implement Federal budgetary programs. The budget outlays associated with these rules are “transfers” from taxpayers to program beneficiaries (or fees collected from program beneficiaries); therefore in past reports OMB has referred to these rules as “transfer” rules. The totals are: USDA, 6 rules; Department of Defense (DoD), 1 rule; HHS, 13 rules; DHS, 1 rule; HUD, 1 rule; DOL, 1 rule; and the Small Business Administration (SBA), 1 rule.

Table 1-6: Agency Rules Implementing Federal Budgetary Programs, October 1, 2004 to September 30, 2005

Department of Agriculture
Tobacco Transition Payment Program
Tobacco Manufacturer and Importer Assessments
2004 Livestock Assistance Program
2004 Crop Disaster Program
Conservation Security Program
User Fees for Agricultural Quarantine and Inspection Services
Department of Defense
Radio Frequency Identification
Department of Health and Human Services
Changes to the Hospital Inpatient Prospective Payment System and FY 2006 Rates (CMS-1500-P)
Prospective Payment System for Inpatient Rehabilitation Facilities for FY 2006 (CMS-1290-P)
Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities--Update for FY 2006 (CMS-1282-P)
Prospective Payment System for Long Term Care Hospitals: Annual Payment Rate Updates and Policy Changes for 2006 (CMS-1483-F)
Medicare Drug Benefit Effective Calendar Year 2006--Title I (CMS-4068-F)
Medicare Advantage Program--Title II (CMS-4069-F)
Prospective Payment System for Inpatient Psychiatric Facilities for FY 2004 (CMS-1213-F)
Changes to the Hospital Outpatient Prospective System and Calendar Year 2005 Payment Rates (CMS-1427-FC)
Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2005 (CMS-1429-FC)
Home Health Prospective Payment System Rate Update FY 2005 (CMS-1265-F)
Revisions to the Appeals Process for Initial Claim Determinations (CMS)
Conditions for Coverage of Power Mobility Devices, including Powered Wheelchairs and Power-Operated Vehicles Scooter(CMS-3017-IFC)
Health Care Infrastructure Improvement Program; Selection Criteria of Loan Program for Qualifying Hospitals Engaged in Cancer-Related Health Care (CMS-1287-IFC)
Department Of Homeland Security
Allocation of H-1B Visas Created by the H-1B Visa Reform Act of 2004
Department of Housing and Urban Development
Operating Fund Allocation Formula
Department of Labor
Claims for Compensation Under the Energy Employees Occupational Illness Compensation Program Act of 2000
Small Business Administration
Small Business Government Contracting Programs

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In addition, there were four HHS/CMS “Notices” which are used to set parts of their payment systems such as premiums and annual deductibles. These notices are not final rules, since they implement changes to CMS payment systems driven by statutory formula and are not subject to notice and comment. We nonetheless list these notices below since they are considered “major” under 5 U.S.C. § 804(2) and are reported to the GAO:

- Fee Schedule for Payment of Ambulance Services-Update for Calendar Year 2005 (CMS-1267-N)
- Inpatient Hospital Deductible and Hospital and Extended Care Services Coinsurance Amounts for Calendar Year 2006 (CMS-8026-N)
- Part A Premiums for Calendar Year 2006 for the Uninsured Aged and for Certain Disabled Individuals Who Have Exhausted Other Entitlement (CMS-8025-N)
- Medicare Part B Monthly Actuarial Rates and Premium Rate Beginning January 1, 2006 (CMS-8027-N)

Please note that rules that transfer Federal dollars often have opportunity costs or benefits in addition to the budgetary dollars spent. Including budget programs in the overall totals would, however, overwhelm the incremental new regulatory impacts identified by this Report and would confuse the distinction between rules that impose costs primarily through the imposition of taxes, and rules that impose costs primarily through mandates on the private sector. We also caution the reader not to assume that these rules were subject to less stringent analytical and review requirements based on our less-detailed presentation of Federal budget rules in this Report. In fact, agencies thoroughly analyze and OMB thoroughly reviews all significant Federal budget rules under E.O. 12866. If economically significant, these rules must be accompanied by regulatory impact analyses that comply with OMB Circular A-4.

D. Major Rules for “Independent” Regulatory Agencies

The congressional review provisions of the Small Business Regulatory Enforcement Fairness Act (SBREFA) (Pub. L. No. 104-121) require the GAO to submit reports on major rules to the committees of jurisdiction, including rules issued by agencies not subject to Executive Order 12866, the so-called “independent” regulatory agencies. We reviewed the information on the costs and benefits of major rules contained in GAO reports for the period of October 1, 2004 to September 30, 2005. GAO reported that four of these agencies issued 11 major rules during this period.¹³

In comparison to the agencies subject to E.O. 12866, these agencies provided in their analyses relatively little quantitative information on the benefits of major rules: of the 19 economically significant rules reviewed by OMB that did not implement homeland security related regulations, about 70 percent (12) reported monetized costs and benefits, whereas about 20 percent (2 of 11) of the rules finalized by independent agencies reported monetized costs and benefits. As Table 1-7 indicates, most of the rules included some discussion of benefits and

¹³Rules promulgated by the Federal Communications Commission (FCC) under the authority of the Telecommunications Act of 1996 are exempt from the definition of “major rule” (5 U.S.C. 804). However, no FCC rules that would otherwise meet the criteria for “major rule” were identified for this period.

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costs, and reported monetized costs. OMB does not know whether the rigor and extent of the analyses conducted by these agencies are similar to those of the analyses performed by agencies subject to the Executive Order, since OMB does not review rules from these agencies.

Table 1-7: Major Rules for “Independent” Regulatory Agencies, October 1, 2004 to September 30, 2005

Agency	Rule	Information on Benefits or Costs	Monetized Benefits	Monetized Costs
Federal Communications Commission	Broadcast Services: Television Stations [69 FR 69325]	No ¹⁴	No	No
Federal Communications Commission	Promoting Efficient Use of Spectrum Through Elimination of Barriers to the Development of Secondary Markets [69 FR 77522]	No ¹⁴	No	No
Federal Communications Commission	Private Land Mobile Services; 800 MHz Public Safety Interference Proceeding [69 FR 67823]	No ¹⁴	No	No
Federal Communications Commission	Facilitating the Provision of Spectrum-Based Services to Rural Areas and Promoting Opportunities for Rural Telephone Companies to Provide Spectrum-Based Services [69 FR 75144]	No ¹⁴	No	No
Federal Trade Commission	Definitions and Implementation Under the CAN-SPAM Act [70 FR 3110]	No ¹⁴	No	No
Nuclear Regulatory Commission	Revision of Fee Schedules [70 FR 30526]	Yes	No	Yes
Securities and Exchange Commission	Securities Offering Reform [70 FR 44722]	Yes	Yes	Yes
Securities and Exchange Commission	Regulation NMS [70 FR 37496]	Yes	Yes	Yes
Securities and Exchange Commission	Mutual Fund Redemption Fees [70 FR 13328]	Yes	No	Yes
Securities and Exchange Commission	Asset-Backed Securities [70 FR 1506]	Yes	No	Yes
Securities and Exchange Commission	Registration Under the Advisers Act of Certain Hedge Fund Advisers [69 FR 7205]	Yes	No	Yes

¹⁴The GAO reported that a Regulatory Flexibility Analysis was conducted to estimate the effect on small businesses, although no Benefit-Cost Analysis was conducted

E. The Impact of Federal Regulation on State, Local, and Tribal Government, Small Business, Wages, and Economic Growth

Sec. 624 (a)(2) of the Regulatory Right-to-Know Act (Pub. L. No. 106-554, 31 U.S.C. § 1105 note) calls on OMB to present an analysis of the impacts of Federal regulation on State, local, and tribal governments, small business, wages, and economic growth.

Impacts on State, Local, and Tribal Governments

Over the past 10 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).¹⁵

- *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

¹⁵We 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.

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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 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

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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.

- *National Primary Drinking Water Regulations: Long Term 2 Enhanced Surface Water Treatment (2005)*: The rule protects against illness due to *Cryptosporidium* and other microbial pathogens in drinking water and addresses risk-risk trade-offs with the control of disinfection byproducts. It requires the use of treatment techniques, along with monitoring, reporting, and public notification requirements, for all public water systems that use surface water sources. EPA estimates the total cost of the rule on Federal and State levels of government, and on the private sector, is between \$60 and \$170 million per year.

Although these seven EPA rules were the only ones over the past 10 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.

Impact on Small Business

The need to be sensitive to the impact of regulations and paperwork on small business was recognized in Executive Order 12866, “Regulatory Planning and Review.” The Executive Order calls on the agencies to tailor their regulations by business size in order to impose the least burden on society, consistent with obtaining the regulatory objectives. It also calls for the development of short forms and other efficient regulatory approaches for small businesses and other entities. Moreover, in the findings section of the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA), Congress stated that “... small businesses bear a disproportionate share of regulatory costs and burdens” (Section 202(2) of Pub. L. No. 104-121). Each firm has to determine whether a regulation applies, how to comply, and whether it is in compliance. As firms increase in size, fixed costs of regulatory compliance are spread over a larger revenue and employee base, which often results in lower regulatory costs per unit of output.

The Office of the Chief Counsel for Advocacy of the Small Business Administration (hereafter “Advocacy”) recently sponsored a study (Crain 2005) that estimated the burden of regulation on small businesses.¹⁶ This is the third in a series of studies on small business regulation conducted on behalf of the Office of Advocacy.¹⁷ This study found that regulatory costs per employee decline as firm size—as measured by the number of employees per firm—increases. Crain estimates that the total cost of Federal regulation (environmental, workplace, economic, and tax compliance regulation) was 45 percent greater per employee for firms with

¹⁶Crain, W.M. 2001. “The Impact of Regulatory Costs on Small Firms.” Report prepared for the Office of Advocacy, U.S. Small Business Administration. Available at <http://www.sba.gov>.

¹⁷The other two reports are Hopkins, T., 1995, “Profiles of Regulatory Costs;” and Crain, W.M. and T. Hopkins 1999, “The Impact of Regulatory Costs on Small Firms.” These reports are also available on Advocacy’s website.

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under 20 employees compared to firms with over 500 employees.

Because of this relatively large impact of regulations on small businesses, President Bush issued Executive Order 13272, which reiterates the need for agencies to assess the impact of regulations on small businesses under the Regulatory Flexibility Act (RFA) (5 U.S.C. § 601-612). Under the RFA, whenever an agency comes to the conclusion that a particular regulation will have a significant economic impact on a substantial number of small entities, the agency must conduct both an initial and final regulatory flexibility analysis. This analysis must include an assessment of the likely burden of the rule on small entities, and an analysis of alternatives that may afford relief to small entities while still accomplishing the regulatory goals.

Advocacy reports annually on the overall performance of agency compliance with the RFA and Executive Order 13272, and Advocacy efforts to improve the analysis of small business impacts and to persuade agencies to afford relief to small businesses.¹⁸ The 2004 comprehensive report contains four main sections. Section one provides a brief overview of the RFA, as amended by SBREFA. Section two details the role of Advocacy. This section also breaks down Advocacy activities in Fiscal Year 2003. Section three provides a snapshot of several of the rulemakings in which Advocacy effectively represented the interests of small entities. Section four of this report provides a brief overview and update on the report submitted to OMB on agency compliance with E.O. 13272 for Fiscal Year 2003. Please visit Advocacy's website at <http://www.sba.gov/advo> to learn more about Advocacy, review regulatory comment letters, and obtain useful research relevant to small entities.

Impact on Wages

The impact of Federal regulations on wages depends upon how “wages” are defined and on the types of regulations involved. If we define “wages” narrowly as workers’ take-home pay, social regulation usually decreases average wage rates, while economic regulation often increases them, especially for specific groups of workers. If we define “wages” more broadly as the real value or utility of workers’ income, the directions of the effects of the two types of regulation can sometimes be reversed.

1. Social Regulation

Social regulation—defined as rules designed to improve health, safety, and the environment—creates benefits for workers, consumers, and the public. Compliance costs, however, must be paid for by some combination of workers, business owners, and/or consumers through adjustments in wages, profits, and/or prices. This effect is most clearly recognized for occupational health and safety standards. As one leading textbook in labor economics suggests: “Thus, whether in the form of smaller wage increases, more difficult working conditions, or inability to obtain or retain one’s first choice in a job, the costs of compliance with health standards will fall on employees.”¹⁹

¹⁸Office of Advocacy, U.S. Small Business Administration 2004. *Report on the Regulatory Flexibility Act, FY 2003: The Annual Report of the Chief Counsel for Advocacy on Implementation of the Regulatory Flexibility Act and Executive Order 13272*. Available at: <http://www.sba.gov>.

¹⁹From Ehrenberg, R. and R. Smith 1991. *Modern Labor Economics*, 4th Edition. HarperCollins, p. 279.

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In the occupational health standards case, where the benefits of regulation accrue mostly to workers, workers are likely to be better off if health benefits exceed compliance costs and such costs are not borne primarily by workers.²⁰ Although wages may reflect the cost of compliance with health and safety rules, the job safety and other benefits of such regulation can compensate for the monetary loss. Workers, as consumers benefiting from safer products and a cleaner environment, may also come out ahead if regulation produces significant net benefits for society.

2. Economic Regulation

For economic regulation, defined as rules designed to set prices or conditions of entry for specific sectors, the effects on wages may be positive or negative. Economic regulation can result in increases in income (narrowly defined) for workers in the industries targeted by the regulation, but decreases in broader measures of income based on utility or overall welfare, especially for workers in general. Economic regulation is often used to protect industries and their workers from competition. These wage gains come at a cost in inefficiency from reduced competition, a cost which consumers must bear. Workers wages do not go as far when prices for goods that are inefficiently produced are relatively higher. Moreover, growth in real wages, which are limited generally by productivity increases, will not grow as fast without the stimulation of outside competition.²¹

These statements are generalizations of the impact of regulation in the aggregate or by broad categories. Specific regulations can increase or decrease the overall level of benefits accruing to workers depending upon the actual circumstances and whether net benefits are produced.

Economic Growth and Related Macroeconomic Indicators

The strongest evidence of the impact of smart regulation on economic growth is the differences in per capita income growth and other indicators of well being experienced by countries under different regulatory systems. A well-known example is the comparison of the growth experience of the present and former Communist state-controlled economies with the more market-oriented economies of the West and Pacific Rim. State-controlled economies may initially have had growth advantages because of their emphasis on investment in capital and infrastructure but, as technology became more complex and innovation a more important driver of growth, the state-directed economies fell behind the more dynamic and flexible market-oriented economies. Less well known are the significant differences in growth rates and indicators of well being, perhaps for the same reasons, seen among economies with smaller

²⁰Based on a cost benefit analysis of OSHA's 1972 Asbestos regulation by Settle (1975), which found large net benefits, Ehrenberg and Smith cite this regulation as a case where workers' wages were reduced, but they were made better off because of improved health (p. 281).

²¹Winston (1998) estimates that real operating costs declined 25 to 75 percent in the sectors that were deregulated over the last 20 years—transportation, energy, and telecommunications. See Winston, C. (1998), "U.S. Industry Adjustment to Economic Deregulation", *Journal of Economic Perspectives* 12(3): 89-110.

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differences in the degree of government control and the quality of regulation.²²

Several groups of researchers have developed indicators of economic freedom to rank countries and compare their economic performance. Since 1995, the Heritage Foundation and the *Wall Street Journal* have published jointly a yearly index of economic freedom for 161 countries. They find a very strong relationship between the index and per capita GDP.²³ The index, based mostly on subjective assessments by in-house experts, is composed of 50 independent variables divided into 10 broad factors that attempt to measure different aspects of economic freedom: trade policy, fiscal burden, government intervention, property rights, banking and finance, wages and prices, regulation, and informal market activity. A correlation between degrees of economic freedom and per capita GDP does not prove that economic freedom causes economic growth. Economic growth could cause economic freedom or both could be correlated with an unknown third factor. More suggestive is the data on changes in these indicators. The authors examine the relationship between the change in the index since 1995 and the average GDP growth rate over seven years. After grouping the 142 countries (for which they had complete data) into quintiles, they find a very strong association between improvement in the index and growth rates. The first quintile of countries grew at a rate of 4.9% per year, almost twice the 2.5% growth rate of the fifth quintile.

Since 1997, the Fraser Institute of Vancouver, B.C. has published the Economic Freedom of the World index for 123 countries.²⁴ The rank of the top ten economies is Hong Kong (1), Singapore (2), New Zealand, Switzerland, the United Kingdom, and the United States (3), Australia and Canada (7), and Ireland and Luxembourg (9). The index, which is based on 38 variables, many of them from surveys published by other institutions, measures five major concepts: size of government, legal structure and security of property rights, access to sound money, freedom of exchange with foreigners, and regulation of credit, labor, and business. The latest report finds that the index is highly correlated not just with per capita income and economic growth, but with other measures of well being, including life expectancy, the income level of the poorest 10%, adult literacy, corruption-free governance, civil liberties, the United Nations' Human Development Index, infant survival rates, and the absence of child labor. Economic growth does not appear to come at the expense of these other measures of well being. This is reassuring because GDP and other economic measures do not capture all the costs and benefits produced by regulation.

Although these statistical associations provide broad support for the claim that excessive and poorly designed regulation reduces economic growth and other indicators of well being, they have several drawbacks. First, the data are based largely on subjective assessments and survey results. In addition, they include non-regulatory indicators as well as indicators of direct regulatory interventions, such as measures of fiscal burden and soundness of monetary policy.

²²A new discipline has developed to examine these differences. See S. Djankov, E. Glaeser, R. La Porta, F. Lopez-de-Salinas, and A. Shleifer, "The New Comparative Economics," *Journal of Comparative Economics* (December, 2003) Vol. 31.4, pp 595-619.

²³Marc A. Miles, Edwin J. Feulner, Jr., Mary Anastasia O'Grady, and Ana I. Eiras, *2004 Index of Economic Freedom*. (Heritage Foundation/WallStreet Journal).

²⁴James Gwartney and Robert Lawson, *Economic Freedom of the World: 2004 Annual Report*. Fraser Institute, Vancouver, BC.

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In an attempt to provide less subjective measures of regulatory quality, the World Bank recently began a multi-year project to catalogue international differences in the scope and manner of regulations based on objective measures of regulatory burden – such as the number of procedures required to register a new business and the time and costs of registering a new business, enforce a contract, or go through bankruptcy. The first volume (*Doing Business in 2004, Understanding Regulation*) of the annual series examines for 130 countries five fundamental aspects of a firm's life cycle: starting a business, hiring and firing workers, enforcing contracts, obtaining credit, and closing a business.²⁵ The second volume (*Doing Business in 2005, Removing Obstacles to Growth*) updates these measures and adds data about registering property and protecting investors.²⁶ The third volume (*Doing Business in 2006, Creating Jobs*) updates the previous measures, expands the number of countries to 155, and adds three more sets of indicators: dealing with licenses, paying taxes, and trading across borders.²⁷ The first volume contained three major conclusions:

- Regulation varies widely around the world;
- Heavier regulation of business activity generally brings bad outcomes, while clearly defined and well-protected property rights enhance prosperity; and
- Rich countries regulate business in a consistent manner. Poor countries do not.

The second volume added three more main findings:

- Businesses in poor countries face much larger regulatory burdens than those in rich countries.
- Heavy regulation and weak property rights exclude the poor from doing business.
- The payoffs from reform appear large.

The third volume added a new conclusion that better performance on the ease of doing business is associated with more jobs.

The World Bank also finds that rich countries regulate less in all respects covered in the report and that common law and Nordic countries regulate less than countries whose legal systems are based on socialist principles. The top ten countries ranked on the ease of doing business based on the ten indicators are in order: New Zealand, Singapore, the United States, Canada, Norway, Australia, Hong Kong (China), Denmark, the United Kingdom, and Japan.²⁸

Like the studies based on broader and more subjective indicators, the World Bank study finds that both labor productivity and employment are positively correlated with less regulation. The World Bank study also finds that heavier regulation is associated with greater inefficiency of public institutions and more corruption. The result is that regulation often has a perverse effect on the people it is meant to protect. Overly stringent regulation of business creates strong

²⁵World Bank. *Doing Business in 2004: Understanding Regulation*. Oxford Press. Washington, DC.

²⁶World Bank. *Doing Business in 2005: Removing Obstacles to Growth*. Oxford Press. Washington, DC.

²⁷World Bank. *Doing Business in 2006: Creating Jobs*. Washington, DC.

²⁸See *Doing Business in 2006*, p. 3. There is a high degree of association between this ranking, which is based on objective measures, and the ranking from the Gwartney and Lawson study, which was based on subjective assessments.

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incentives for businesses to operate in the underground or informal economy. The study cites the example of Bolivia, one of the most heavily regulated economies in the world, where an estimated 82% of business activity takes place in the informal sector. The study also found that women's share of private sector employment was also correlated with less rigid regulation of labor markets.

Third, the study finds that rich countries tend to regulate consistently across the five indicators, as measured by the statistical significance of their 15 cross correlations compared to the cross correlations of poor countries. The World Bank suggests that poor countries have made some progress in some reform areas but not others and that this finding suggests some optimism that these reforms may spread. The study estimates that if the countries in the bottom three quartiles were able to move up to the top quartile in the "doing business" indicator rankings, they would be able to realize a 2% increase in annual economic growth.

Based on its analysis of the impact of regulation on economic performance, the World Bank concludes that countries that have performed well have five common elements to their approach to regulation:

1. Simplify and deregulate in competitive markets.
2. Focus on enhancing property rights.
3. Expand the use of technology.
4. Reduce court involvement in business matters.
5. Make reform a continuous process.

It is interesting to note that these principles correspond fairly closely to the principles of regulatory reform that the U.S. has attempted to follow over the last 25 years.²⁹

The strong relationship between excess regulation and economic performance persists even when the sample of countries is confined to the 30 mostly high-income democracies in the Organization for Economic Cooperation and Development (OECD). The OECD also has underway major work on this subject. A recent report by Giuseppe Nicoletti summarizes the findings of the OECD work as follows:

"The empirical results suggest that regulatory reforms have positive effects not only in product markets, where they tend to increase investment, innovation and productivity, but also for employment rates."³⁰

²⁹For a description of the United States' regulatory reform program, see Executive Order 12291, Federal Regulation, (February 17, 1981), Executive Order 12866, Regulatory Planning and Review, (September 30, 1993) and Chapter 1 of *Stimulating Smarter Regulation: 2002 Report to Congress on the Costs and Benefits of Regulations and Unfunded Mandates on State, Local, and Tribal Entities*. Office of Management and Budget and OMB Circular A-4, Regulatory Analysis, reproduced as Appendix D in *Informing Regulatory Decisions: 2003 Report to Congress on the Costs and Benefits of Regulations and Unfunded Mandates on State, Local, and Tribal Entities*, Office of Management and Budget.

³⁰Giuseppe Nicoletti, "The Economy-Wide Effects of Product Market Reform". (OECD. Paris, December 2003). Also see Nicoletti and Stefano Scarpetta, "Regulation, Productivity, and Growth: OECD Evidence," World Bank Policy Research Paper 2944 (January 2003).

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According to the OECD's database of objective measures assembled in 2001, the OECD countries with least restrictive regulation in order are: the United States, the United Kingdom, Canada, Ireland, and New Zealand and the five with the most restrictive regulation in order are: Portugal, Greece, Italy, Spain, and France.³¹ One of the most interesting findings of the OECD work is that the least regulated countries tended to show the greatest improvement in their rates of multifactor productivity growth over the 1990s compared to the 1980s. Those countries also tended to show both the largest increase in the number of new small and medium-sized firms and in the rate of investment in research and development in manufacturing. These factors are thought to be important in increasing the growth rate of productivity and per capita income.

The major efforts to determine the effect of regulatory policies on economic performance described all use quite different indicators of regulatory quality and include different types of regulation, yet reach very similar conclusions. Nicoletti and Pryor examined three different indices of regulation, one objectively estimated and two based on subjective surveys of businessmen; one that just examined product markets, one that examined product and labor markets and one that includes financial and environmental regulations. The paper found statistically significant correlations among the three indices despite the differences in coverage and methodologies.³² A second group of researchers, who have done work for the World Bank, also finds a strong correlation between regulation of entry into markets and the regulation of labor. They attribute this to their finding that the legal origin of regulation explains regulatory style. As they put it ... "countries have regulatory styles that are pervasive across activities and shaped by the origin of their laws."³³ Thus, countries with good records on entry regulation (which they point out includes some environmental regulation) also have good records on labor regulation.³⁴

A more recent body of literature, which combines the data sets of regulatory indicators discussed above as well as others, provides additional support to the supposition that excess regulation tends to reduce growth. Several papers by Loayza, Oviedo, and Servén use instrumental variable techniques to isolate the exogenous variation in regulation and determine the causal impact of regulation on economic growth, thereby reducing the reverse causality problem discussed above.³⁵ These studies also find that when the quality of regulation as measured by indicators of better governance (such as democratic accountability and absence of corruption) increases, the regulatory burden effect is smaller. These studies also find that both the volatility of economic growth and the size of the informal sector increase with regulation.

This pattern of findings provides strong support for policies that pursue "Smarter" or

³¹See Giuseppe Nicoletti and Frederic Pryor, "Subjective and Objective Measures of the Extent of Government Regulation," *Journal of Economic Behavior and Organization* (forthcoming), Table 3.

³²*Ibid.*

³³Juan Botero, Simeon Djankov, Rafael La Porta, Florencio Lopez-de-Salinas, and Andrei Shleifer, "The Regulation of Labor," *The Quarterly Journal Of Economics* (2004).

³⁴*Ibid.*

³⁵Norma Loayza, Ana Maria Oveido, Luis Seven, "Regulation and Macroeconomic Performance," World Bank Policy Research Paper No. 3469 (2005) and Norma Loayza, Ana Maria Oveido, Luis Seven. "The Impact of Regulation on Growth and Informality: Cross-Country Evidence" AEI-Brookings Joint Center (May 2005).

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“Better” regulation³⁶ -- whether the country is a high-income OECD country or a developing country. The results are also consistent with economic theory, which predicts that economic growth is enhanced by regulatory policies that promote competitive markets, secure property rights, and intervene to correct market failures rather than to increase state influence.³⁷

The World Bank measures of regulation, in particular, are weighted toward economic policy, although the recent inclusion of licensing requirements in *Doing Business 2006* reduces that tendency. The ease of getting construction permits, which are mainly justified as safety measures, is used as the regulatory indicator. It is important to point out that these findings likely hold for social as well as economic regulation.³⁸ Both types of regulation, if poorly designed, harm economic growth as well as the social benefits that follow from economic growth. Our regulatory analysis guidelines (OMB Circular A-4) have a presumption against price and entry controls in competitive markets and thus deregulation is often appropriate.³⁹ For social regulation, Circular A-4 requires an analysis of the costs and benefits of regulations and their alternatives. In this case, smarter regulation may cause rules that are more stringent, less stringent, or just better designed to be more cost-effective. Regulation that utilizes performance standards rather than design standards or uses market-oriented approaches rather than direct controls is often more cost-effective because it enlists competitive pressures for social purposes. Social regulation often clarifies or defines property rights so that market efficiency is enhanced. Regulation that is based on solid economic analysis and sound science is also more likely to provide greater benefits to society at less cost than regulation that is not.⁴⁰ Thus a smarter or better regulation program relies on sound analysis and utilizes competition to improve economic growth and individual well-being in similar ways for both economic and social regulation. It is not surprising that countries that do well with one type of regulation tend to do well with the other. Nevertheless, more research is needed to determine how different types of regulation (e.g., economic versus social rules or product market versus labor market regulations) influence economic growth and well being.

³⁶The US uses the term “Smarter Regulation” and the UK, Canada, Ireland and the EU all use the term “Better Regulation” to describe their reform programs.

³⁷See S. Djankov, E. Glaeser, R. La Porta, F. Lopez-de-Salinas, and A. Shleifer, “The New Comparative Economics,” *Journal of Comparative Economics* (December, 2003) Vol. 31.4, pp 595-619.

³⁸Note that there is no bright line between economic and social regulation. Social regulation often establishes entry barriers and protects the status quo through the use of stringent requirements for new plants, products, or labor. Perhaps for this reason researchers are now using the term product market and labor market regulation to describe the different types of regulation.

³⁹Although many of the rules reviewed by OMB are social regulation, OMB also reviews many economic regulations and many social regulations have economic components. For example, OMB recently reviewed a series of rules that deregulated the computer reservation system used by travel agents and airlines due to changes in the market structure and technology. OMB also reviews labor, housing, pension, agricultural, energy, and some financial regulations, which also may be viewed as economic regulation.

⁴⁰The benefits of such a regulatory program will not show up just as an increase in measured GDP but will also show up as improvements in health, safety, and the environment. First, the regulations are designed to provide such public goods in the most cost-effective way, and second, the higher economic growth provided by a well-run regulatory reform program will increase the demand for, and the ability of the economy to supply, such public goods.

CHAPTER II: TRENDS IN BENEFIT AND COST ESTIMATES

Since OMB began to compile records in 1981 until the end of 2005, Federal agencies have published 118,375 final rules in the *Federal Register*. Of these final rules, 20,928 were reviewed by OMB under Executive Order procedures. Of these OMB-reviewed rules, 1,164 were considered "major" rules, primarily due to their anticipated impact on the economy (e.g., estimated costs and/or benefits were in excess of \$100 million annually). As discussed in Chapter I, many major rules implement budgetary programs and involve transfers from taxpayers to program beneficiaries. Since 1981, OMB has reviewed 249 major rules with estimated costs and/or benefits to the private sector or State and local governments of over \$100 million annually.

Last year's Report presented some preliminary estimates of the overall costs of major rules issued by Federal agencies from 1981 to 2004. The estimates are based on the *ex ante* cost estimates found in agency regulatory impact analyses reviewed by OMB under EO 12291 prior to September 1993 and EO 12866 since then. The Report pointed out some of the concerns we had with these estimates, including the concern that, because they are prospective, they might not present an accurate picture of these regulations' actual impacts. Chapter III of last year's Report surveys what we know about the validation of *ex ante* estimates of costs and benefits of Federal regulation by *ex post* studies.

Last year's Report also suggested that a theoretically superior measure of the overall value of regulation would be net benefits; that is, benefits to society minus costs to society. We said we would explore the feasibility of constructing such a measure. Below we present cost and benefit measures for the years 1992 to 2005 for 124 rules, for which reasonably complete monetized estimates of both costs and benefits were available. In addition, we extend the cost estimates back to 1981, the beginning of the regulatory review program at OMB, and include regulations with cost but not benefit estimates.⁴¹

In exploring the impact of rulemaking on the economy in the early 1980's, we found that several important de-regulatory actions resulted in a net decrease in compliance costs in the first two years of the Reagan Administration. We include the net cost savings generated by these regulations as "negative costs" for those years. To be consistent, we have also modified our estimates for later years to include regulatory actions that reduced net costs. In 2004, DOT issued two regulations that resulted in net cost savings: one rule reduced minimum vertical separation for airspace and the second increased competition in the computer reservation system for airline travel. In addition, OSHA's ergonomics rule issued November 14, 2000 but repealed by Senate Joint Resolution No. 6 passed by Congress and signed by the President in March 2001 (Pub. L. No. 107-5) is recorded as a \$4.8 billion cost addition in 2000 and a \$4.8 billion cost savings in 2001. This approach is consistent with treatment for earlier years. Another important change is the inclusion of DOT's 1993 air bag rule, which had been left out of our calculations in

⁴¹To present cost and benefit estimates by year, we generally used agency estimates of central tendency when available and took midpoints when not available.

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1993 because Congress had mandated the rule.⁴² We made this change to be consistent with OMB Circular A-4, Regulatory Analysis, issued September 2003. The Circular states that in situations where a rule simply restates statutory requirements, incremental costs and benefits should be measured relative to the pre-statute baseline.

Finally, EPA adopted significantly more stringent National Ambient Air Quality Standards (NAAQS) for ozone and fine particulate matter (PM) in 1997. At that time, EPA estimated that the actions necessary to meet the revised standards would yield benefits ranging from \$20 to \$120 billion per year and would impose costs of \$10 to \$22 billion per year. In the five years following the promulgation of the 1997 ozone and fine PM NAAQS, EPA adopted several key rules that will achieve emission reductions and impose costs that account for a major portion of the benefit and cost estimates associated with the NAAQS rules. Thus, to prevent double-counting, we noted in our 2002 Report that in developing aggregate estimates of regulatory benefits and costs we had decided to exclude the estimates for the 1997 revisions of the ozone and fine PM NAAQS and use instead the estimates associated with the several "implementing" rules promulgated in subsequent years. Although the pattern of benefits and costs of the rules presented below is affected by the decision to focus on the implementing rules, we believe these cost and benefit estimates provide a better measure of the actual impacts and timing of those impacts.

Figure 2-1 presents the cost estimates from January 20, 1981 through September 30, 2005. Over the last 25 years, \$123 billion of annual regulatory costs (2001 dollars) have been added by the major regulations issued by the executive branch agencies and reviewed by OMB. This means that, on average, almost \$5 billion in annual costs have been added each year over this period. Several patterns are present. Note, in particular, the tendency for regulatory costs to be highest in the last year before a President leaves office (1988, 1992, and 2000). Note also that the annual average increase in regulatory costs in this Administration is lower than in any of the three previous Administrations. The average annual costs of the regulations issued during this Administration were 54 percent lower than the average annual costs of the regulations issued during the previous 20 years, and 64 percent lower than those issued during the previous eight years.

⁴²Our estimate of \$4 billion in annual benefits and \$3 billion in annual costs reflects the assumption that without the rule, 50 percent of the costs and benefits of airbags would have been provided by the market.

Figure 2-1: Costs of Major Rules (1981-2005)

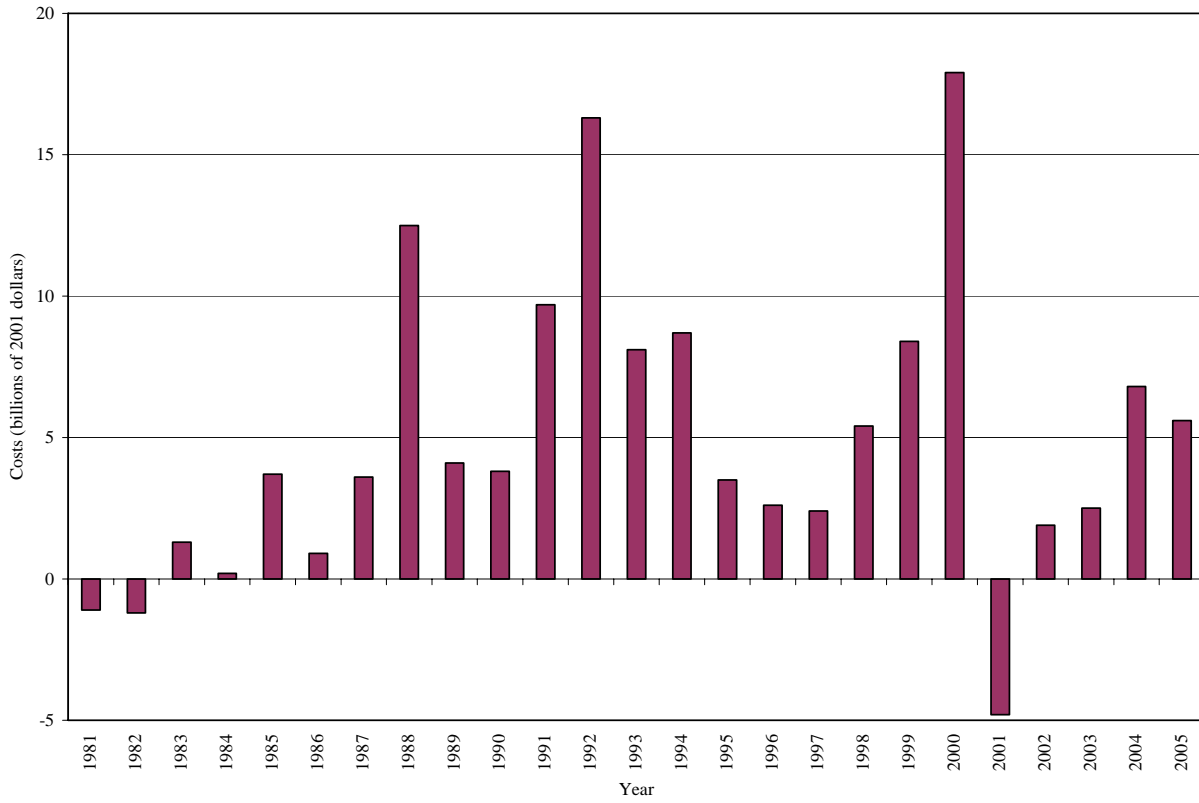
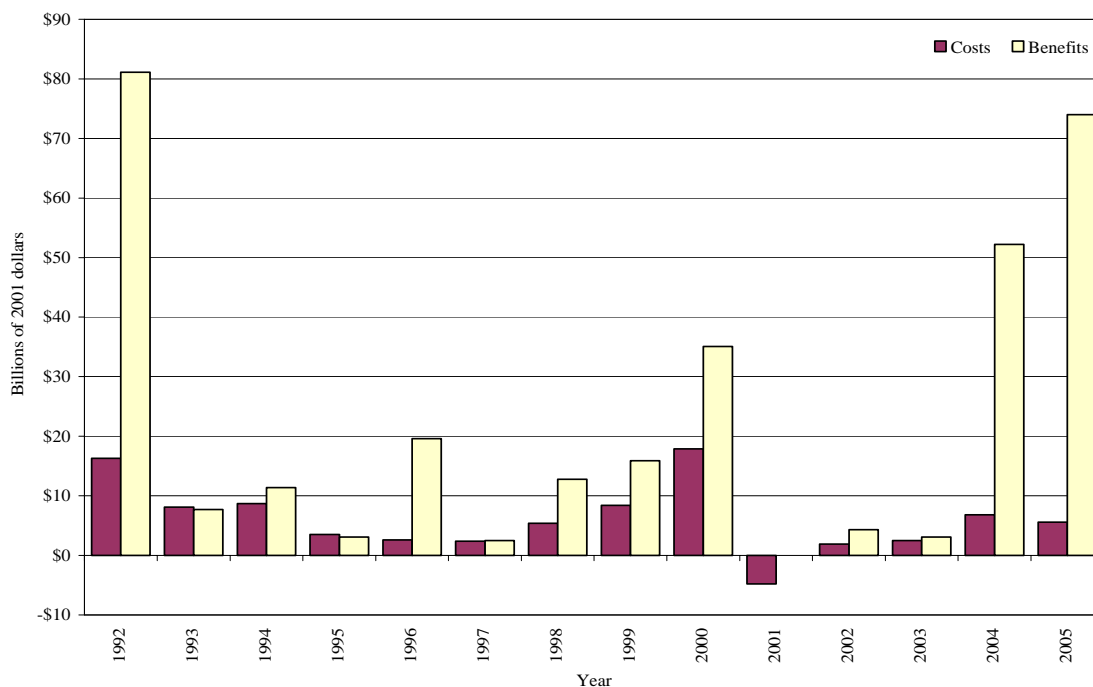


Figure 2-2 shows the costs and benefits of major rules issued from October 1, 1992 to September 30, 2005. Benefit estimates for the rules (with two noted exceptions)⁴³ that comprise the overall estimates are presented in various tables in the eight annual reports (including this draft report) that OMB has completed. Note that the three highest years for benefits, 1992, 2004, and 2005 are mostly explained by three EPA regulations, the 1992 acid rain permits regulation and the 2004 non-road diesel engine rule, and the 2005 interstate air quality rule. Since more major rules had cost estimates than benefit estimates, it is likely that benefit estimates are understated relative to the cost estimates included in Figure 2. The figure also shows that, during its first 56 months in office, this Administration has issued regulations with average yearly benefits 112 percent greater than the average annual benefits of the rules issued during the previous eight years.

⁴³The two exceptions, as discussed above, are NHTSA’s 1993 airbag rule and OSHA’s 2000 ergonomics rule. We did not include benefit estimates for the ergonomics rule because of the speculative nature of the estimates and the difficulty of determining the cause and/or mitigation of the great majority of ergonomic injuries. After the rule was overturned under provisions of the Congressional Review Act, the number of muscular skeletal disorders (MSDs) declined significantly more than OSHA’s RIA predicted would occur under the standard. The RIA estimated that MSDs would decline from 647,344 to 517,344 after 10 years of compliance. Instead, three years after the standard (which had never gone into effect) had been overturned, MSDs declined to 435,180 in 2003 (the last year for which data is available). The reason that voluntary actions to reduce MSDs are effective may be that employers and employees alike have strong incentives, due to worker’s compensation costs and loss productivity, to reduce the incidence of MSDs.

Figure 2-2: Costs and Benefits of Major Rules (1992-2005)



The difference between cost and benefits shows the net benefits of major regulations from 1992 through September 2005. We were unable to go back beyond 1992 because of a lack of comparable data on benefits. Note that again the two end years dominate. The figure also shows that in no year were costs significantly greater than benefits, even though benefits are likely understated relative to the cost estimates since some rules had estimated costs but not estimated benefits.⁴⁴ Figure 2-2 also shows that this Administration issued regulations with net benefits over its first 56 months at a yearly average rate that is 280 percent greater than the rate of net benefits produced by the regulations issued during the previous Administration.

However, we wish to emphasize that (1) these estimates are preliminary (2) as discussed in other sections of this Report (see Appendices A and B) as well as previous Reports, the aggregate estimates of costs and benefits derived from different agency's estimates and over different time periods are subject to methodological inconsistencies and differing assumptions, and (3) the groundwork for the regulations issued by one administration are often begun in a previous administration.⁴⁵

⁴⁴In 1993 and 1995, costs exceeded benefits by about \$400 million in each year.

⁴⁵For example, FDA's trans fat rule was proposed by the previous Administration and issued by the Bush Administration while the groundwork for EPA's 2004 non-road diesel engine rule was set by the NAAQS rules issued in 1997. Moreover, Congress and the Judiciary also play a role in the timing and outcomes of regulations.

CHAPTER III: INTERNATIONAL DEVELOPMENTS IN REGULATORY POLICY

OMB has been involved in several collaborate efforts with other countries and international organizations to promote regulatory reform and reduce regulatory barriers to trade. As discussed in Chapter I, research has demonstrated a strong relationship between high quality regulation and economic growth. U.S. efforts to encourage other countries to adopt sound regulatory practices therefore serve to develop overseas markets for U.S. manufacturers, and ultimately raise living standards for Americans.

It is important to note that efforts to facilitate international trade and harmonize regulation are done in a manner that respects national sovereignty. As has been noted by the United States Trade Representative (USTR), none of the provisions in the World Trade Organization (WTO) agreements, North American Free Trade Agreement (NAFTA), or other Free Trade Agreements restricts the authority of the United States to enact or enforce domestic laws and regulations that protect American businesses, State, local, and tribal governments, consumers, public health and safety, and the environment. Rather, all of these agreements call on governments to ensure that the standards that they develop are non-discriminatory, transparent, and not unnecessarily trade restrictive.

This chapter of the 2006 Annual Report to Congress on the Costs and Benefits of Federal Regulations provides an update on recent developments in international regulatory cooperation. While the U.S. has embarked on several cooperative initiatives with a number of trading partners—including a new initiative to promote greater regulatory cooperation between Canada, Mexico, and the U.S.—this chapter focuses on U.S. cooperative activities with the European Union (EU). U.S. and EU efforts to increase transatlantic regulatory cooperation are based on a mutual recognition that most remaining transatlantic trade barriers are due primarily to regulatory differences, not to tariffs.

The rationale for promoting transatlantic trade through greater regulatory cooperation is clear. The U.S.-EU bilateral trade and investment relationship is the largest in the world, with approximately 14 million jobs in the U.S. and EU depending on transatlantic commerce.⁴⁶ Mutual understanding of the central importance of this bilateral trade relationship led to a 2002 agreement on U.S.-EU Guidelines on Regulatory Cooperation and Transparency, which set the stage for subsequent initiatives to facilitate transatlantic trade through the easing of regulatory barriers.

Moreover, the timing for greater transatlantic regulatory cooperation is good, as there is now strong political support in Europe for regulatory reform. The EU's executive authority, the European Commission (EC), is pursuing a robust "Better Regulation" agenda under the leadership of Commission President José Manuel Barroso. A key objective of this agenda is simplifying EU legislation and subjecting new legislative proposals to impact assessments.

⁴⁶European Commission Communication, "A stronger EU-US Partnership and a more open market for the 21st century," COM(2005) 196, May 18, 2005, p. 5.
http://europa.eu.int/comm/external_relations/us/revamping/com2005_196_en.pdf

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The EC's interest in better regulation was underscored in June 2005 when the EC issued updated guidelines on conducting impact assessments of Commission regulatory proposals. The guidelines were revised to ensure that EC policymakers consider policy options other than "classical" forms of regulation, and they emphasized the principles of subsidiarity (determining whether EU regulation is more appropriate than regulation by member states) and proportionality (limiting regulation to what is necessary to achieve policy objectives). In announcing the new guidelines, President Barroso said, "This Commission is serious about cutting-red tape and reducing unnecessary regulation." Commission Vice President Günter Verheugen added, "Better impact assessments will bring more coherence and quality and self-restraint to the Commission's work. We want to be able to say what our proposals mean in practice to have a sound basis for policymakers." This chapter provides a brief description of regulatory cooperation between the EU and the U.S., and a comparison of the EC's guidelines and OMB's guidance to agencies on regulatory impact analysis.

A. Regulatory Cooperation Between the U.S. and European Union

Recent U.S.-EU Summits have underscored the strong transatlantic commitment to improving regulatory cooperation between American and European Commission authorities. Stakeholders on both sides of the Atlantic have supported these efforts. Most recently, on June 20, 2005, the United States and EC issued the 2005 Roadmap for U.S.-EU Regulatory Cooperation and Transparency, as part of a broader Initiative to Enhance Transatlantic Economic Integration and Growth.⁴⁷ The 2005 Roadmap builds upon and expands existing U.S.-EU regulatory activities. Specifically, the 2005 Roadmap called for the

- creation of a senior-level dialogue on best regulatory policies and practices;
- identification of ways to facilitate exchanges of U.S. and EU regulatory experts; and
- expansion of successful sectoral initiatives.

The aims of the 2005 Roadmap are to promote better quality regulation, minimize regulatory differences, increase consumer confidence, and facilitate transatlantic commerce, all while respecting the regulatory autonomy of the U.S. and the EU. The Roadmap outlined a range of proposed cooperative initiatives that the United States and the European Commission intend to advance in 2005-06, including specific sectoral activities and horizontal initiatives to address cross-cutting matters.

Sectoral Initiatives

The 2005 Roadmap identified 15 sectors in which the U.S. and EU agreed to increase regulatory harmonization. These areas include pharmaceuticals, consumer product safety, nutritional labeling, food safety, chemicals, energy efficiency, telecommunications, and medical devices.

⁴⁷For detailed information about 2005 Roadmap, go to:
http://www.ustr.gov/World_Regions/Europe_Middle_East/Europe/US_EU_Regulatory_Cooperation/2005_Roadmap_for_EU-US_Regulatory_Cooperation_Transparency.html

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Another sector, automobile safety regulation, is the focus of collaboration between the Department of Transportation's National Highway Traffic Safety Administration (NHTSA) and the EC's Directorate General (DG) for Enterprise and Industry/Automobile Unit. The initiative on automobile safety builds on an existing regulatory dialogue between NHTSA and DG Enterprise that was established in June 2003. This dialogue has addressed a number of topics, including regulatory cooperation on the safety of hydrogen fuel cell vehicles and vehicle compatibility. Moving forward, NHTSA and DG Enterprise will develop workplans for these regulatory cooperation projects. In addition, they have agreed to explore other areas of possible cooperation, such as collision mitigation technologies, electronic stability systems, and international harmonization of dummies used in side-impact vehicle crash tests. Box 2-1 provides background on related efforts by NHTSA and DG Enterprise to promote a science-based approach to global technical regulations (GTRs) under the 1998 United Nations Economic Commission for Europe (UN/ECE) Global Agreement on Vehicle Regulation.

Box 2-1: 1998 Global Agreement on Vehicle Regulation⁴⁸

The purpose of the 1998 Agreement is improved safety, environmental protection, energy efficiency and anti-theft performance. The Agreement seeks to ensure that the working parties develop and adopt as GTRs only those regulations whose requirements, test conditions and test procedures contribute to achieving those goals. Similarly, the Agreement requires the working groups recommending new GTRs to submit written reports demonstrating that they have considered technical feasibility and economic feasibility; examined benefits, including those of any alternative regulatory requirements and approaches considered; and compared potential cost effectiveness of the recommended regulation to that of the alternative regulatory requirements and approaches considered.

The first GTR established under the Agreement demonstrated that U.S./EU regulatory cooperation provides for increased safety and for harmonized standards, which are science-based and free of unjustified requirements. If adopted into domestic law by the U.S. and EU, the GTR on door locks and door retention systems would essentially eliminate the differences between the U.S. and EU standards for reducing the likelihood that a vehicle's doors will open in a crash, thus allowing the ejection of the vehicle's occupants. Further, the GTR replaced some existing tests in the U.S. and EU standards with more effective ones, added some new tests and eliminated some outdated ones. Adopting amendments based on the GTR will not only result in improvements to the U.S. standard, but also to the EU standard. This will also benefit other countries since the EU standard is the United Nations' Economic Commission for Europe regulation (ECE R.11), which is used by the majority of the world community. In addition to the sliding door test procedure, the rear-hinged side door requirements, and the inertial test procedure that are discussed above, ECE R. 11, when amended per the GTR, will benefit from the inclusion of back door requirements and rear door locking requirements. Both NHTSA and the European Commission initiated their internal rulemaking processes to adopt this GTR into law.

The establishment of the first GTR also demonstrated that the rulemaking process outlined in the 1998 Agreement works and could be used as an example for other sectors. Other global technical regulations are on the horizon. In the next two years, NHTSA expects to continue working with the European Community and other governments on the establishment of other global regulations in the area of head restraints, motorcycle brakes, and glazing.

⁴⁸The full text of the agreement is available at:
<http://www.unece.org/trans/main/wp29/wp29wgs/wp29gen/wp29glob/globale.pdf>

Horizontal Initiatives

In the Annex to the June 2005 Initiative to Enhance Transatlantic Economic Integration and Growth, U.S. and EU leaders agreed to establish a senior-level dialogue on best regulatory policies and practices and identify resources and mechanisms for exchanges of U.S. and EU regulatory experts. These horizontal, cross-cutting initiatives include general exchanges of information about approaches to regulation in the U.S. and in the EU and discussion of cross-cutting matters of regulatory practice, including comparisons of how regulatory impact assessments are conducted on both sides of the Atlantic.

OMB and EC officials began this dialogue in Washington, D.C., in September 2005, when OIRA hosted a three-day seminar attended by senior European Commission regulators. The seminar provided an overview of the U.S. regulatory process from the perspective of practitioners in OIRA, Federal regulatory agencies, and outside experts.

The U.S. and EC also agreed to launch a Regulatory Cooperation Forum in 2006. The EC-hosted the initial event in Brussels in January 2006, attended by OIRA Administrator John Graham, that focused on good regulatory practices. A second event, scheduled for spring 2006 in Washington, will address best cooperative practices and identify possible new areas for regulatory cooperation.

B. Preliminary Comparison of U.S. and EC Guidelines on Regulatory Analysis

Analysts from OMB and the European Commission have begun to study and compare the various procedures and guidelines that govern the regulatory process and regulatory analysis. The primary procedures for US regulatory analysis are found in OMB Circular A-4, which is available at <http://www.whitehouse.gov/omb/inforeg/regpol.html>, and the primary procedures for EC regulatory analysis—which is referred to as an impact assessment (IA)—can be found at http://europa.eu.int/comm/secretariat_general/impact/docs/SEC2005_791_IA%20guidelines_annexes.pdf. In both the U.S. and the European Union, however, many other guidelines and statutes govern how agencies analyze and issue regulations, thus any discussion that focuses on a direct comparison of two analytical documents is necessarily incomplete.

In this section we present a summary of the scope of the activities the two guidelines cover and how they interact with other requirements. The two guidelines also cover each key element of a regulatory analysis in considerable detail, including specifying a need for the regulation, identifying alternatives, analyzing the impact of a regulation and the alternatives, standards for cost-benefit analysis and cost-effectiveness analysis, appropriately considering uncertainty, the use of discount rates, and in the case of the EC guidelines a requirement for monitoring the impact of a regulatory program after it has been put in place.

In general, the EC guidelines are broader in scope than the U.S. guidelines in OMB Circular A-4. The Commission Impact Assessment (IA) guidelines state that an IA is needed for “items on the Commission’s Work Programme, which means all regulatory proposals, white papers, expenditure programmes and negotiating guidelines for international agreements (with

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economic, social or environmental impacts).”⁴⁹ In the U.S., regulatory analysis is required by Executive Order (E.O.) 12866 for all significant regulatory actions, and more elaborate analysis that complies with OMB Circular A-4 is required for all “economically significant” regulatory actions. Economic significance is defined primarily as a rule that has an impact on the economy (costs, benefits, or transfers) of greater than \$100 million in any one year. As explained in Chapter I of this Report, OMB believes that analysis is especially essential for economically significant rulemakings because the costs and benefits of economically significant, major rules capture the vast majority of the total costs and benefits of all rules subject to OMB review.

U.S. statutes are close in character to primary legislation in the EU. In both the U.S. and EU, these broad grants of statutory authority are implemented through “secondary legislation,” or what is referred to in the U.S. as regulation. A significant regulatory action in the U.S. is therefore probably closest in character to a piece of significant secondary legislation in the European Union.⁵⁰ Statutes often give agencies broad authority, while the details of the program itself will be set in a regulation, which when finalized has the force of law. In the EU process, the primary legislation itself is also subject to the impact assessment guidelines.

The difference in scope can also be explained by the various other U.S. laws requiring other types of analysis that in the EU would be covered by these EC guidelines. For example, the U.S. National Environmental Policy Act (NEPA; 42 U.S.C. §4321 et seq.) requires Federal agencies to consider the environmental impacts of their proposed actions and reasonable alternatives to those actions. To meet this requirement, Federal agencies prepare an Environmental Impact Statement (EIS). An analysis focusing on environmental impacts would likely be governed directly by the EC guidelines, but is not directly discussed in Circular A-4. Other examples are the U.S. Unfunded Mandates Reform Act (2 U.S.C. § 1501 note), which requires cost-benefit analysis (CBA) of all rules imposing expenditures on state or local governments or the private sector of greater than \$100 million a year (adjusted for inflation), and the Regulatory Flexibility Act (5 U.S.C. § 601 note), which requires an impact analysis for any rule expected to have a “significant impact on a substantial number of small businesses.”

Proportionality

A final reason for the narrower scope of OMB Circular A-4 may be what the EC guidelines call *proportionality*. This is the simple concept that the time and effort devoted to analysis should reflect the potential size or importance of the regulation. The \$100 million threshold for expanded regulatory analysis in Executive Order 12866 is an explicit proportionality test, as it tries to ensure that resources are directed to those rules that have the potential to more seriously affect the US economy. The principle of proportionate analysis applies to the Commission’s IAs; however, the EC guidelines do cover even the smaller analysis that would not be subject to Circular A-4. In practice, this may not be a substantive difference, as EO 12866 still requires agencies to consider the costs and benefits of regulatory actions that are significant but do not meet the definition of economically significant.

⁴⁹EC guidelines, p. 6.

⁵⁰Regulations in the U.S., however, often deal with wide ranging issues that may be more likely to be addressed in primary legislation in the EU.

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Even within economically significant rulemakings, Circular A-4 also asks agencies to ensure that there is a balance between thoroughness, particularly with regard to considering alternatives to regulation, and “the practical limits on your analytical capacity.”⁵¹ The obligation to quantify impacts, however, and to use both CBA and Cost Effectiveness Analysis (CEA), prescribes a minimum amount of analysis that is always required for economically significant rulemakings. There appears to be more discretion in the EC guidelines for choosing the level of proportionality.

C. Other International Initiatives

The rationale for transatlantic regulatory cooperation also applies to U.S. relationships with other key trading partners. Accordingly, the U.S. has undertaken initiatives with its North American neighbors and with the Asian Pacific Economic Cooperation (APEC) forum – an international organization created in 1989 to promote free trade and international cooperation among the Pacific Rim countries. In addition, work by the Organization for Economic Cooperation and Development (OECD) on regulatory reform has helped promote efforts to improve the quality of regulations throughout the world.

North American Security and Prosperity Partnership

On March 23, 2005, Canada, Mexico, and the U.S. announced the Security and Prosperity Partnership (SPP). The SPP is a trilateral effort to increase security and enhance prosperity among the three countries through improved cooperation and information-sharing. One of the SPP initiatives commits the three countries to develop a trilateral Regulatory Cooperation Framework by 2007. The three governments are currently working together on this important initiative. This work includes holding a seminar on North American regulatory cooperation in spring 2006.⁵²

APEC-OECD Integrated Checklist for Regulatory Reform

U.S. efforts within APEC have focused on the Integrated Checklist for Regulatory Reform. The Integrated Checklist is a self-assessment tool that reflects a holistic approach to regulatory reform, including regulatory, anti-trust, and market-openness policies.⁵³ The Checklist was the product of the APEC-OECD Cooperative Initiative on Regulatory Reform, a collaborative effort between APEC and the OECD. Following the endorsement of the Integrated Checklist at a June 2005 ministerial-level meeting held in Jeju Island, Korea, APEC has begun a dialogue on capacity building, which will include the voluntary use of the Integrated Checklist in country self-assessments.

⁵¹ Circular A-4, page 7.

⁵² Additional information on this and other SPP prosperity initiatives is available at: http://spp.gov/spp/report_to_leaders/prosperity_annex.pdf

⁵³ A copy of the Integrated Checklist is available at: http://www.apec.org/apec/documents_reports/economic_committee/2005.html

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OECD Work on Regulatory Management and Reform

The OECD is an international forum comprised of 30 market-oriented democracies that work together to promote sustainable economic growth by addressing economic, social, and governance challenges faced by member countries. OECD staff conducts research on topics of interest to OECD member countries, and representatives of member countries meet to exchange information in committees devoted to key issues.

One of these issues is regulatory management and reform. In 1995, OECD Ministers asked the OECD to assess the regulatory policies of member countries. The resulting 1995 Recommendations for Improving the Quality of Government Regulation were the first-ever internationally accepted statement of regulatory principles.⁵⁴ The OECD expanded its examination of regulatory policy to include market openness and anti-trust policy in a multidisciplinary framework—embodied in the 1997 Recommendations for Regulatory Reform—which it used to review reform efforts in member countries. To date, the OECD has conducted 20 country reviews, including the first review of a non-member country: Russia.

Based on the lessons learned from the country reviews and developments in member countries, in April 2005 the OECD adopted Guiding Principles for Regulatory Quality and Performance. While the 2005 principles reaffirmed the 1997 recommendations, several issues were given more prominence, including policy coherence through multi-level governmental coordination, ex ante impact assessments of regulatory policies, and market openness.

⁵⁴See “Stimulating Smarter Regulation: 2002 Report to Congress on the Costs and Benefits of Regulations,” p. 65. http://www.whitehouse.gov/omb/infoereg/2002_report_to_congress.pdf

APPENDIX A: CALCULATION OF BENEFITS AND COSTS

Chapter I presents estimates of the annual costs and benefits of selected major final regulations reviewed by OMB between October 1, 1995 and September 30, 2005. OMB presents more detailed explanation of these regulations in several documents.

- Rules from October 1, 1992 to September 30, 1995: Tables C-1 through C-3 in Appendix C of this Report.
- Rules from October 1, 1995 to March 31, 1999 can be found in Chapter IV of our 2000 Report.
- Rules from April 1, 1999 to September 30, 2001: Table 19 of the 2002 Report.
- Rules from October 1, 2001 to September 30, 2002: Table 19 of the 2003 Report.
- Rules from October 1, 2002 to September 30, 2003: Table 12 of the 2004 Report.
- Rules from October 1, 2003 to September 30, 2004: Tables 1-4 and A-1 of the 2005 Report.
- Rules from October 1, 2004 to September 30, 2005: Tables 1-4 and A-1 of this draft Report.

In assembling estimates of benefits and costs presented in Table 1-4, 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).

All benefit and cost estimates were adjusted to 2001 dollars using the latest GDP deflator, available from the Bureau of Economic Analysis at the Department of Commerce.⁵⁵ In instances where the nominal dollar values the agencies use for their benefits and costs is unclear, we assume the benefits and costs are presented in nominal dollar values of the year before the rule is finalized. In periods of low inflation such as the past few years, this assumption does not impact the overall totals. All amortizations are performed using a discount rate of 7%, unless the agency has already presented annualized, monetized results using a different explicit discount rate.

OMB discusses, in this Report and in previous reports, the difficulty of estimating and aggregating the costs and benefits of different regulations over long time periods and across many agencies. In addition, where OMB has monetized quantitative estimates where the agency has not done so, we have attempted to be faithful to the respective agency approaches. 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; however, the agencies have used different methodologies and valuations in quantifying and monetizing effects. Thus,

⁵⁵National Income and Product Accounts, available at <http://www.bea.gov>

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an aggregation involves the assemblage of benefit and cost estimates that are not strictly comparable.

In part to address this issue, the 2003 Report included OMB's new regulatory analysis guidance, also released as OMB Circular A-4, which took effect on January 1, 2004, for proposed rules and January 1, 2005 for final rules. The guidance recommends what OMB considers to be "best practice" in regulatory analysis, with a goal of strengthening the role of science, engineering, and economics in rulemaking. The overall goal of this guidance is a more competent and credible regulatory process and a more consistent regulatory environment. OMB expects that as more agencies adopt our recommended best practices, the costs and benefits we present in future reports will become more comparable across agencies and programs. The 2006 Report will be the first Report that includes final rules subject to OMB Circular A-4. OMB will work with the agencies to ensure that their impact analyses follow the new guidance.

Table A-1 below presents the unmodified information on the impacts of 21 major rules reviewed by OMB from October 1, 2004 through September 30, 2005, and includes additional explanatory text on how agencies calculated the impacts for these rulemakings. Unless otherwise stated, the totals presented in Table A-1 are annualized impacts in 2001 dollars, which is the requested format in OMB Circular A-4. Table 1-4 in Chapter 1 of this Report presents the adjusted impact estimates for the 11 rules finalized in 2004 that were added to the Chapter 1 accounting statement totals.

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Table A-1: Summary of Agency Estimates for Final Rules
 October 1, 2004 to September 30, 2005 (As of Date of Completion of OMB Review)

Rule [FR Cite]	Agency	Benefits	Costs	Other Information
Bovine Spongiform Encephalopathy: Minimal Risk Regions and Importation of Commodities [70 FR 460]	USDA-APHIS	\$572-\$620 million (7%) \$588-\$639 million (3%)	\$557-\$604 million (7%) \$574-\$623 million (3%)	<p>Benefits: According to an agricultural multi-sector analysis, the rule will result in a decline in consumer expenditures for beef in 2005 of about 1%.</p> <p>Costs: According to an agricultural multi-sector analysis, the rule will result in a decline in gross revenues in 2005 for the combined livestock, feed, and grain sectors of 1.4% to 1.7%.</p> <p>Other Details: Both benefits and costs were annualized over 5 years. Sensitivity analyses were conducted of near-term price effects based on smaller elasticities, and of welfare effects based on imports of one-half the backlog and one-half the assumed number of fed cattle displaced from Canadian slaughter.</p> <p>Note that these impacts are technically economic transfers from domestic producers to domestic consumers and foreign producers. According to circular A-4, however, impact analysis should be performed from the U.S. perspective. Therefore, for the purposes of this Report, transfers from the U.S. are considered costs, and transfers from other nations to the U.S. are considered benefits.</p> <p>The full RIA can be found at http://www.aphis.usda.gov/lpa/issues/bse/bse.html</p>

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Rule [FR Cite]	Agency	Benefits	Costs	Other Information
Mexican Hass Avocado Import Program [69 FR 69748]	USDA-APHIS	\$122-\$184 million (7% and 3%)	\$71-\$114 million (7% and 3%)	<p>Benefits: Change in consumer welfare due to the lower prices and expanded quantities of avocados in the U.S. market.</p> <p>Costs: Change in producer welfare. USDA also analyzed the risk of the introduction of quarantine pests into the U.S., and concluded that there was no such additional risk due to expanded trade in avocados. The risk assessment prepared by USDA establishes that the annual number of avocados infested by quarantine pests imported into the United States is zero.</p> <p>Other details: The analysis directly estimates the annual impacts for a three year period following the liberalization of the avocado trade. Economic impacts were analyzed using a partial equilibrium model that does not provide annualized data for subsequent years.</p> <p>The full RIA can be found at http://www.aphis.usda.gov/ppq/avocados/</p>
Designate Critical Habitat for 13 Evolutionarily Significant Units (ESUs) of Pacific Salmon and Steelhead in Washington, Oregon and Idaho [70 FR 52630]	DOC-NOAA	Not estimated	\$118-\$284 million (7%) \$114-\$275 million (3%)	<p>Benefits: Section 7 of the ESA requires every federal agency to ensure that any action it authorizes, funds or carries out is not likely to result in the destruction or adverse modification of critical habitat, which are identified by this rule. This complements the requirement that federal agencies ensure their actions are not likely to jeopardize the continued existence of a listed species. Another possible benefit is that the designation of critical habitat can serve to educate the public regarding the potential conservation value of an area. This may focus and contribute to conservation efforts by clearly delineating areas of high conservation value for certain species.</p> <p>Costs: Costs are annualized and monetized over 20 years. Monetized costs include the changes in federal activity on the lands used as critical habitat. In addition, non-monetized costs include changes in flow regimes for dams and other water supply structures that could potentially affect the supply of energy and the production of agricultural crops and other outputs dependent on water supply.</p> <p>The full RIA can be found at: http://www.nwr.noaa.gov/Salmon-Habitat/Critical-Habitat/CH-Designation-Info.cfm</p>

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Rule [FR Cite]	Agency	Benefits	Costs	Other Information
Amendments 18 and 19 to the Fishery Management Plan for Bering Sea/Aleutian Islands King and Tanner Crabs--Crab Rationalization Program [70 FR 10174]	DOC-NOAA	0-3 lives	\$8 million	<p>Benefits: Safety benefits are based on a NIOSH 1999 study of Alaska fisheries occupational mortality. In addition to safety benefits, due to the spread of harvesting effort across a longer period of time and eliminating the fishing "derby," DOC discussed non-quantified benefits. There is a potential for increased consumer surplus from increased availability due to longer seasons, increased product recovery rates, and quality improvements. Producer surplus to harvesters and processors will increase as harvesting and processing costs decline. Producer surplus may increase if benefits from increases in quality and quantity are captured by producers (harvesters and processors). Improved management and less wasteful fishing may also lead to improvements in productivity of the stocks, which could lead to potential increases to producer and consumer surplus.</p> <p>Costs: Monetized costs are due to increased information collections. Other non-quantified costs may arise due to surplus vessels entering other fisheries and imposing external costs. There are also potential transactions costs in quota share markets.</p> <p>Other details: The analysis estimated annual impacts for a 10-year period. Although this rule does not have monetized costs or benefits exceeding \$100 million in any one year, it was designated economically significant because the value of the fishery itself, and therefore the estimated value of the tradable quotas allocated to participants, is greater than \$100 million yearly.</p> <p>The full RIA can be found at: http://www.fakr.noaa.gov/sustainablefisheries/crab/eis/index.htm. Note that the RIA is located in an appendix to the Environmental Impact Statement.</p>

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Rule [FR Cite]	Agency	Benefits	Costs	Other Information
Use of Ozone-Depleting Substances: Removal of Essential Use Designation; Albuterol [70 FR 17168]	HHS-FDA	1,200 ton reduction in CFC emissions per year	300,000-900,000 MDIs not sold per year.	<p>Benefits: CFC reductions will occur from 12/31/08 until relevant patents for albuterol substitutes expire around 12/31/2010 or 12/31/2017. This estimate is based on 2004 utilization of CFCs for albuterol. Projecting emissions reductions for future years is complicated by changes in the size of the market and changes in future CFC allocations by the parties to the Montreal Protocol.</p> <p>Costs: This is an estimate of the decrease in albuterol MDI use that will result from price increases caused by the rule. FDA assumed these reductions will occur between 12/31/08 and 12/31/10 or 12/31/17, depending on the expiration of relevant patents. This estimate was based on 2004 utilization and prices.</p> <p>Other details: FDA also estimated substantial transfers and budget effects due to this rule. First, they estimated an annual increase in Medicare/Medicaid payments to the inhaler industry of \$298 million due to the higher prices of albuterol substitutes. They also estimated an \$830 million transfer from 3rd party insurers and albuterol users to substitute manufacturers and marketers. This is based on price differences and utilization data by payer type from the 1st half of 2004. It is an estimate of how much extra these payers would have had to pay if CFC albuterol MDIs were not available in 2004.</p> <p>The full RIA was published in the FR notice.</p>

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Rule [FR Cite]	Agency	Benefits	Costs	Other Information
Amendments to the Performance Standard for Diagnostic X-Ray Systems and Their Major Components [70 FR 33998]	HHS-FDA	\$320 (\$88-\$1,161) million (7%) \$716 (\$197-\$2,593) million (3%)	\$31 million (7%) \$30 million (3%)	<p>Benefits: The amendments will benefit patients by enabling physicians to reduce fluoroscopic radiation doses and associated detriment and, hence, to use the radiation more efficiently to achieve medical objectives. The monetized health benefits of lowering doses are reductions in the potential for radiation induced cancers and in the numbers of skin burns associated with higher levels of x-ray exposure during fluoroscopically guided therapeutic procedures. FDA believes that the amendments will not degrade the quality of fluoroscopic images produced while reducing the radiation doses.</p> <p>Costs: The rule will impose costs on manufacturers of fluoroscopic and radiographic systems by requiring new design features on their equipment, and on FDA for increased compliance activities. Some costs represent one-time expenditures to develop new designs or manufacturing processes to incorporate the regulatory changes. Other costs are the ongoing costs of providing improved equipment performance and features with each installed unit.</p> <p>Other details: FDA annualized estimated impacts over 10 years.</p> <p>The summary RIA was published in the FR notice. The full RIA is on display in the Division of Dockets Management.</p>

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Rule [FR Cite]	Agency	Benefits	Costs	Other Information
Establishment and Maintenance of Records Pursuant to the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 [69 FR 71562]	HHS-FDA	\$17 (\$7 - \$25) million (\$2003 at 7% and 3%)	\$133 (\$126 - \$139) million (\$2003 at 7%) \$131 (\$124 - \$136) million (\$2003 at 3%)	<p>Benefits: The monetized benefits are FDA's estimate of the improvement in their standard food borne outbreak investigations due to the recordkeeping requirements of this rule. In addition, FDA stated that the rule will help reduce the number of people who become ill during deliberate foodborne outbreaks by reducing the time required for preventive action. Furthermore, the final rule will eliminate the recurrence of outbreaks that may have been prevented had poor records quality not resulted in prematurely terminating the initial traceback investigation. Since a substantial portion of the benefits of this rule, improvements to homeland security, were not monetized, this rule was not included in the Chapter 1 totals even though FDA did monetize the relatively small non-security benefits. Costs: FDA estimated startup costs for learning, records redesign, and planning for records access requests in the first 2 years following publication of the rule. Additional records maintenance costs and records retention costs are incurred each year following publication of the rule beginning in the second year for large and small firms, and in the third year for very small firms. Learning costs and records access planning costs for new entrants are also incurred each year following publication of the final rule beginning after the second year. Costs are annualized over 20 years.</p> <p>The full RIA was published in the FR notice.</p>
Immunization Standard for Long Term Care Facilities [70 FR 58834]	HHS-CMS	\$12.1 billion (\$2005 at 7% and 3%)	\$7 million (\$2005 at 7% and 3%)	<p>Benefits: Are based on the lives saved based on the higher immunization rates in long term care facilities due to this rule. CMS assumed that before the rule, 74% of long-term care residents receive annual influenza vaccinations and between 39-56 percent receive pneumococcal vaccinations. CMS assumes that this rule will increase both vaccination rates to 90%.</p> <p>Costs: Are the direct cost of administering the increased vaccinations and for facilities developing new policies and procedures for administration.</p> <p>Other details: CMS also estimated \$30 million per year cost to Medicare and Medicaid due to paying for increased number of vaccinations.</p> <p>The full RIA was published in the FR notice.</p>

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Rule [FR Cite]	Agency	Benefits	Costs	Other Information
Electronic Transmission of Passenger and Crew Manifests for Vessels and Aircraft [70 FR 17820]	DHS-BCBP	Homeland Security	\$127 million	<p>Benefits: DHS stated that submission of manifest information to DHS from the airlines and ships is a necessary component of the nation's continuing program of ensuring aviation and vessel safety and protecting national security. The required information also will assist in the efficient inspection and control of passengers and crew members and thus will facilitate the effective enforcement of the customs, immigration, and transportation security laws.</p> <p>Costs: In the first year this rule is in effect, DHS estimates the cost will be \$166 million as companies reprogram existing systems and purchase necessary equipment. Once reprogramming is complete and equipment is in place, DHS estimates an average annual cost of \$135 million as users submit information electronically. The annual cost is driven primarily by passenger counts and crew loads in air and cruise ship travel. The costs were annualized over 10 years.</p> <p>The full RIA was published in the FR notice.</p>
Regulation of Fannie Mae and Freddie Mac Housing Goals [69 FR 63580]	HUD	Not quantified	Not quantified	<p>Benefits: HUD stated that homeownership and accessibility of homeownership are expected to increase due to the rulemaking.</p> <p>Costs: HUD stated that Fannie Mae and Freddie Mac (GSEs) will exert additional underwriting and marketing efforts in order to better serve the goal populations.</p> <p>Other details: HUD estimated a within market transfer of approximately \$180 million per year (studied over 3 years) from lenders and GSEs to the target borrowers, due to a 25 basis point drop in borrower interest costs.</p> <p>The full RIA is available online at http://www.hud.gov/offices/hsg/gse/gse.cfm</p>

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Rule [FR Cite]	Agency	Benefits	Costs	Other Information
Migratory Bird Hunting; 2005-2006 Migratory Game Bird Hunting Regulations: Early Season [70 FR 51521]	DOI-FWS	\$899 (\$734 - \$1.0) billion (\$2003)	Not Estimated	<p>Benefits: The listed benefits represent estimated consumer surplus. Data to estimate producer surplus are not available; producer surplus is likely minimal compared to consumer surplus, but would also be a benefit of the rule if monetized.</p> <p>Costs: The economic model did not produce a separate estimate of the costs of the rulemaking.</p> <p>Other details: DOI performed an economic impact analysis to jointly estimate the impact of all of early and late season migratory bird hunting regulations for the 2004-2005 season, but did not update that estimate for the 2006 season. DOI finalized a total of three Early Season regulations, the Final Framework (70 FR 51521), the Bag and Possession Limits (70 FR 51983), and the Regulations on Certain Federal Indian Reservations and Ceded Lands (70 FR 51983). This analysis looks at the economic effects of duck hunting, the major component of all migratory bird hunting. Sufficient data exists for duck hunting to generate an analysis of hunter behavior in response to regulatory alternatives. The analysis for all migratory bird hunting is not possible because of data limitations, but can be inferred from the results of the duck hunting analysis presented here.</p> <p>The RIA is not available online.</p>

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Rule [FR Cite]	Agency	Benefits	Costs	Other Information
Migratory Bird Hunting; 2005-2006 Migratory Game Bird Hunting Regulations: Late Season [70 FR 55665]	DOI-FWS	See "Early Season" benefits above.	Not Estimated	<p>Benefits: The listed benefits represent estimated consumer surplus. Data to estimate producer surplus are not available; producer surplus is likely minimal compared to consumer surplus, but would also be a benefit of the rule if monetized.</p> <p>Costs: The economic model did not produce a separate of estimate the costs of the rulemaking.</p> <p>Other details: DOI performed an economic impact analysis to jointly estimate the impact of all of early and late season migratory bird hunting regulations for the 2004-2005 season, but did not update that estimate for the 2006 season. DOI finalized a total of three Late Season regulations, the Final Framework (70 FR 55665), the Bag and Possession Limits (70 FR 54483), and the Regulations on Certain Federal Indian Reservations and Ceded Lands (70 FR 56531). See above for a summary of the impacts of hunting regulations.</p> <p>The RIA is not available online.</p>
Electronic Orders for Schedule I and II Controlled Substances [70 FR 16919]	DOJ-DEA	<p>\$284 million (\$2003 at 7%)</p> <p>\$286 million (\$2003 at 3%)</p>	<p>\$122 million (\$2003 at 7%)</p> <p>\$112 million (\$2003 at 3%)</p>	<p>Benefits: The rule allows registrants who order Schedule I and II controlled substances to issue orders electronically, using a digital certificate provided by DEA to sign the orders. The electronic form system provides for many efficiencies, such as an avoidance of the need to transcribe data from electronic systems to paper and back again, the resources that must be dedicated to physically handling and accounting for the paper documents, and the time required to transmit the paper document from the customer to the supplier before an order can be filled.</p> <p>Costs: Compliance costs for the electronic system include one time costs for the installation of software and the cost of obtaining digital certificates, and ongoing annual costs for processing orders. The electronic order costs assume that registrants take 5 years to adopt electronic orders, so electronic order costs include a mix of paper and electronic for the first four years. Initial compliance costs are also annualized over 5 years.</p> <p>The full RIA is available at http://www.deadiversion.usdoj.gov/fed_regs/rules/2005/index.html</p>

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Rule [FR Cite]	Agency	Benefits	Costs	Other Information
Hours of Service of Drivers [70 FR 49978]	DOT-FMCSA	\$20 million (\$2004 at 7% and 3%)	-250 million (\$2004 at 7% and 3%)	<p>Benefits: The positive benefits are the safety benefits due to the elimination of the 2003 rule's allowance of split resting periods in the truck's sleeper berth.</p> <p>Costs: The negative costs primarily represent the relaxed requirements for short haul trucking.</p> <p>Other Details: The baseline for the costs and benefits of this rule is the 2003 final Hours of Service rule, which is also included in the totals presented in Tables 1-1 and 1-2. DOT also performed an extensive sensitivity analysis of allowing the 11-th hour of truck driving.</p> <p>The full RIA is available online at: http://www.fmcsa.dot.gov/rules-regulations/topics/hos/regulatory-impact.htm</p>
Tire Pressure Monitoring Systems [70 FR 18136]	DOT-NHTSA	<p>\$1,012-\$1,097 million (7%)</p> <p>\$1,218-\$1,316 million (3%)</p>	<p>\$1,238 (\$938-\$1,991) million (7%)</p> <p>\$1,266 (\$966-\$2,282) million (3%)</p>	<p>Benefits: The agency estimates the total quantified safety benefits from reductions in crashes due to skidding/loss of control, stopping distance, flat tires, and blowouts. The unit of analysis in DOT rulemakings is equivalent lives saved, which weights injuries of different severities. DOT was unable to quantify the impact of higher tire inflation on hydroplaning and crashes or on overloading the vehicle and the risk of tire failure. The benefits also include lower fuel consumption, less tread wear, less property damage, and less travel delay.</p> <p>Costs: DOT estimated costs are primarily due to vehicle redesign and maintenance, and the opportunity cost of refilling tires. Although the agency quantified the major impacts on maintenance costs from having batteries in the system, they could not quantify other potential maintenance problems.</p> <p>Other details: The range of uncertainty reflects the different technologies that may be chosen by auto manufacturers in order to comply with the rule.</p> <p>The full RIA is available online at: http://www.nhtsa.dot.gov/cars/rules/rulings/TPMS-FMVSS-No138-2005/index.html</p>

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Rule [FR Cite]	Agency	Benefits	Costs	Other Information
Occupant Crash Protection: Rear Center Lap/Shoulder Belt Requirement-- Standard 208 [69 FR 70904]	DOT-NHTSA	\$184 million (\$2000 at 7%) \$230 million (\$2000 at 3%)	\$158 million (\$2000 at 7%) \$197 million (\$2000 at 3%)	Benefits: DOT estimates benefits based on fewer fatalities and injuries. The unit of analysis in DOT rulemakings is equivalent lives saved, which weights injuries of different severities. Costs: DOT assumes that the manufacturers will choose to comply with today's requirements using either integrated or detachable seat belt designs, depending on vehicle characteristics and perceived customer desires. Other details: Benefits and costs were annualized over 25 years. The full RIA is available online at: http://dmses.dot.gov/docimages/pdf90/307712_web.pdf
Upgrade of Head Restraints [69 FR 74847]	DOT-NHTSA	\$113 million (\$2002 at 7%) \$141 million (\$2002 at 3%)	\$84 million (\$2002 at 7% and 3%)	Benefits: The benefits estimates are based on a reduction of whiplash injuries in both the front and back seats Costs: The estimates are derived from tear down studies of head restraints from a variety of motor vehicles. DOT studied both integral and adjustable head restraints and found little difference in the cost per inch. Other details: Benefits and costs were annualized over 25 years. The full RIA is available online at: http://dmses.dot.gov/docimages/pdf90/307424_web.pdf
Clean Air Interstate Rule [70 FR 25162]	EPA-AR	\$86.3 billion in 2015 (\$1999 at 7%) \$101 billion in 2015 (\$1999 at 3%)	\$2.6 billion in 2015 (\$1999 at 7%) \$3.1 billion in 2015 (\$1999 at 3%)	Benefits: The benefits estimates are based primarily on fewer fatalities, non-fatal heart attacks, cases of chronic bronchitis, and asthma due to reductions in particulate matter and ozone. EPA also stated that the rule leads to non-quantified ecological and visibility benefits. Costs: Costs are based primarily on the installation of control technology in the electric power sector. Other details: EPA also conducted an uncertainty analysis, but did not include ranges around the presentation of their primary estimates. The full RIA is available online at: http://www.epa.gov/cleanairinterstaterule/pdfs/finaltech08.pdf

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Rule [FR Cite]	Agency	Benefits	Costs	Other Information
Clean Air Visibility Rule: Best Available Retrofit Technology (BART) [70 FR 39104]	EPA-AR	\$2,200 - \$12,200 million in 2015 (\$1999 at 7%) \$2,600 - \$14,300 million in 2015 (\$1999 at 3%)	\$300 - \$2,900 million in 2015 (\$1999 at 7%) \$400 - \$2,300 million in 2015 (\$1999 at 3%)	<p>Benefits: The benefits estimates are based primarily on fewer fatalities, non-fatal heart attacks, cases of chronic bronchitis, and asthma due to reductions in particulate matter. EPA also stated that the rule leads to non-quantified ecological and visibility benefits.</p> <p>Costs: Costs are based primarily on the installation of the control technology in the electric power sector.</p> <p>Other details: The uncertainty range for benefits and costs reflect different modeling scenarios concerning the actions States may take to implement the BART requirements in this rule. Benefit and cost analyses for BART have the Clean Air Interstate Rule (CAIR) in the baseline; therefore, emission reductions from Electricity Generating Units (EGUs) in the CAIR region are not included in the benefits and costs estimates for this rule. See RIA Chapters 4, 7, 8, and Appendix G for more information.</p> <p>The full RIA is available online at http://www.epa.gov/air/visibility/pdfs/bart_ria_2005_6_15.pdf</p>
Clean Air Mercury Rule-- Electric Utility Steam Generating Units [70 FR 28606]	EPA-AR	\$0.2 - \$2 million in 2020 (\$1999 at 7%) \$0.4 - \$3 million in 2020 (\$1999 at 3%)	\$896 million in 2020 (\$1999 at 7%) \$848 million in 2020 (\$1999 at 3%)	<p>Benefits: EPA analyzed changes in mercury emissions, deposition, and the physical and biological processes that lead to the uptake of methylmercury in fish. The benefit estimates reflect the value of avoided IQ decrements in children who had prenatal exposure via maternal fish consumption. The range reflects different assumptions about the toxicity of mercury and whether a threshold exists for IQ impacts. This primary estimate does not include the value of co-benefits of direct PM reductions, other possible health effects (e.g. some epidemiological studies suggest that methylmercury is associated with cardiovascular disease in some populations), and possible ecosystem benefits.</p> <p>Costs: These are the social costs of the rule, and are primarily the result EPA's Integrated Planning Model of the impact of the rule on the utility industry.</p> <p>Other details: Both benefits and costs are presented for the year 2020, 2 years after the final Phase II cap becomes effective.</p> <p>The full RIA is available online at: http://www.epa.gov/ttn/atw/utility/ria_final.pdf</p>

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Rule [FR Cite]	Agency	Benefits	Costs	Other Information
National Primary Drinking Water Regulations: Long Term 2 Enhanced Surface Water Treatment Rule [71 FR 654]	EPA-WATER	<p>\$25 - \$3,195 million (\$2003 at 7%, traditional COI)</p> <p>\$31 - \$3,929 million (\$2003 at 3%, traditional COI)</p> <p>\$45 - \$3,998 million (\$2003 at 7%, enhanced COI)</p> <p>\$55 - \$4,941 million (\$2003 at 3%, enhanced COI)</p>	<p>\$70 - \$168 million (\$2003 at 7%)</p> <p>\$62 - \$150 million (\$2003 at 3%)</p>	<p>Benefits: The quantified benefits are due to avoided endemic cryptosporidiosis illnesses and associated deaths. In addition to quantified benefits, EPA also states that the following are non-quantified benefits of the rule: reduction in non-fatal risk to sensitive subpopulations, reduction in risk and response costs during outbreaks, reduction in co-occurring/emerging pathogen risk, reduction in endemic morbidity and mortality risk associated with uncovered finished water reservoirs, improved aesthetic water quality, and reduced costs of averting behaviors.</p> <p>Costs: EPA estimates costs for all rule activities including: rule implementation, source water monitoring, adding treatment, and compliance reporting. EPA assumes nearly all surface water and <i>Ground Water Under the Direct Influence of Surface Water</i> systems will incur rule implementation and initial source water monitoring costs.</p> <p>Other details: Costs and Benefits annualized over 25 years. The range of benefits and costs reported here are due to different analytical datasets and valuation methodologies. The “traditional” cost of illness (COI) approach values the benefits based on medical costs avoided, while EPA developed an “enhanced” COI approach, which adds a value for pain and suffering.</p> <p>The full RIA is available online in EPA’s Docket on www.regulations.gov Docket number EPA-HQ-OW-2002-0039-0760, 0760.1, and 0760.2.</p>

APPENDIX B: VALUATION ESTIMATES FOR REGULATORY CONSEQUENCES⁵⁶

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 effects which 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.

Injury. For NHTSA 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.⁵⁷

For 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.
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 article⁵⁸
3. Change in Emissions of Air Pollutants. Please see the following paragraphs for an explanation of these values. All values are in 2001 dollars.

Hydrocarbon:	\$600 to \$2,700 per ton
Nitrogen Oxide (stationary):	\$370 to \$3,800 per ton
Nitrogen Oxide (mobile):	\$1,100 to \$11,600 per ton
Sulfur Dioxide:	\$1,700 to \$18,000 per ton
Particulate Matter:	\$10,000 to \$100,000 per ton

⁵⁶The following discussion updates the monetization approach used in previous reports and draws on examples from this and previous years.

⁵⁷National Highway Traffic Safety Administration, *The Economic Cost of Motor Vehicle Crashes, 1994*, Table A-1. <http://www.nhtsa.dot.gov/people/economic/ecomvc1994.html> Note that the light truck average fuel economy rule NHTSA finalized in 2003 did present quantified and monetized costs and benefits, which we did not adjust.

⁵⁸Brown and Savage, "The Economics of Double-Hulled Tankers," *Maritime Policy and Management*, Volume 23(2), 1996, pages 167-175.

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The estimates for reductions in hydrocarbon emissions were obtained from EPA's RIA for the 1997 rule revising the primary National Ambient Air Quality Standards (NAAQS) for ozone and fine particulate matter (PM).

EPA believes that there are a number of reasons to expect that reductions in NO_x emissions from ground-level mobile sources achieve different air quality improvements relative to reductions from electric utilities and other stationary sources with "tall stacks". In response, OMB has adopted different benefit transfer estimates for NO_x reductions from stationary sources (e.g., electric utilities) and from mobile sources.⁵⁹ For the central estimate of NO_x emissions for mobile sources, we used estimates from the Tier II/Gasoline Sulfur rule RIA, while recognizing that the Tier II analysis was based on an air quality fate and transport model that had limited treatment of atmospheric chemistry.⁶⁰ Based on the final Tier 2/Gasoline Sulfur RIA, EPA estimated that NO_x reductions would yield benefits of \$4900 (1999\$) per ton. Analysis of recent EPA rules yield several estimates for the central estimate of NO_x benefits per ton from stationary 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 mortality-based benefits of NO_x reductions from stationary sources (electric utilities) are estimated to be \$1,300 (1999\$) per ton.⁶¹ New results based on EPA's ongoing analyses supporting the suite of Clean Air Rules (including the Clean Air Interstate Rule, Clean Air Visibility Rule, and Clean Air Mercury Rule) may provide better estimates for future reports. NO_x benefit estimates are difficult to transfer to other applications, however. The location of reductions, reductions in other PM precursors, air chemistry, meteorology, emission release heights, baseline conditions, etc. can have dramatic effects on the relationship between NO_x emission reductions and ambient PM concentrations. Further, the understanding of the atmospheric chemistry characterizing PM formation, and photochemical air quality modeling are rapidly evolving.

EPA also developed central estimates for the benefits associated with reductions in SO₂ 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 \$7,300 per ton.

We also developed ranges around these central estimates of the per-ton value of benefits of emission reduction in nitrogen oxides and sulfur dioxide. EPA calculated ratios of the high and low benefits estimates to the central estimate for the four fairly recent rules for which there was sufficient information to do so. Those rules are Tier 2, Section 126/Ozone Transport, Heavy-Duty Diesel Engines, and Non-Road Diesel Engines. The mean ratio of the low benefit estimates to the corresponding central estimates for these four rules was .22. The mean ratio of the high benefit estimates to the mean was 2.27. This implies an average ratio of high to low

⁵⁹The five key assumptions underlying the benefit estimates for reductions in NO_x emissions are described on p. 7.

⁶⁰Additional details on the Tier II benefits analysis are available in the Tier II/Sulfur Final Rulemaking RIA, available on the web at <http://www.epa.gov/oms/fuels.htm>.

⁶¹This memo reported that: "Based on previous EPA analyses, the average mortality-related benefits per ton of NO_x reduced are around \$1300 and the average benefits per ton of SO₂ reduced are around \$7300 for electricity-generating units."

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benefit estimates of approximately 10 (2.27/.22). Therefore we applied this factor of 10 as an uncertainty range in our presentation of the benefits of several rules regulating mobile and stationary sources of emissions. These rule are: Deposit Control Gasoline, Federal Test Procedures, and Marine Engines (1996-1997); New Locomotives (1996-1997); Non-Road Diesel Engines II and Non-Handheld Engines (1998-1999); Hand-Held Engines Phase II (1999-2000); 2004 Heavy Duty Engines (2000-2001); Municipal Waste Combustors (1995-1996); Acid Rain NO_x Phase II (1996-1997); Steam Generating Units (1998-1999); National Emission Standards for Hazardous Air Pollutants (NESHAP) for Stationary Reciprocating Internal Combustion Engines; and NESHAP for Plywood and Composite Wood Products.

As mentioned above, OMB only monetized benefits estimates for rules that were not otherwise monetized by the agencies. Therefore, these per ton benefits estimates were only applied to EPA rules in which emission impacts were quantified but not monetized by EPA. We will continue to work with EPA on updating the range of benefits in order to more accurately represent the magnitude and the substantial range of uncertainty inherent in these estimates. In order to help address the uncertainty and difficulty inherent in the benefit transfer approach, we have asked EPA to provide us with the Agency's estimates of the benefits per ton using the Agency's air quality models and other tools for all air rules that were finalized without such an estimate. We hope to be able to use these estimates in future Reports to Congress, thereby reducing somewhat the uncertainty and providing a more consistent approach to benefits.

A. 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.

B. 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—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

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

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APPENDIX C: THE BENEFITS AND COSTS OF 1992-1995 MAJOR RULES

Tables C-1 to C-3 list the rules that were omitted from the 10-year running totals presented in Chapter 1 of our Reports to Congress. Table C-1 consists of the annualized, monetized costs and benefits of rules for which OMB concluded review between October 1, 1994 and September 30, 1995. These rules were included in Chapter 1 of the 2005 Report as part of the 10-year totals, but are not included in the draft 2006 Report. Table C-2 lists the rules completed between October 1, 1993 and September 30, 1994, and Table C-3 lists the rules completed between October 1, 1992 and September 30, 1993. Please note that since publication of the 2004 Report, we have updated the benefits per ton ranges based on a new analysis of the sources of uncertainty in EPA air regulations. This analysis is explained in more detail in Appendix B above. In order to be consistent with Chapter 1 impacts, for rules presented in Tables C-1 to C-3 where OMB monetized EPA estimates of the tons of pollutants avoided, we updated the impact estimates to reflect the new benefits per ton ranges.

We continue to believe that the 10-year window is the appropriate time period for which to limit the Chapter 1 accounting statement, since we do not believe that the pre-regulation estimates of the costs and benefits of rules issued over ten years ago are very reliable or useful for informing current policy decisions. In order to provide transparency, however, we have included in this Appendix all rulemakings that have been omitted because of our decision to limit our accounting statement to 10 years.

**Table C-1: Estimates of Annual Benefits and Costs of Nine Major Federal Rules
October 1, 1994 to September 30, 1995**
(millions of 2001 dollars per year)

REGULATION	AGENCY	BENEFITS	COSTS	EXPLANATION
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.
Stability Control of Medium and Heavy Vehicles During Braking	DOT- NHTSA	1,650-2,539	694	We valued each "equivalent fatality" at \$3 million.
Head Impact Protection	DOT- NHTSA	1,746-1,964	633	We valued each "equivalent fatality" at \$3 million.
Bay/Delta Water Quality Standards	EPA	2-26	37-248	
Federal Standards for Marine Tank Vessel Loading and Unloading Operations and NESHAP for Marine Tank Vessel Loading and Unloading Operations	EPA	185-829	131-175	

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**Table C-2: Estimates of Annual Benefits and Costs of Nine Major Federal Rules
October 1, 1993 to September 30, 1994**
(millions of 2001 dollars per year)

REGULATION	AGENCY	BENEFITS	COSTS	EXPLANATION
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.
Controlled Substances and Alcohol Use and Testing	DOT – FHWA	1,539	114	No adjustments to agency estimates.
Prevention of Prohibited Drug Use in Transit Operations	DOT	107	37	We amortized the agency’s present value estimates over 10 years.
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	122-947	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-\$11,600 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.
Hazardous Organic NESHAP	EPA	593-2,628	295-333	We valued VOC emissions at \$600-\$2700 per ton and NO _x emissions (which are a cost in this instance) at \$370 - \$3,800 per ton. We did not value changes in CO emissions.
Non-Road Compression Ignition Engines	EPA	647 – 6,821	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 \$1,000 - \$11,600 per ton.

**Table C-3: Estimates of Annual Benefits and Costs of Ten Major Federal Rules
October 1, 1992 to September 30, 1993**
(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	No adjustments to agency estimates.
Manufactured Housing Wind Standards	HUD	103	63	No adjustments to agency estimates.
Permit Required 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.
Vessel Response Plans	DHS/USCG	9	295	We amortized the agency's present value estimates over 30 years. We valued each barrel of oil not spilled at \$2,000.
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.
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.