

**Draft 2008 REPORT TO CONGRESS
ON THE BENEFITS AND COSTS OF FEDERAL REGULATIONS AND
UNFUNDED MANDATES ON STATE, LOCAL, AND TRIBAL ENTITIES**

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EXECUTIVE SUMMARY

This Report to Congress on the Benefits and Costs of Federal Regulations (Report) 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.” This is the eleventh annual Report since the Office of Management and Budget (OMB) began issuing this Report in 1997.

A key feature of this Report is the estimates of the total benefits and costs of regulations reviewed by OMB. Similar to previous Reports, the Report includes a ten-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, 1997 to September 30, 2007 range from \$122 billion to \$656 billion, while the estimated annual costs range from \$46 billion to \$54 billion. These totals are somewhat higher than those reported last year.
- During the past year, agencies quantified and monetized benefits and costs for 12 “major” final rules. These rules added \$28.6 billion to \$184.1 billion in annual benefits compared to \$9.4 billion to \$10.6 billion in annual costs.
- Six additional major final rules adopted last year did not have quantified and monetized estimates of both benefits and costs. The Department of Homeland Security implemented four of these rules, at an estimated annual cost of \$1.1 billion to \$2.7 billion. The benefits of improved security are very difficult to quantify and monetize. The other two implemented migratory bird hunting regulations and estimated only the benefits of bird hunting activities and qualitatively discussed the administrative costs.

In addition, we report the latest results of our ongoing historical examination of the trends in Federal regulatory activity. As explained in Chapter II of this Report, the data reveal that:

- The average annual costs of regulations issued over the last seven years is about 24% less than the annual average costs over the previous 20 years.
- Over the last 27 years, the major regulations reviewed by OMB have added at least \$139 billion to the overall yearly costs of regulations on the public.
- The estimated benefits of major regulations issued from 1992 to 2007 exceed the estimated costs by more than four fold.

The Report also provides a summary of the analysis of major regulatory activity by the so-called “independent” regulatory agencies over the past ten years.

Chapter III provides an update on agency implementation of the Information Quality Act (IQA) (Section 515 of the Treasury and General Government Appropriations Act, 2001 (Pub. L. No. 106-554, 31 U.S.C. § 3516 note)). The chapter summarizes the a) current status of correction requests that were received by agencies in FY 2007, and includes an update on the status of requests received in FY 2003, FY 2004, FY 2005, and FY 2006; b) agency annual reports for the Information Quality Bulletin for Peer Review for FY 2006 and FY 2007; c) implementation status of the Good Guidance Practices Bulletin; d) implementation status of the Memorandum on the Principles of Risk Analysis.

This Report is being submitted along with the Thirteenth Annual Report to Congress on Agency Compliance with the Unfunded Mandates Reform Act (UMRA), (Pub. L. No. 104-4, 2 U.S.C. § 1538). OMB reports on agency compliance with Title II of UMRA, which requires that each agency, before promulgating any proposed or final rule that may result in expenditures of more than \$100 million (adjusted for inflation) in any one year by State, local, and tribal governments, or by the private sector, to conduct a cost-benefit analysis and select the least costly, most cost-effective, or least burdensome alternative. Each agency must also seek input from State, local, and tribal government.

PART I: 2008 REPORT TO CONGRESS
ON THE BENEFITS AND COSTS OF FEDERAL REGULATIONS

INTRODUCTION

The Regulatory Right-to-Know Act calls for the Office of Management and Budget (OMB) to submit each year to Congress “an accounting statement and associated report” including:

- (A) an estimate of the total annual benefits and costs (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 are 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 Unfunded Mandates Reform Act of 1995 (UMRA),² and
- Rules designated as “economically significant” under section 3(f)(1) of Executive Order 12866.³

Chapter I examines the benefits and costs of major Federal regulations issued in fiscal year 2007 and summarizes the benefits and costs of major regulations issued between September 1997 and 2007. It also discusses regulatory impacts on State, local, and tribal governments, small business, wages, and economic growth. Chapter II examines trends in regulation since OMB began to compile benefit and cost estimates records in 1981. Chapter III provides an update on implementation of the Information Quality Initiatives, and Chapter IV summarizes agency compliance with UMRA.

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 benefits and costs 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 one 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.”

CHAPTER I: THE BENEFITS AND COSTS OF FEDERAL REGULATIONS

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 2007 (September 30, 2007). Like the 2007 and prior-year Reports, this chapter uses a ten-year look-back: estimates are based on the major regulations reviewed by OMB from October 1, 1997 to September 30, 2007.⁴ This means that 10 rules reviewed from October 1, 1996 to September 30, 1997 (fiscal year 1997) were included in the totals for the 2007 Report but are not included in the 2008 Report. A list of these FY 1997 rules can be found in Appendix B (see Table B-1). The removal of the FY 1997 rules from the ten-year window is accompanied by the addition of 12 FY 2007 rules.

All 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 primarily on data provided by these agencies to the Government Accountability Office (GAO) under the Congressional Review Act. Also in this chapter, in response to public suggestions on previous reports, we seek comment on possible metrics for evaluating agency compliance with relevant OMB guidance on regulatory impact analysis.

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

Table 1-1 presents an estimate of the total benefits and costs of 93 regulations reviewed by OMB over the ten-year period from October 1, 1997 to September 30, 2007 that met two conditions:⁷ (1) each rule was estimated to generate benefits or costs of at least \$100 million in any one year, and (2) a substantial portion of its benefits and costs were quantified and monetized by the agency or, in some cases, monetized by OMB. The estimates are therefore not

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 Gross Domestic Product (GDP) deflator and all amortizations are performed using a discount rate of 7 percent, 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 benefits and costs 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 that took effect on January 1, 2004 for proposed rules and January 1, 2005 for final rules. The guidance recommends what OMB defines as "best practices" 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 benefits and costs 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.

a complete accounting of all the benefits and costs of all regulations issued by the Federal Government during this period.⁸ As discussed in previous Reports, OMB has chosen a ten-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 benefits and costs of Federal regulations over the period October 1, 1997 to September 30, 2007 are based on agency analyses conducted prior to issuance of the regulation and subjected to public notice and comments and OMB review under Executive Order 12866.

The aggregate benefits and costs reported in Table 1-1 are larger than those presented in the 2007 Report. The increase in benefits and costs are due primarily to three rulemakings issued in FY 2007: the EPA Clean Air Fine Particle Implementation and Control of Hazardous Air Pollutants from Mobile Sources rules, and the DOT Electronic Stability Control rule. As can be seen in Tables 1-1 and 1-2, EPA rules continue, as in prior years, to be responsible for the majority of estimated benefits and costs generated by Federal regulation.

Table 1-1: Estimates of the Total Annual Benefits and Costs of Major Federal Rules, October 1, 1997 to September 30, 2007 (millions of 2001 dollars)

Agency	Number of Rules	Benefits	Costs
Department of Agriculture	6	906-1,315	1,014-1,353
Department of Education	1	633-786	349-589
Department of Energy	5	4,834-5,209	3,033-3,080
Department of Health and Human Services	18	20,565-32,850	3,834-4,331
Department of Housing and Urban Development	1	190	150
Department of Justice	1	275	108-118
Department of Labor	6	1,085-4,215	449-458
Department of Transportation	15	10,407-18,149	5,029-8,756
Environmental Protection Agency ⁹	40	83,298-592,567	32,252-35,058
Total	93	122,190-655,556	46,219-53,894

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 major rules in the last ten years with monetized benefits and costs.

The ranges of benefits and costs presented in Tables 1-1 and 1-2 are not necessarily

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.

⁹ These totals include EPA's March 2005 final "Clean Air Interstate Rule." On July 11, 2008, the D.C. Circuit vacated this rule. EPA is reviewing the Court's decisions.

correlated. In other words, when interpreting the meaning of these ranges, the reader should not assume that the low end of the benefit range is necessarily associated with the low end of the cost range, or similarly, that the high end of the benefit range is necessarily associated with the high end of the cost range. Thus, for example, it is possible that the net benefits of EPA’s water program rules, taken together, could range from negative \$1.6 billion to positive \$8.3 billion per year.

Table 1-2: Estimates of Annual Benefits and Costs of Major Federal Rules: Selected Programs and Agencies, October 1, 1997-September 30, 2007 (millions of 2001 dollars)

Agency	Number of Rules	Benefits	Costs
Department of Agriculture			
Animal and Plant Health Inspection Service	3	862-1,163	726-931
Department of Energy			
Energy Efficiency and Renewable Energy	5	4,834-5,209	3,033-3,080
Department of Health and Human Services			
Food and Drug Administration	11	2,491-13,870	914-1,219
Center for Medicare and Medicaid Services	5	16,831-17,300	2,626-2,818
Department of Labor			
Occupational Safety and Health Administration	4	1,075-4,204	491-500
Department of Transportation			
National Highway Traffic Safety Administration	10	9,454-17,185	3,982-7,710
Environmental Protection Agency			
Office of Air	27	79,351-573,326	26,347-28,847
Office of Water	10	2,022-11,539	3,277-3,644

Based on the information contained in this and the previous ten Reports, the total benefits and costs of all Federal rules now in effect (major and non-major, including those adopted more than ten years ago) may be significantly larger than the sum of the benefits and costs reported in Table 1-1. More research is necessary to provide a stronger analytic foundation for comprehensive estimates of total benefits and costs 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 benefits and costs, 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 that 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 editions of this Report, and in this Report in Table A-1 of Appendix A. Table A-1 also provides links to agency analyses that are available electronically.

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 benefits and costs 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: this is the uncertainty in the reduction of premature deaths associated with reduction in particulate matter and the monetary value of reducing mortality risk.

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:

- The analyses assume that 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.
- The analyses assume that 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 analyses assume that 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 assumed to be 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.¹⁰

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

In this section, we examine in more detail the estimated benefits and costs of the 39 major final rules for which OMB concluded review during the 12-month period beginning October 1, 2006, and ending September 30, 2007. These major rules represent approximately 13 percent of the 296 final rules reviewed by OMB, and approximately one percent of the 3,552 final rules published in the *Federal Register* during this period. OMB believes, however, that the benefits and costs of major rules capture the majority of the total benefits and costs of all rules subject to OMB review.¹¹

Of the 39 rules, 18 were “social regulations,” which may require substantial additional private expenditures as well as provide new social benefits.¹² Of the 18 social regulations, we are able to present estimates of both monetized benefits and costs for 12 rules. The estimates are aggregated by agency in Table 1-3, and each rule is summarized in Table 1-4. Four of the rules for which we were not able to present estimates of both costs and benefits were rules designed to improve homeland security. The benefits of improved security are very difficult to quantify and monetize; however, the Department of Homeland Security did estimate the cost of all of these rules, which are summarized in Table 1-5.¹³ The Department of the Interior did not estimate costs for two other final rules setting conditions for migratory bird hunting. We did not include those migratory bird hunting rules in the totals in Tables 1-1 through 1-3. It is difficult to estimate the costs of these two rules since costs are typically associated with requirements or restrictions on activities imposed by rules. Instead, the agency estimated the value the rule provides to hunters. We attempt to summarize the available information on the non-monetized impacts, and/or provide links to such information where available, for all 18 of these rules in the “other information” column of Table A-1.

The remaining 21 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 Executive Order 12866 and OMB Circular A-4, and are fully reviewed by OMB, past Reports have focused primarily on regulations that impose

¹⁰For 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>).

¹¹We 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 benefits and costs of all rules promulgated by these agencies and reviewed by OMB.

¹²The *Federal Register* citations for these rules and links to available RIAs appear in Table A-1 in Appendix A.

¹³See Chapter 4 in the 2003 Report (pp. 64-80) for a more detailed discussion of this issue.

costs primarily through private sector mandates. This focus was in part because, by their nature, transfer rules are assumed to have a one-to-one effect on benefits and costs. Their effects on net benefits, if any, are much smaller than the magnitude effect on the net benefits of regulations with private sector mandates.

Social Regulation

Of the 39 economically significant rules reviewed by OMB, 18 regulations require substantial private expenditures or provide new social benefits. We are able to present monetized benefits and costs for 67 percent (12 of 18) of the rules, and for about 83 percent (10 of 12) of the non-homeland security-related rules. Since OMB began to compile this Report in 1997, this is among the highest percentage of economically significant rules presenting both monetized benefits and monetized costs. Table 1-3 presents total estimated 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 estimated benefits and costs, OMB has applied a uniform format for the presentation to make agency estimates more closely comparable with each other (for example, annualizing benefit and cost estimates), and OMB 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 Appendix A of this Report and in Appendix B of our 2007 Report, which can be found at http://www.whitehouse.gov/omb/inforeg/regpol-reports_congress.html. Table A-1 in Appendix A also reports other qualitative information as reported by the agencies on the 18 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 1, 2006 to September 30, 2007 (millions of 2001 dollars)

Agency	Number of Rules	Benefits	Costs
Department of Agriculture	2	169-340	185-415
Department of Energy	1	490-865	381-428
Department of Health and Human Services	2	38-209	97-303
Department of Labor	2	10	-42
Department of Transportation	2	6,723-12,340	1,314-1,969
Environmental Protection Agency	3	21,143-170,391	7,475-7,584
Total	12	28,574-184,156	9,410-10,657

**Table 1-4: Estimates of the Total Annual Benefits and Costs of Major Rules Reviewed
Between October 1, 2006 and September 30, 2007 (millions of 2001 dollars)**

Rule	Agency	Benefits	Costs	Explanation of OMB Calculations
Prohibition of the Use of Specified Risk Materials for Human Food and Requirements for the Disposition of Non-Ambulatory Disabled Cattle	USDA/ FSIS	0	87-221	We converted agency annual impact estimates to 2001 dollars.
Bovine Spongiform Encephalopathy (BSE); Minimal-Risk Regions and Importation of Commodities	USDA/ APHIS	169-340	98-194	
Energy Efficiency Standards for Electric Distribution Transformers	DOE/ EERE	490-865	381-428	We converted agency annual impact estimates to 2001 dollars.
Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Dietary Ingredients and Dietary Supplements	HHS/ FDA	10-79	87-293	We converted agency annual impact estimates to 2001 dollars.
Current Good Manufacturing Practice for Blood and Blood Components: Notification of Consignees and Transfusion Recipients Receiving Blood and Blood Components at Increased Risk of Transmitting HCV Infection	HHS/ FDA	28-130	11	We converted agency annual impact estimates to 2001 dollars.
Revision of the Form 5500 Series	DOL/ EBSA	0	(83)	We counted this burden reduction as a cost reduction instead of a benefit. We also converted the agency cost savings estimate to 2001 dollars.
Emergency Mine Evacuation	DOL/ MSHA	10	41	This rule is economically significant and major, since MSHA estimated first year cost of approximately \$150 million. We also converted agency annual impact estimates to 2001 dollars.
Electronic Stability Control (ESC)	DOT/ NHTSA	5,987- 11,282	913-917	We converted agency annual impact estimates to 2001 dollars.
Side Impact Protection	DOT/ NHTSA	736-1,058	401- 1,051	We converted agency annual impact estimates to 2001 dollars.
Control of Hazardous Air Pollutants From Mobile Sources	EPA/ Air	2,310- 2,983	298-346	We converted agency annual impact estimates to 2001 dollars.
Clean Air Fine Particle Implementation	EPA/ Air	18,833- 167,408	7,324	We converted agency annual impact estimates to 2001 dollars.
Oil Pollution Prevention; Spill Prevention, Control, and Countermeasure (SPCC) Requirements--Amendments	EPA/ SWER	0	(148)- (86)	We counted this burden reduction as a cost reduction instead of a benefit. We also converted agency annual impact estimates to 2001 dollars.
Total		28,574- 184,156	9,410- 10,657	

Homeland Security Regulation

Table 1-5 presents the available impact information on the 4 major homeland security regulations adopted in the past year by the Department of Homeland Security (DHS). Because the benefits of homeland security regulation 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 agency forecasts that the rule will improve security or otherwise prevent or mitigate the consequences of a terrorist attack.

Table 1-5: Estimates of the Total Annual Benefits and Costs of Major Federal Rules: Major Homeland Security Regulations, October 1, 2006-September 30, 2007 (millions of 2001 dollars)

Rule	Agency	Benefits	Costs	Other Information
Chemical Facility Anti-Terrorism Standards	DHS/ OS	The goal of this rule is to reduce the vulnerability of high-risk chemical facilities to a terrorist attack.	835-1,535	We converted agency annual cost estimates to 2001 dollars.
Passenger Manifest for Commercial Aircraft and Vessels Arriving In and Departing From the United States	DHS/ CBP	The goal is to prevent high-risk passengers from boarding aircraft bound for or departing from the U.S., and to prevent such passengers and crew from departing on vessels leaving the U.S. DHS performed a break-even analysis, which identified annual risk reductions required for the rule to breakeven for three attack scenarios. DHS also estimated quantified benefits of \$14 million per year, primarily due to fewer diverted aircraft.	94-134	We converted agency annual cost estimates to 2001 dollars.
Documents Required for Travel Within the Western Hemisphere	DHS/ CBP	The goal of this rule is to increase security in the air environment by requiring a passport at all airports of entry. The rule addresses a vulnerability of the U. S. to entry by terrorists or other persons by false documents or fraud under the previous documentary exemptions for travel within the Western Hemisphere. These vulnerabilities have been noted extensively by Congress and others.	131-664	We converted agency annual cost estimates to 2001 dollars.
Transportation Worker Identification Credential (TWIC) Implementation in the Maritime Sector	DHS/ TSA	The goal of the rule is to increase the security of the maritime transportation sector by reducing the number of high-risk individuals with access to secure areas in vessels and facilities.	88-415	We converted agency annual cost estimates to 2001 dollars.
Total			1,149- 2,748	

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, agencies have finalized 14 major homeland security regulations that impose a total cost on the economy of between \$3.4 billion to \$6.9 billion a year.¹⁴

C. Regulations Implementing or Adjusting Federal Budgetary Programs

Of the 39 economically significant rules reviewed by OMB, 21 implement or adjust Federal budgetary programs. Of these, two rules were issued by the Department of Commerce, one by the Department of Labor, two rules were issued by the Departments of Agriculture (USDA), two by the Department of Education (ED), twelve by the Health and Human Services (HHS), one by Veterans Affairs (VA), and one by the Social Security Administration (SSA). The budget outlays associated with these rules are “transfers” from taxpayers to program beneficiaries, on behalf of program beneficiaries, or fees collected from program beneficiaries; therefore, consistent with past Reports, OMB refers to these rules as “transfer” rules. These rules are summarized below in Table 1-6.

Table 1-6: Agency Rules Implementing or Adjusting Federal Budgetary Programs, October 1, 2006 to September 30, 2007¹⁵

Rule [FR Cite]	Agency	Beneficiary	Description
Implement and Administer a Coupon Program for Digital-to-Analog Converter Boxes [72 FR 12097]	DOC	\$1.34 billion, beginning October 1, 2006 Federal Government to US households	This regulation implements and administers a coupon program for digital-to-analog converter boxes authorized under the section 3005 of Public Law 109-171, known as the Digital Television Transition and Public Safety Act of 2005.
Public Safety Interoperable Communications (PSIC) Grant Program	DOC	\$1 billion Federal Government to State governments	The Public Safety Interoperable Communications (PSIC) Grant Program is a one-time formula-based, matching grant program intended to enhance public safety interoperable communications with respect to voice, data, and/or video signals.

¹⁴ Although OMB began compiling this list since the creation of DHS, this list includes rulemakings from other agencies, such as the Food and Drug Administration (FDA) regulations implementing the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, which have improving homeland security as a primary benefit.

¹⁵ The benefit and cost estimates for these rules should be treated with caution and may not reflect actual amounts transferred due to a variety of reasons, such as other legislation, changes in program participation, changes in market conditions, etc. Prospective impacts are estimated at the time of rulemaking to reflect, in part or whole, requirements for estimating regulatory impacts as described in Circular A-4 for economically significant rules, and are in general different from annual budget accounting practices, which details current levels of expenditures from these rules. Agencies have used different methodologies and valuations in quantifying and monetizing effects.

Rule [FR Cite]	Agency	Beneficiary	Description
Claims for Compensation Under the Energy Employees Occupational Illness Compensation Program Act of 2000, as Amended	DOL	\$955.70 million(7% discount rate), \$944.70 million (3% discount rate) from 2007 to 2011 Federal Government to eligible employees or survivors	This regulation amends the interim final rule that provides lump-sum payments and medical benefits to covered employees and, where applicable, to survivors of such employees, of the Department of Energy (DOE), its predecessor agencies and certain of its vendors, contractors and subcontractors and to individuals found eligible by the Department of Justice (DOJ) under section 5 of the Radiation Exposure Compensation Act (RECA).
Institutional Eligibility Under the Higher Education Act of 1965, as Amended; Student Assistance General Provisions and Federal Student Aid Programs [71 FR 64378]	ED	964.5 million (7% discount rate), 975.7 million (3% discount rate) from 2006 to 2010 Postsecondary Students; Student Aid Program Participants to Federal Government	The Secretary is amending the Federal Student Aid Program regulations to implement the changes to the Higher Education Act of 1965, as amended (HEA), resulting from the Higher Education Reconciliation Act of 2005 (HERA), Pub. L. 109-171, and other recently enacted legislation specifically for provisions of direct assessment, identity theft, and special allowance payments.
Student Assistance General Provisions and Federal Student Aid Programs--Academic Competitiveness and National Science and Mathematics Access To Retain Talent Grant Programs [71 FR 64402]	ED	\$693.9 million (7% discount rate), \$694.2 million (3% discount rate) in 2005 Federal Government To Postsecondary Students	These final regulations for the Academic Competitiveness Grant Program (ACG) and National SMART Grant programs specify the eligibility requirements for a student to apply for and receive an award under these programs for the 2007-2008 award year, implementing the provisions of the Higher Education Act of 1965 (HEA), as amended by the Higher Education Reconciliation Act of 2005 (HERA) .
Home Health Payment System Rate Update for CY 2007 and Deficit Reduction Act of 2005 Changes to Medicare Payment for Oxygen Equipment and Capped Rental Durable Medical Equipment (CMS-1304-F) [71 FR 65884]	HHS	\$410 million (3 & 7% discount rates, \$2006) in 2007 Federal Government To Medicare home health service providers	This final rule sets forth an update to the 60-day national episode rates and the national per-visit amounts under the Medicare prospective payment system for home health services and sets forth policy changes related to Medicare payment for certain durable medical equipment for the purpose of implementing sections 1834(a)(5) and 1834(a)(7) of the Social Security Act, as amended by section 5101 of the Deficit Reduction Act of 2005.
Changes to the Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates; and Changes to the ASC Payment System in CY 2007 (CMS-1506-F) [71 FR 67960]	HHS	\$620 million in 2007 Federal Government to OPPTS Medicare Providers \$150 million in 2007: Premium Payments from Beneficiaries to Federal Government	This final rule revises the Medicare hospital outpatient prospective payment system, updating the conversion factor and the wage index adjustment for hospital outpatient services, revising the relative APC payment weights using claims data from January 1, 2005, through December 31, 2005, and updated cost report information, and continuing increased payments to rural SCHs, including EACHs.
Revisions to Payment Policies under the Physician Fee Schedule and Ambulance Fee Schedule for Calendar Year 2007 (CMS-1321-FC) [71 FR 69624]	HHS	\$2800 million (\$2007) in 2007 Federal Government to physicians	This final rule with implements certain provisions of the Deficit Reduction Act of 2005, as well as making other changes to Medicare Part B payment policy, intended to ensure that our payment systems are updated to reflect changes in medical practice and the relative value of services.

Rule [FR Cite]	Agency	Beneficiary	Description
Competitive Acquisition for Certain Durable Medical Equipment (DME), Prosthetics, Orthotics, and Supplies (CMS-1270-F) [71 FR 16794]	HHS	\$522.10 million (7% discount rate, \$2007), \$547.9 million (3% discount rate, \$2007) in 2011 from DME suppliers to Federal Government \$130.5 million (7% discount rate, \$2007), \$137 million (3% discount rate, \$2007) in 2011 from DME suppliers to Medicare beneficiaries	This final rule establishes competitive bidding programs for certain Medicare Part B covered items of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) throughout the United States in accordance with sections 1847(a) and (b) of the Social Security Act.
Prospective Payment System for Long-Term Care Hospitals RY 2008: Annual Payment Rate Updates and Policy Changes (CMS-1529-F) [72 FR 26869]	HHS	\$156 million (3% and 7% discount rates) in 2008 Long-term care hospitals to Federal Government	The estimated decrease in Federal payments to LTCH providers for rate year 2008 reflects an updated "Federal rate" increase of 0.6%, a decrease of 1.0% to the "area wage adjustment", a decrease of 0.9% to the revision of the "short stay outlier" policy and a decrease of 2.5% in the "high cost outlier threshold."
Cost Limits for Governmentally-Operated Providers (CMS-2258-F) [72 FR 29748]	HHS	\$735.6 million (7% discount rate, \$2007), \$757.3 million (3% discount rate, \$2007) in 2007-2011(? Check time line?) State governments to Federal Government	This regulation is designed to ensure that Medicaid payments to governmentally-operated health care providers are based on actual costs of providing services to Medicaid individuals and that the financing arrangements supporting those payments are consistent with the statute. Private health care providers are generally unaffected by this rule, except for limited situations where the clarification provided by the regulation may require a change to current financing arrangements.
Medicaid Prescription Drugs--Average Manufacturer Price (CMS-2238-F) [72 FR 39142]	HHS	\$957.8 million (7% discount rate), \$973.6 million (3% discount rate) from 2007 to 2011 Federal Government to State governments \$683.8 million (7% discount rate), \$695.1 (3% discount rate) from 2007 to 2011 State governments to pharmacies	This rule sets the Federal upper reimbursement limit (FUL) as 250 percent of the average manufacturer price (AMP) for drugs on the FUL list, and will clarify the requirements and manner in which AMPs are determined for multiple-source drugs and other drug payment revisions. This rule also lists the physician administered multiple-source drugs that the Secretary determines have the highest dollar volume of dispensing in Medicaid and will require manufacturers to include authorized generics when they report their AMP and best price for covered outpatient drugs to the Secretary.

Rule [FR Cite]	Agency	Beneficiary	Description
Revised Payment System for Services Furnished in Ambulatory Surgical Centers (ASCs) Effective January 1, 2008 (CMS-1517-F) [72 FR 42470]	HHS	<p>Zero net effect;</p> <p>An increase in Medicare payments to ASCs for CY 2008 compared to CY 2007 of approximately \$308 million;</p> <p>Reduced Medicare spending in HOPDs and physicians' offices on services that migrate from these settings to ASCs that offset the increase payments to ASCs;</p> <p>The revised ASC payment system will result in Medicare savings of \$220 million over 5 years as the revised payment rates are fully phased in.</p>	This rule revises the method by which Medicare sets payment rates for ASC facility services and includes illustrative new payment rates for ASC services in accordance with that methodology. This rule finalizes policies proposed as part of the August 23, 2006, CY 2007 Outpatient Prospective Payment System rule.
Prospective Payment System for Inpatient Rehabilitation Facilities for FY 2008 (CMS-1551-P) [72 FR 44283]	HHS	<p>\$150 million in 2008</p> <p>Federal Government to Medicare providers</p>	The estimated increase reflects both an updated "market basket" increase of \$195 million or 3.2% and a decrease to the outlier threshold update of \$45 million or 0.7%
Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities—Update for FY 2008 (CMS-1545-P) [72 FR 43412]	HHS	<p>\$690 million in 2008</p> <p>Federal Government to nursing facilities</p>	This final rule updates the payment rates used under the prospective payment system (PPS) for skilled nursing facilities (SNFs) for fiscal year (FY) 2008.
Changes to the Hospital Inpatient Prospective Payment Systems and FY 2008 Rates (CMS-1533-P) [72 FR 47130]	HHS	<p>\$3837 million in 2008</p> <p>Federal Government to Medicare providers</p>	The rule implements an overall increase of 3.5 percent in operating payments, including hospital reporting of quality data program costs (\$1.89 million) and all operating payment policies, and a capital payments increase of 0.6 percent per case, yielding an estimated capital payments increase of \$282 million in FY 2008 compared to FY 2007.
Home Health Prospective Payment System Refinements and Rate Update for Calendar Year 2008 (CMS-1541-P) [72 FR 49761]	HHS	<p>\$20 million in 2008</p> <p>Federal Government to home health agencies</p>	This rule implements the 3.0 percent home health market basket increase (an estimated additional \$430 million in CY 2008 expenditures attributable only to the CY 2008 home health market basket update), and the 2.75 percent decrease (-\$410 million for the first year of a 3-year phase in) to the HH PPS national standardized 60-day episode rate to account for the nominal increase in case-mix under the HH PPS.

Rule [FR Cite]	Agency	Beneficiary	Description
Medicare Part B Income-Related Monthly Adjustment Amount (2101F) [71 FR 62923]	SSA	Certain High-Income Medicare Part B Beneficiaries to the Medicare SMI Trust Fund. Annual transfers of the rule are expected to be \$1.37 billion (7% discount rate) or \$1.398 billion (3% discount rate) from 2007 to 2011.	Starting in January 2007, the Medicare Part B premium subsidy will be reduced for an estimated 4 to 5 percent of the approximately 40 million Medicare Part B beneficiaries. The reduction of the Federal premium subsidy will result in beneficiaries with modified adjusted gross income above the threshold paying more of the cost of their Medicare Part B benefits through an income-related monthly adjustment amount that will be added to the Medicare Part B standard monthly premium plus any applicable premium increase for late enrollment or reenrollment.
Traumatic Injury Protection Rider to Service members' Group Life Insurance [72 FR 10362]	VA	\$400 million (3% and 7% discount rates, \$2005) where the covered period is 2005 Federal government to beneficiaries	Section 1032 of the "Emergency Supplemental Appropriations Act for Defense, the Global War on Terror, and Tsunami Relief, 2005" established an automatic traumatic injury protection rider to Service members' Group Life Insurance (SGLI) for any SGLI insured who sustains a serious traumatic injury that results in certain losses as prescribed by the Secretary of Veterans Affairs in collaboration with the Secretary of Defense. This rule modifies the interim final rule to provide that a service member must suffer a scheduled loss within 2 years after a traumatic injury, rather than one year. This rule also amends to clarify that a service member does not have to be insured under SGLI in order to be eligible for TSGLI based upon incurrence of a traumatic injury between October 7, 2001, and December 1, 2005, if the member's loss was a direct result of injuries incurred in OEF or OIF.
2005 Hurricane Disaster Assistance Programs [72 FR 875]	USDA	\$250 million (3% and 7% discount rates) where 2005 is the covered period Federal government to farm producers	This final rule sets forth the Farm Service Agency (FSA) regulations for the 2005 Section 32 Hurricane Disaster Programs in response to emergency agricultural situations caused by the 2005 hurricanes Dennis, Katrina, Ophelia, Rita, and Wilma in certain counties in Alabama, Florida, Louisiana, Mississippi, North Carolina, and Texas. This final rule also sets forth provisions related to the 2006 Livestock Assistance Grant Program.
2006 Disaster Assistance Programs [72 FR 6435]	USDA	\$150.5 million (3% and 7% discount rates, \$2006) in 2007 Federal government to farm producers	The rule establishes seven disaster programs to provide funds to eligible producers in counties affected by the 2005 hurricanes Katrina, Ophelia, Rita, Wilma, or a related condition.

It is important to note that rules that transfer Federal dollars often have opportunity costs or benefits in addition to the budgetary dollars spent because they can affect incentives and thus lead to changes in the way people behave (e.g., in their investment decisions). Including budget programs in the overall totals would, however, 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. OMB feels this Report is properly focused on regulations that impose costs primarily through private sector mandates.

At the same time, economists recognize that transfers impose real costs on society because they cause people to change behavior, either by directly prohibiting or mandating certain activities, or by altering prices and costs. The costs resulting from these behavior changes are referred to as the “deadweight loss” associated with the transfer. OMB Circular A-94 suggests that transfers that result from increased taxes may be associated with a marginal excess burden (deadweight loss) of 25 cents per dollar of federal revenue collected (p. 12). More recent estimates noted in the 2008 *Economic Report of the President* range from 30 to 50 cents per dollar of federal revenue collected (p. 116).¹⁶ We seek comment on how to treat these costs in future reports.

We also caution the reader not to assume that these rules were subject to less stringent analysis and review. In fact, agencies thoroughly analyze and OMB thoroughly reviews all significant Federal budget rules under Executive Order 12866. If economically significant, these rules must be accompanied by regulatory impact analyses.

D. Major Rules Issued by Independent Regulatory Agencies

The congressional review provisions of the Small Business Regulatory Enforcement Fairness Act (SBREFA) (Pub. L. No. 104-121) require the Government Accountability Office (GAO) to submit to Congress reports on major rules, including rules issued by agencies not subject to Executive Order 12866 — the so-called independent regulatory agencies. In preparing this Report, we reviewed the information on the benefits and costs of major rules contained in GAO reports for the period of October 1, 2006 to September 30, 2007. GAO reported that three of these agencies issued a total of ten major rules during this period.

As Table 1-7 indicates, one of the rules monetized benefits and costs; two rules monetized benefits and two 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 Executive Order 12866, since OMB does not review rules from these agencies.

OMB provides in the Appendix C of this Report a summary of the information available on the regulatory analyses for major rules by the independent agencies over the past ten years. This summary is similar to the ten-year look-back for social regulation included in recent Reports. It examines the number of major rules promulgated by independent agencies as reported to the GAO from 1998 through 2007, which we present in Table C-1. The reader should note that OMB did not finalize a Report in 1999. OMB reconstructed the estimates for this period based on GAO reports. Prior to the 2003 Report, OMB did not report on independent agency major rules on a fiscal year basis, but rather on an April-March cycle. Similar to last year, OMB is reporting all of the rules from 1998 through 2007 on a fiscal year basis (see Table C-1). The number of rules presented in earlier Reports therefore, may not match the number of rules presented here. We also present information on the extent to which the independent agencies reported benefit and cost information for these rules in Tables C-2 through C-4.

¹⁶ Council of Economic Advisers (2008). *Economic Report of the President*, p. 116.

**Table 1-7: Major Rules Issued by Independent Regulatory Agencies,
October 1, 2006 to September 30, 2007**

Agency	Rule	Information on Benefits or Costs	Monetized Benefits	Monetized Costs
Federal Communications Commission	Service Rules for the 698-806 MHz Band, Revision of the Commission's Rules Regarding Public Safety Spectrum Requirements, and a Declaratory Ruling on Reporting Requirement under the Commission's Anti-Collusion Rule (72 FR 48814)	No	No	No
Federal Communications Commission	Review of the Emergency Alert System (72 FR 62123)	No	No	No
Nuclear Regulatory Commission	Revision of Fee Schedules; Fee Recovery for FY 2007 (72 FR 31402)	No	No	No
Securities and Exchange Commission	Executive Compensation and Related Person Disclosure (71 FR 53158)	Yes	No	Total cost of over \$250 million
Securities and Exchange Commission	Mutual Fund Redemption Fees (71 FR 58257)	Yes	No	\$668 million in one-time capital cost savings; \$175 million in annual cost savings
Securities and Exchange Commission	Internal Control Over Financial Reporting in Exchange Act Periodic Reports of Non-Accelerated Filers and Newly Public Companies (71 FR 76580)	Yes	No	No
Securities and Exchange Commission	Internet Availability of Proxy Materials (72 FR 4148)	Yes	\$16-\$80 million annually	\$48.3-\$241.4 million annually
Securities and Exchange Commission	Termination of a Foreign Private Issuer's Registration of a Class of Securities Under Section 12(g) and Duty to File Reports Under Section 13(a) or 15(d) of the Securities Exchange Act of 1934 (72 FR 16934)	Yes	No	\$200 million in 1 st year
Securities and Exchange Commission	Amendments to the Rules Regarding Management's Report on Internal Control Over Financial Reporting (72 FR 35310)	Yes	No	No
Securities and Exchange Commission	Shareholder Choice Regarding Proxy Materials (72 FR 42222)	Yes	\$2.7-\$29.4 million	No

E. Scorecard Measures for Compliance with Relevant OMB Guidance on Quality of Regulatory Analysis

A number of peer reviewers and commenters on the draft 2007 Report to Congress on the Benefits and Costs of Federal Regulation and previous reports urged us to develop “scorecards” to evaluate the extent to which agencies’ regulatory analyses comply with OMB guidance and to report the scorecard results in the future reports. The relevant guidance would include OMB Circular A-4 and Circular A-94. Their recommendations include:

- Developing a minimum scorecard based on OMB guidance (e.g., Circular A-4, Circular A-94) for all rules with “outs” for statutory exemptions;
- Including a scorecard showing the number and percentage of final regulations that pass or fail a benefit-cost test based strictly on factors that can be quantified and expressed in monetary terms;
- Requesting that all agencies report on the extent to which they comply with OMB’s guidelines for conducting regulatory analysis using a regulatory scorecard and OMB should summarize the information and present it in a user-friendly format;
- Holding agencies accountable both for following guidelines and reporting the extent to which that happens.

For such a scorecard to be effective, the metrics should be both objective and meaningful, which is challenging. Objective metrics can measure whether an agency performed a particular type of analysis, but may not indicate how well the agency performed this analysis. In addition, the metrics may be too broad to reflect agency compliance with specific guidance on technical matters (e.g., how to conduct an underlying contingent valuation study that provides key information to a regulatory analysis). We seek comment on the following possible questions for use in a scorecard:

1. Does the analysis include a statement of need for Federal regulation, including market failure or other compelling public purpose?
2. Does the analysis identify and examine a sufficient number of reasonable alternative approaches?
3. Does the analysis quantify and monetize benefits and costs of proposed action?
4. Does the analysis quantify and monetize benefits and costs of main alternative approaches?
5. Does the analysis discount future benefit and cost streams at 3% and 7%?
6. For public health and safety regulations, does the analysis include cost-effectiveness analysis?
7. Are uncertainties in estimates clearly presented? Does the analysis contain a formal uncertainty analysis if rulemaking has more than a \$1 billion cost or benefit in any one year?
8. Does the analysis provide a separate description of significant distributional effects?
9. Is a break-even analysis presented for rules with substantial unquantifiable benefits?

We noted in OMB Circular A-4 that an agency

cannot conduct a good regulatory analysis according to a formula. Conducting high quality analysis requires competent professional judgment. Different

regulations may call for different emphases in the analysis, depending on the nature and complexity of the regulatory issues and the sensitivity of the benefit and cost estimates to the key assumptions.¹⁷

We are concerned that publishing scorecards may inadvertently introduce incentives for agencies to attempt to apply a cookbook-approach to regulatory analyses. To that end we seek comment on the usefulness of the scorecard concept.

We are particularly interested in comments addressing the following questions:

1. Are the metrics objective?
2. Are there other objective measures that indicate compliance with OMB guidance?
3. Is there a concern that limiting a scorecard to a relatively small number of measures will have the perverse effect of increasing compliance with the bare minimum requirements on the scorecard at the expense of overall quality of the analysis because the scorecard fails to address critical elements of regulatory analysis?
4. Should the agencies report the extent to which they comply with relevant OMB guidance?

F. The Impact of Federal Regulation on State, Local, and Tribal Governments, 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 ten 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 Reform Act of 1995).¹⁸

- *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

¹⁷ OMB Circular A-4, p. 3. <http://www.whitehouse.gov/omb/circulars/a004/a-4.pdf>

¹⁸We 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." (2U.S.C. § 1532 (a)) 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." (H.R. Conf. Rep. No. 104-76 at 39 (1995)) 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.

14,000 of the estimated 75,000 covered water systems nationwide. The costs of the rule are estimated at \$700 million annually. The quantified benefits estimates range from zero to 9,300 avoided bladder cancer cases annually, with an estimated monetized value of \$0 to \$4 billion per year. Possible reductions in rectal and colon cancer and adverse reproductive and developmental effects were not quantified.

- *EPA's National Primary Drinking Water Regulations: Interim Enhanced Surface Water Treatment (1998)*: This rule establishes new treatment and monitoring requirements (primarily related to filtration) for drinking water systems that use surface water as their source and serve more than 10,000 people. The purpose of the rule is to enhance health protection against potentially harmful microbial contaminants. EPA estimated that the rule will impose total annual costs of \$300 million per year. The rule is expected to require treatment changes at about half of the 1,400 large surface water systems, at an annual cost of \$190 million. Monitoring requirements add \$96 million per year in additional costs. All systems will also have to perform enhanced monitoring of filter performance. The estimated benefits include average reductions of 110,000 to 338,000 cases of cryptosporidiosis annually, with an estimated monetized value of \$0.5 to \$1.5 billion, and possible reductions in the incidence of other waterborne diseases.
- *EPA's National Pollutant Discharge Elimination: System B Regulations for Revision of the Water Pollution Control Program Addressing Storm Water Discharges (1999)*: This rule expands the existing National Pollutant Discharge Elimination System program for storm water control. It covers smaller municipal storm sewer systems and construction sites that disturb one to five acres. The rule allows for the exclusion of certain sources from the program based on a demonstration of the lack of impact on water quality. EPA estimates that the total cost of the rule on Federal and State levels of government, and on the private sector, is \$803.1 million annually. EPA considered alternatives to the rule, including the option of not regulating, but found that the rule was the option that was “most cost effective or least burdensome, but also protective of the water quality.”
- *EPA's National Primary Drinking Water Regulations; Arsenic and Clarifications to Compliance and New Source Contaminants Monitoring (2001)*: This rule reduces the amount of arsenic that is allowed to be in drinking water from 50 ppb to 10 ppb. It also revises current monitoring requirements and requires non-transient, non-community water systems to come into compliance with the standard. This rule may affect either State, local or tribal governments or the private sector at an approximate annualized cost of \$206 million. The monetized benefits of the rule range from \$140 to \$198 million per year. The EPA selected a standard of 10 ppb because it determined that this was the level that best maximizes health risk reduction benefits at a cost that is justified by the benefits, as required by the Safe Drinking Water Act.
- *EPA's 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.

- *EPA's National Primary Drinking Water Regulations: Stage 2 Disinfection Byproducts Rule* (2006): The rule protects against illness due to drinking water disinfectants and disinfection byproducts (DBPs).¹⁹ The rule effectively tightens the existing standards by making them applicable to each point in the drinking water distribution system individually, rather than only on an average basis to the system as a whole. EPA has determined that this rule may contain a Federal mandate that results in expenditures of \$100 million or more for the State, local, and tribal governments, in the aggregate in the private sector in any one year. While the annualized costs fall below the \$100 million threshold, the costs in some future years may be above the \$100 million mark as public drinking water systems make capital investments and finance these through bonds, loans, and other means. EPA's year-by-year cost tables do not reflect that investments through bonds, loans, and other means spread out these costs over many years. The cost analysis in general does not consider that some systems may be eligible for financial assistance such as low-interest loans and grants through such programs as the Drinking Water State Revolving Fund.
- *DHS's Chemical Facility Anti-Terrorism Standards Rule* (2007): This rule establishes risk-based performance standards for the security of our nation's chemical facilities. It requires covered chemical facilities to prepare Security Vulnerability Assessments (SVAs), which identify facility security vulnerabilities, and to develop and implement Site Security Plans (SSPs), which include measures that satisfy the identified risk-based performance standards. The rule also provides DHS with the authority to seek compliance through the issuance of Orders, including Orders Assessing Civil Penalty and Orders for the Cessation of Operations. DHS has determined that this rule constitutes an unfunded mandate on the private sector. In the regulatory impact assessment published with this rule, DHS estimated that there are 1,500 to 6,500 covered chemical facilities. DHS also assumed that this rule may require certain municipalities that own and/or operate power generating facilities to purchase security enhancements. Although DHS was unable to determine if this rule will impose an enforceable duty upon State, local, and tribal governments of \$100 million (adjusted annually for inflation) or more in any one year, for the sake of completeness, we have included it in this list.

Although these seven rules were the only ones over the past ten years to require expenditures by State, local and tribal governments exceeding \$100 million (adjusted for inflation), they were not the only rules with impacts on other levels of governments.

¹⁹ While causal links have not been definitively established, a growing body of evidence has found associations between exposure to DBPs and various forms of cancer, as well as several adverse reproductive endpoints (e.g., spontaneous abortion).

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.

Research by the Small Business Administration (SBA) Office of Advocacy suggests that small entities disproportionately shoulder regulatory and paperwork burdens. The Office of Advocacy has sponsored three studies that estimate the burden of regulation on small businesses.²⁰ The most recent study, published in 2005, found that regulatory costs per employee decline as firm size—as measured by the number of employees per firm—increases. The Office of Advocacy estimates that the total cost of Federal regulation (environmental, workplace, economic, and tax compliance regulation) was 45 percent greater per employee for firms with fewer than 20 employees compared to firms with over 500 employees. The Office of Information and Regulatory Affairs (OIRA), along with the Office of Advocacy and other Federal regulatory agencies, is working both to minimize unnecessary burdens, and also to help America’s small businesses comply with regulatory and reporting requirements.

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 is expected to 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.

²⁰Crain, W.M. 2005. “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/advo/research/rs264tot.pdf>. The 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 the Office of Advocacy’s website.

1. Annual Report of the Chief Counsel for Advocacy on Implementation of the Regulatory Flexibility Act

The Office of Advocacy reports annually on the overall performance of agency compliance with the RFA and Executive Order 13272, and the Office of Advocacy efforts to improve the analysis of small business impacts and to persuade agencies to afford relief to small businesses. The comprehensive report for FY 2007 is available at <http://www.sba.gov/advo/laws/flex>. It provides a summary of agency compliance in FY 2007 with Executive Order 13272 and the RFA, and an agency-by-agency review of RFA compliance. In addition, the FY 2007 report adds a new chapter on the RFA's "lookback" provision, section 610. RFA section 610 requires agencies, in addition to examining the effects of proposed regulations, to review existing regulations to determine if they are outdated, duplicative, or overly complex.

2. Small Business Regulatory Review and Reform Initiative, and Section 610 Review of Regulations

To facilitate better agency compliance with the RFA section 610, the Office of Advocacy launched a new initiative in FY 2007, the Regulatory Review and Reform or "r3" initiative. The initiative is designed to (1) assist agencies and small business stakeholders to better understand and benefit from section 610 reviews of existing rules, and (2) give interested small entities the opportunity to nominate existing agency rules for review and potential reform.

The r3 initiative consists of two related activities. First, after a process in which more than 80 nominations were received, the Office of Advocacy identified the top 10 rules to be put forward for agency review in 2008. Four of the reforms recommended, DOL's Mine Safety and Health Administration's explosives standards, and EPA rules on community drinking water systems, spill prevention control and countermeasure requirements, and recycling solid waste, are similar to nominations OMB received in our 2004 manufacturing initiative and previous reform nomination cycles²¹. More information about the r3 initiative can be found at <http://www.sba.gov/advo/r3/>.

Second, in the fall of 2007 Advocacy released revised and more comprehensive best practice guidance on section 610 analysis. This guidance is available at http://www.sba.gov/advo/r3/r3_section610.html. Advocacy recommends that agencies focus on: whether or not the rule is still needed, whether the public has submitted complaints, whether the rule can be simplified, whether other rulemaking accomplish the same purpose, and whether circumstances have fundamentally changed that may affect the need for the rule. Especially important, according to the guidance, is to consider changes in technology, economic circumstances, competitive forces, and the cumulative burden faced by regulated entities. The guidance also gives "best practice" examples, including the Federal Railway Administration's 2003 review of railroad workplace safety, EPA's Resource Conservation and Recovery Act

²¹ Please see Appendix D for an update to the 2004 OMB manufacturing regulatory reform nominations.

review leading to recordkeeping changes in 2006, OSHA's 2007 evacuation standard review, and FCC's 2005 comprehensive review of rules adopted from 1993-1995.

Agencies also have an obligation to publish their scheduled 610 reviews in their semi-annual Unified Regulatory Agenda. In the fall of 2007, for the first time, all such agenda entries became available in an electronic format that offers users an enhanced ability to obtain and search for information on upcoming regulations. More information on Section 610 reviews performed by agencies can be found by using the advanced search features of the "e-agenda" available at <http://www.reginfo.gov/public/do/eAgendaAdvancedSearch>.

Please visit the Office of Advocacy's website at <http://www.sba.gov/advo> to learn more about the Office of Advocacy, review regulatory comment letters, and obtain useful research relevant to small entities.

3. The Paperwork Reduction Act and Small Businesses

One regulatory burden of particular concern to small business is paperwork burden. In conducting our reviews of agency information collection requests, OIRA is particularly sensitive to collections that affect small businesses. Indeed, in the Paperwork Reduction Act (PRA) statement of "purposes" identifies as a key PRA goal minimizing the "paperwork burden" on "small businesses." The PRA also provides specific direction to agencies on how they can minimize the burdens that they impose on small businesses, using approaches such as "(i) establishing differing compliance or reporting requirements or timetables that take into account the resources available to those who are to respond; (ii) the clarification, consolidation, or simplification of compliance and reporting requirements; or (iii) an exemption from coverage of the collection of information, or any part thereof."

When the PRA was reauthorized in 1995, Congress added a requirement that agencies certify, as part of their requests for OMB approval of an information collection, that the collection "reduces to the extent practicable and appropriate the burden" on small businesses and other small entities. OMB added this certification requirement to the OMB PRA implementing regulations (5 C.F.R. 1320.9(c)). In addition, agency information collection requests submitted to OMB must indicate whether the information collection will have a "significant economic impact on a substantial number of small entities."

The Small Business Paperwork Relief Act of 2002 (SBPRA) further reinforced the PRA's focus on minimizing small business paperwork burdens by establishing a multi-agency Task Force to address this issue. On June 28, 2003, the SBPRA Task Force submitted its first report to Congress, which included a number of recommendations to streamline the Federal information submission process and reduce small business paperwork burdens. Specifically, the report outlined steps to consolidate information collections, develop a listing of these collections, and allow for electronic submission of forms.

One year later, the SBPRA Task Force submitted a second report to Congress that made recommendations concerning the dissemination of information by agencies to facilitate

compliance with Federal paperwork requirements. The SBPRA also amended the PRA to require agencies to “make efforts to further reduce the information collection burden for small business concerns with fewer than 25 employees.”

Motivated by these statutory requirements, Federal agencies have taken a number of steps over the past several years to reduce the amount of information they collect from small businesses and to ease their compliance burdens, often through the innovative use of information technology. Nonetheless, we have seen government-wide paperwork burdens increase over time, as OMB has documented in its annual Information Collection Budget report (ICB) submitted to Congress pursuant to the PRA. Government-wide PRA burden increased from 8.92 billion hours in FY 2006 to 9.64 billion hours in FY 2007, an increase of more than 8 percent.

A recurring theme of the ICB in recent years has been the very large role played by the Internal Revenue Service (IRS) in the Federal government’s information collection activities. Because of the Federal income tax system, the IRS is an important part of the lives of all taxpayers, including businesses large and small. This fact was again reflected in this year’s ICB, when OMB reported that IRS was responsible for about 79 percent of the Federal government’s total reporting burden on the public in FY 2007.

Despite these broader trends of aggregate burden increases, agencies have been able to achieve some notable burden reduction successes. For example, the Internal Revenue Service has made changes to the Employer’s Annual Federal Tax Program. As reported in last year’s ICB, the IRS Office of Taxpayer Burden Reduction recently launched an initiative to reduce burden on small business taxpayers who owe \$1,000 or less in Employment Tax (ET) by establishing new rules and processes that will allow them to file their ET returns, as well as pay the ET tax due, on an annual rather than a quarterly basis. As long as these filers remain at \$1,000 or less in total Employment Tax they will remain filers of Form 944, the Employer’s Annual Employment Tax Return. Those businesses that exceed this threshold will be subject to the requirement to file Form 941, the Employer’s Quarterly Employment Tax Return. By allowing smaller businesses to file annually instead of quarterly, IRS estimated that reporting burdens would drop by almost 30 million hours.

4. Small Business Administration Business Gateway

OMB also works with SBA’s Business Gateway program which offers businesses a single access point to Federal regulatory and paperwork compliance resources, including forms and tools. The program, which includes Business.gov, Forms.gov, and data harmonization activities, reduces the amount of resources business owners spend on complying with Federal regulations and associated paperwork. Specifically, Business.gov simplifies and improves businesses’ ability to locate government compliance guides and forms they deal with on a regular basis, thereby reducing the effort needed to comply with government regulations. Using a voluntary customer satisfaction survey on Business.gov, business owners have self-reported saving over 2.9 million hours (between October 2007 and July 2008) by using the portal. Since the re-launch of Business.gov in October 2006, business owners have self-reported a total of almost 6.2 million hours saved.

Business.gov is an innovative and search-focused website where businesses can access up-to-date regulatory and paperwork compliance information and save time doing so. The information available through Business.gov was assembled by reaching across agency silos to make content accessible and relevant to the business community. Business Gateway epitomizes the spirit and intent of the PRA by helping businesses save time getting answers to important questions including: (1) What laws and regulations apply to me?; (2) How do I comply?; and (3) How do I stay in compliance?

The Business Gateway program also promotes “data harmonization,” which is defined as the reduction of regulatory reporting burden on citizens and business by reducing the complexity of reporting processes and improving the reuse and distribution of information across Federal, State, and local agencies. Business Gateway supports data harmonization by advocating for and supporting data harmonization solutions. Business Gateway released a comprehensive analysis on data harmonization in August 2008. The analysis includes five case studies to depict various levels of Federal, State, agency, and industry participation.

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.²²

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 their associated wage costs and such costs are not borne primarily by workers.²³ Although wages may reflect the cost of compliance with health and safety rules, the job safety and other benefits of such regulation

²²From Ehrenberg, R. and R. Smith 1991. *Modern Labor Economics*, 4th Edition. HarperCollins, p. 279.

²³Based 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).

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.²⁴ 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, as consumers, they face higher prices for goods that are inefficiently produced. Moreover, growth in real wages, which are limited generally by productivity increases, will not grow as fast without the stimulation of outside competition.²⁵

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 understood are the relationships between growth rates and indicators of well being with the degree of government control and the quality of regulation among mixed economies.²⁶

Several groups of researchers have developed indicators of economic freedom to rank countries and compare their economic performance. Since 1995, the Heritage Foundation and

²⁴ Historical examples of economic regulation were the Federal regulations on the airline and trucking industries before these markets were deregulated.

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

²⁶ A 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.

the *Wall Street Journal* have published jointly a yearly index of economic freedom. For 2008 it includes 162 countries.²⁷ The index is composed of independent variables divided into ten broad factors that attempt to measure different aspects of economic freedom: business freedom, trade freedom, fiscal freedom, government size, monetary freedom, investment freedom, financial freedom, property rights, freedom from corruption, and labor freedom. The report finds a very strong relationship between the index and per capita Gross Domestic Product (GDP). According to the index presented in the 2008 report, the world's freest countries have twice the average per capita income of the second quintile of countries, and over five times the average income of the fifth quintile of countries. A correlation between degrees of economic freedom and per capita GDP cannot 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 overtime. The data indicate that countries that improved their index of economic freedom over the 14 years of the index improved their economic growth.

Since 1997, the Fraser Institute of Vancouver, B.C. has published the Economic Freedom of the World index, which now includes data for 141 countries.²⁸ The rank order of the top ten economies is Hong Kong, Singapore, New Zealand, Switzerland, Canada, United Kingdom, United States, Estonia, Australia and Ireland. The index, which now includes 42 data points, 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 percent, adult literacy, corruption-free governance, civil liberties, the United Nations' Human Development Index, infant survival rates, the environment 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 benefits and costs 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 limitations. 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.

In an attempt to provide less subjective measures of regulatory quality, the World Bank has undertaken 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. Five volumes have been published. The first volume (*Doing Business in 2004, Understanding Regulation*) of the annual series examines

²⁷The latest version of this Report is *The 2008 Index of Economic Freedom*. (Heritage Foundation/WallStreet Journal).

²⁸The latest version of this Report is James Gwartney and Robert Lawson, *Economic Freedom of the World: 2007 Annual Report*. Fraser Institute, Vancouver, BC.

for five fundamental aspects of a firm's life cycle: starting a business, hiring and firing workers, enforcing contracts, obtaining credit, and closing a business.²⁹ The second volume (*Doing Business in 2005, Removing Obstacles to Growth*) updates these measures and adds data about registering property and protecting investors.³⁰ *Doing Business in 2006, Creating Jobs*, updates the previous measures and added three more sets of indicators: dealing with licenses, paying taxes, and trading across borders.³¹ *Doing Business in 2007, How to Reform*, and *Doing Business 2008* document specific reforms that countries have made to improve their ranking and refine the methodology and data used in the rankings. Each volume expanded the number of countries rated. The 2004 volume examined 130 countries; the 2008 volume examined 178.

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 higher ranking on the ease of doing business metrics is associated with job creation. The fourth and fifth volumes refine the methodology and data, and reinforce these findings.

The World Bank found that rich countries regulate less in all respects covered in the report and that common law and Nordic countries regulated less than countries whose legal systems are based on socialist principles. The World Bank study found that both labor productivity and employment were positively correlated with less regulation. The study found that heavier regulation was associated with greater inefficiency of public institutions and more corruption. The resulting regulation often had a perverse effect on the people it was meant to protect. Overly stringent regulation of business created strong incentives for businesses to operate in the underground or informal economy. The study estimated 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 percentage point increase in annual economic growth.

Based on its analysis of the impact of regulation on economic performance, the World Bank concluded 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.

²⁹World Bank. *Doing Business in 2004: Understanding Regulation*. Oxford Press. Washington, DC.

³⁰World Bank. *Doing Business in 2005: Removing Obstacles to Growth*. Oxford Press. Washington, DC.

³¹World Bank. *Doing Business in 2006: Creating Jobs*. Washington, DC.

3. Expand the use of technology.
4. Reduce court involvement in business matters.
5. Make reform a continuous process.

In 2008, the top ten countries ranked on the ease of doing business based on the ten indicators were in order: Singapore, New Zealand, the United States, Hong Kong (China), Denmark, the United Kingdom, Canada, Ireland, Australia, and Iceland.³²

Also in 2008, the Independent Evaluation Group (IEG), an independent unit within the World Bank, issued a report, *Doing Business: An Independent Evaluation* that found that the Doing Business report had been highly effective in measuring and drawing attention to the burdens of business regulation. It also offered recommendations to make the indicators more transparent and useful, and warned that policy should not be based just on indicators that can be easily measured. In the same report, the World Bank Group management concurred with the broad thrust of the conclusions and pledged to continue to refine and improve the indicators as well as more fully utilize the expertise of World Bank country and regional units.³³

The negative 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 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.³⁴

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.³⁵ 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.

³²See *Doing Business in 2008*, p. 6. 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.

³³ See IEG, *Doing Business: An Independent Evaluation*, 2008.

³⁴Giuseppe 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).

³⁵See Giuseppe Nicoletti and Frederic Pryor, "Subjective and Objective Measures of the Extent of Government Regulation," *Journal of Economic Behavior and Organization* (2006), vol 59(3), Table 3.

The major efforts to determine the effect of regulatory policies on economic performance use different indicators of regulatory quality and examine different types of regulation, yet reach very similar conclusions. Giuseppe Nicoletti and Frederic Pryor examined three different indices of regulation, one objectively estimated and two based on subjective surveys of businessmen: one index examined only product markets, a second index examined both product and labor markets, and the final index includes financial and environmental regulations. The paper found statistically significant correlations among the three indices, despite the differences in coverage and methodologies.³⁶ A second group of researchers, who have done work for the World Bank, also found 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.”³⁷ Thus, countries with good records on entry regulation (which they point out includes some environmental regulation) also have good records on labor regulation.³⁸ A recent paper by Aghion, Algan, Cahuc, and Shleifer explores the cultural explanation for regulatory differences and the correlation between the different forms of regulation more fully.³⁹ It finds strong correlations for 56 countries between distrust (as measured by the World Values Index) and various measures of the degree of regulation including measures developed by the World Bank. They explain that distrust fuels support for government control over the economy while excessive regulation, itself, leads to distrust. When individuals distrust others it creates a negative externality causing a demand for regulation. In turn, regulations are implemented and enforced by officials, who the public resents thereby reducing investment in social capital and increasing distrust. As they point out their analysis points to a broad complementarity between social capital and free market economics, which calls for further research.

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.⁴⁰ 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.⁴¹ For

³⁶*Ibid.*

³⁷Juan Botero, Simeon Djankov, Rafael La Porta, Florencio Lopez-de-Salinas, and Andrei Shleifer, “The Regulation of Labor,” *The Quarterly Journal Of Economics* (2004).

³⁸*Ibid.*

³⁹ See Philippe Aghion, Yann Algan, Piere Cahac, and Andrei Shlifer, “Regulation and Distrust” Havard Economic Department Papers (July 3, 2008).

⁴⁰Note 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 terms product market and labor market regulation to describe the different types of regulation.

⁴¹Although 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.

social regulation, Circular A-4 requires identification of market failure or other compelling need, and an analysis of the benefits and costs of regulations and their alternatives. In this case, smarter regulation may result in 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. Finally, social regulation as well as economic regulation can be motivated by rent seekers.⁴²

G. eRulemaking Program: The First Five Years and a Benefit-Cost Analysis

eRulemaking is a cross-agency Program that facilitates *Regulations.gov* and the back-end “feeder” system to *Regulations.gov*, the Federal Docket Management System (FDMS).

Regulations.gov has transformed the way the public can search, view, and comment on all federal regulatory actions. The government-wide portal increases transparency of the entire federal regulatory process by making complete dockets of information easily accessible and available for comment. By leveraging technology, *Regulations.gov* enables a rule watcher, especially a “first time” commenter, to find relevant rules without having first to know which agency is issuing the rule or a specific tracking number. The searchable database provides context at the docket level showing each stage of the rulemaking process including the Unified Agenda, supporting documents, public comments and final rule. The portal has also adopted innovative features that, five years ago, were not considered an important part of the rulemaking process, such as RSS feed, email notifications, book marking, and electronic records management.

Regulations.gov currently serves 31 departments and agencies comprising over 175 federal entities. One hundred percent of the federal government's regulatory actions are available for comment, and approximately 90 percent of these include the entire docket of information (e.g. supporting materials).

Prior to *Regulations.gov*, most federal entities conducted paper-based operations and may or may not have operated a central docket location. If members of the public were interested in accessing materials supporting an agency's regulatory proposal or action, they often had to contact an individual and make arrangements to view a copy or pay photocopying costs. Agencies can now make these materials available on the Internet for the public to view or download at no cost.

In June 2007, the eRulemaking program conducted a benefit-cost analysis of alternative approaches to providing the public the ability to participate in the regulatory process. One option evaluated was for agencies to operate strictly paper-based processes without offering electronic access to the public. The analysis estimated that over the course of five years, the government would spend over \$30 million more in associated paper management processes compared to the centralized solution provided by *Regulations.gov*. These estimated costs were above and beyond

⁴² See Bruce Yandle, “Bootleggers and Baptists: the Education of a Regulatory Economist” *Regulation* 7, no.3 (1983):12.

the lost benefits electronic access provides both users and government agencies. In addition to the paper-based option, the benefit-cost analysis compared two other alternatives, each providing electronic access and similar services currently provided by Regulations.gov. One alternative was for all agencies serviced by *Regulations.gov* to create their own system and the other alternative was for larger departments to each create a system that its sub-agencies could use. The analysis estimated that these alternatives would cost an additional \$129 and \$106 million respectively, compared to the centralized solution that *Regulations.gov* provides to all federal entities.

Another eRulemaking initiative was the publication of the Unified Agenda of Federal Regulatory and Deregulatory Actions as a fully-searchable electronic database in 2007. The shift from paper to the Internet will help save Federal regulatory agencies an estimated \$800,000 per year, and for the first time, allow the public to search current regulatory information and historical content.

In June 2007, the eRulemaking program conducted a Benefit Cost Analysis to quantify alternatives that would provide the public with the ability to participate in the regulatory process via the Internet. *Regulations.gov* is the current solution that the eRulemaking Program manages, which currently services 31 Departments and independent agencies comprising over 175 federal entities. Although 100 percent of the federal government's regulatory actions are available for comment, approximately 90 percent of these include the entire docket of information (e.g. supporting materials).

Prior to *Regulations.gov*, most federal entities conducted paper-based operations and may or may not have operated a central docket location. If members of the public were interested in accessing materials supporting an agency's regulatory proposal or action, they often had to contact an individual and make arrangements to view a copy or pay photocopying costs. Agencies can now make these materials available on the Internet and the public can view or download at no cost.

The Benefit Cost Analysis conducted by the eRulemaking program included estimated costs for agencies to operate strictly paper-based processes without offering electronic access to the public and found that over the course of five (5) years, it would cost the government over \$30 million more in associated paper management processes without realizing the benefits of electronic access than it does to use the centralized solution provided by *Regulations.gov* discounting all of the additional benefits electronic access provides. In addition to the paper-based option, the Benefit Cost Analysis also compared two other alternatives--each providing electronic access and similar services currently provided by Regulations.gov. One alternative was for all agencies serviced by *Regulations.gov* to create their own system and the other alternative was for larger departments to each create a system that its sub-agencies could use. The analysis found that each of these alternatives were estimated to cost an additional \$129 million and \$106 million respectively as compared to the centralized solution that *Regulations.gov* provides to all federal entities.

CHAPTER II: TRENDS IN BENEFIT AND COST ESTIMATES

Since OMB began to compile records in 1981 through the end of fiscal year 2007, Federal agencies have published 125,709 final rules in the *Federal Register*. Of these final rules, 21,549 were reviewed by OMB under Executive Order 12866 or its predecessor, Executive Order 12291. Of these OMB-reviewed rules, 1,231 were considered “major” rules, primarily due to their anticipated impact on the economy (e.g., estimated benefits and/or costs 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 279 major rules with estimated benefits and/or costs to the private sector or State and local governments of over \$100 million annually.

Previous reports have also presented estimates of the overall costs of major rules issued by Federal agencies since 1981. The estimates are based on the *ex ante* cost estimates found in agency regulatory impact analyses reviewed by OMB under Executive Order 12291 prior to September 1993 and under Executive Order 12866 since then. The reports point out some of the concerns we have with these estimates, including that, because they are prospective, they might not present an accurate picture of these regulations’ actual impacts. Chapter III of our 2005 Report surveys what we know about the validation of *ex ante* estimates of benefits and costs of Federal regulation by *ex post* studies.

The best measure of the overall value of regulation is net benefits; that is, benefits to society minus costs to society. Below we present benefits and cost measures for the years 1992 to 2007 for 146 rules, for which reasonably complete monetized estimates of both benefits and costs are 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.⁴³

In exploring the impact of rulemaking on the economy in the early 1980s, we found that several important deregulatory actions resulted in a net decrease in compliance costs. 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, the Department of Transportation (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. Similarly, Occupational Safety and Health Administration’s (OSHA) 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 2001.⁴⁴ Another important change is the inclusion of DOT’s 1993 air bag rule, which had been left out of our calculations in 1993

⁴³To present benefits and cost estimates by year, we generally used agency estimates of central tendency when available and took midpoints when not available. OMB does not have benefits estimates for years prior to 1992. We include the estimated costs of the 2005 Department of Homeland Security’s air cargo security requirements rule in Table 2-1, but not in net benefits estimates for lack of quantifiable benefits attributable to this rule. Similarly, we include benefits for the 2005 migratory bird rules, but not the costs.

⁴⁴We have used alternative methods to account for OSHA’s ergonomics rule and its repeal (i.e., excluding costs as well as benefits of the rule in 2000 and 2001), which results in small changes to trends reported in this chapter, but not their direction. We note these changes where appropriate.

because Congress had mandated the rule.⁴⁵ We made this change to be consistent with OMB Circular A-4, Regulatory Analysis, issued in September 2003. Circular A-4 states that in situations where a rule simply restates statutory requirements, incremental benefits and costs 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 finalized several key implementing 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 benefit and cost 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, 2007. Over the last 27 years, \$139 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, a little over \$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). The average annual costs of the regulations issued over the past seven years is 24 percent lower than the average annual costs of the regulations issued during the previous 20 years.⁴⁶

⁴⁵Our estimate of \$4 billion in annual benefits and \$3 billion in annual costs reflects the assumption that without the rule, 50 percent of the benefits and costs of airbags would have been provided by the market.

⁴⁶Note that this trend would have been 7 percent if the ergonomics rule were not included.

Figure 2-1: Costs of Major Rules (1981-2007)

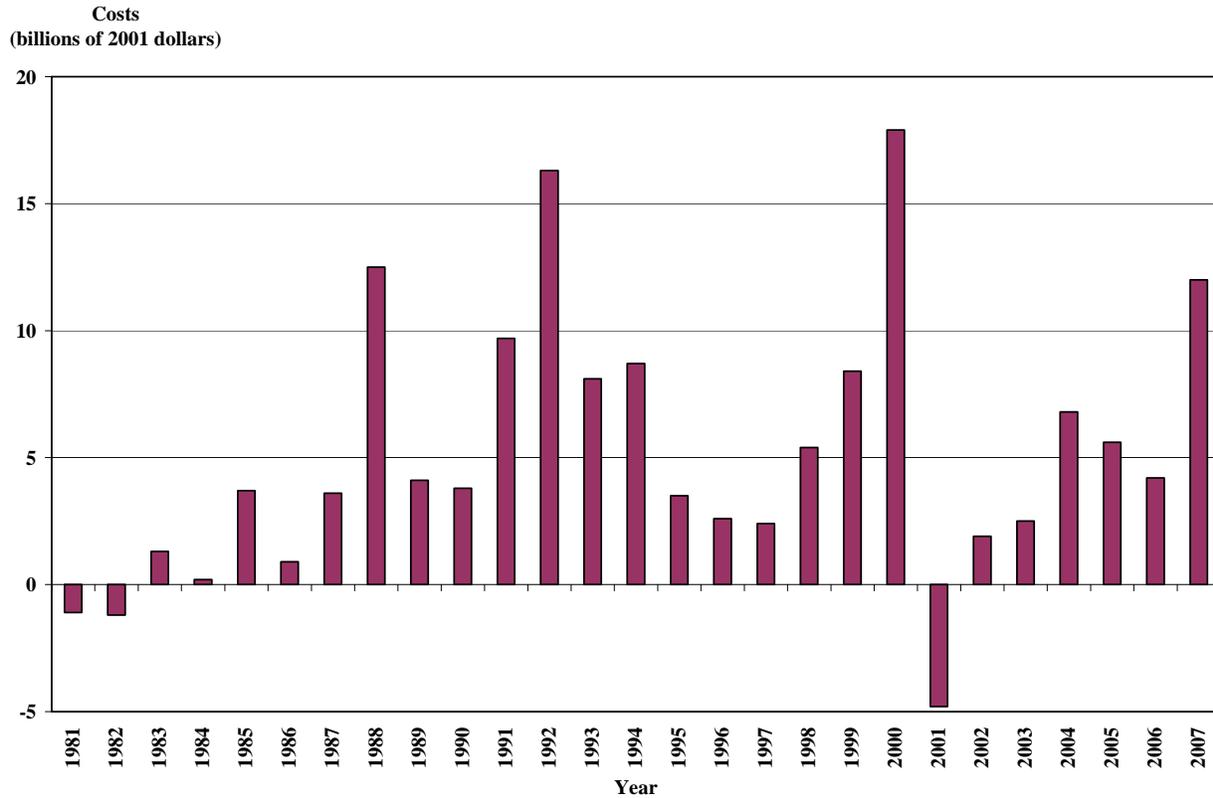
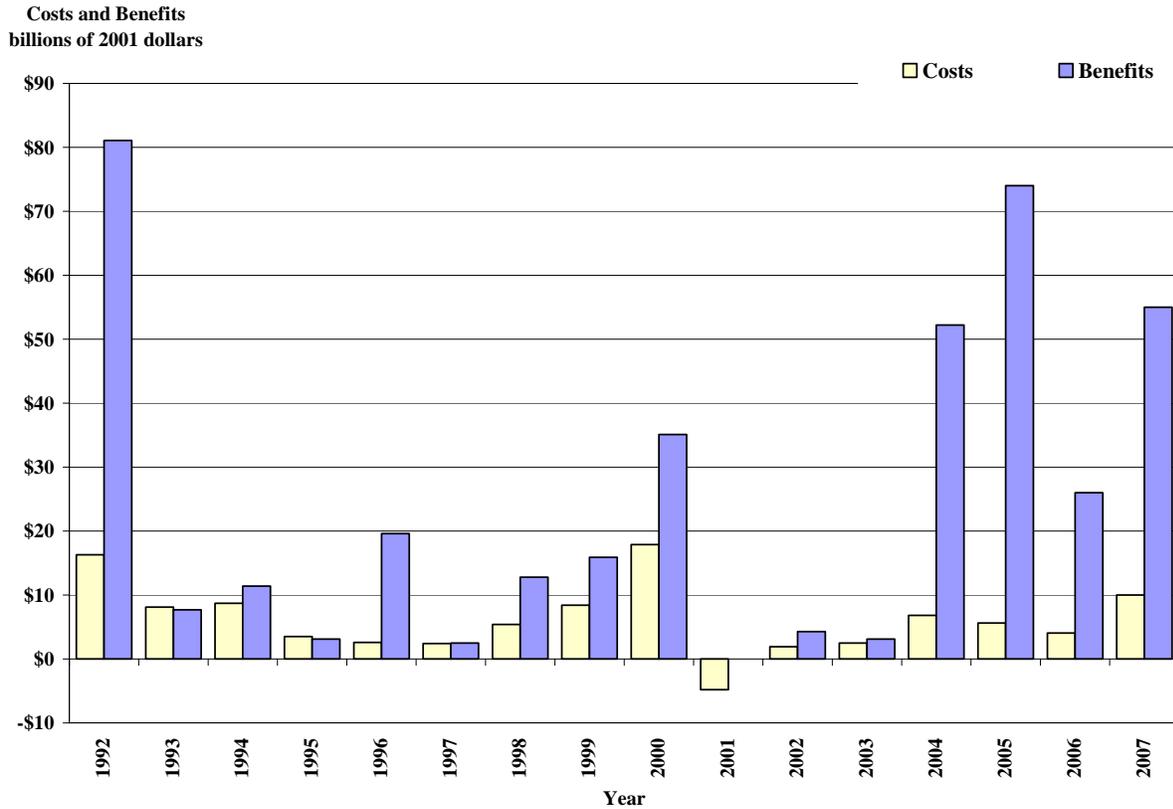


Figure 2-2 shows the benefits and costs of major rules issued from October 1, 1992, to September 30, 2007. Benefit estimates for the rules (with three noted exceptions)⁴⁷ that comprise the overall estimates are presented in various tables in the 11 annual Reports (including this Report) that OMB has completed. Note that the four highest years for benefits, 1992, 2004, 2005, and 2007 are mostly explained by three EPA regulations: the 1992 acid rain permits regulation, the 2004 non-road diesel engine rule, the 2005 interstate air quality rule, and the clean air fine particulate implementation rule. On July 11, 2008, the DC Circuit vacated this rule. EPA is reviewing the Court’s decision.

⁴⁷The exceptions, as discussed above, are DOT’s 1993 airbag rule, OSHA’s 2000 ergonomics rule, and DHS’s 2005 air cargo security requirements 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 regulatory impact analysis (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 lost productivity, to reduce the incidence of MSDs.

Figure 2-2: Benefits and Costs of Major Rules (1992-2007)



The difference between benefit and cost shows the net benefits of major regulations from 1992 through September 2007. We were unable to go back beyond 1992 because of a lack of comparable data on benefits.

We wish to emphasize that (1) these are *ex ante estimates*, (2) as discussed elsewhere in this Report (see Appendix A) as well as previous Reports, the aggregate estimates of benefits and costs 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.⁴⁸

⁴⁸For 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: UPDATE ON THE IMPLEMENTATION OF OMB'S INFORMATION QUALITY INITIATIVES

Objective and high quality analysis leads to better regulatory decisions, and OMB and the regulatory agencies have several initiatives to improve the rigor and transparency of analysis supporting public policy. Of particular importance within the context of regulatory analysis is OMB's Circular A-4, "Regulatory Analysis," which was issued in 2003 after public comment, interagency review, and peer review. It defines good regulatory analysis and standardizes the way benefits and costs of Federal regulatory actions are measured and reported. This guidance is available at: <http://www.whitehouse.gov/omb/circulars/a004/a-4.pdf>.

In this chapter of the report, we discuss the other interagency initiatives designed to improve the objectivity of regulatory analyses as well as the quality of government disseminations more generally. These initiatives include:

- 2002: **Government-Wide Information Quality Guidelines**, which provide policy and procedural guidance to Federal agencies for ensuring and maximizing the quality of the information they disseminate. These guidelines are available at: <http://www.whitehouse.gov/omb/fedreg/reproducible2.pdf>.
- 2004: **Information Quality Bulletin for Peer Review**, which provides further guidance for pre-dissemination review of influential scientific information. This Bulletin is available at: <http://www.whitehouse.gov/omb/memoranda/fy2005/m05-03.pdf>.
- 2007: **Final Bulletin for Agency Good Guidance Practices** (Good Guidance Bulletin), which establishes policies and procedures for the development, issuance, and use of significant guidance documents by Executive Branch departments and agencies and is intended to increase the quality and transparency of agency guidance practices and the significant guidance documents produced through them. This Bulletin is available at: <http://www.whitehouse.gov/omb/memoranda/fy2007/m07-07.pdf>.
- 2007: **Updated Principles for Risk Analysis**, which reiterates the risk analysis principles released by OMB in 1995 and reinforces them with more recent guidance from the scientific community. This Memorandum is available at: <http://www.whitehouse.gov/omb/memoranda/fy2007/m07-24.pdf>.

This chapter discusses each of these initiatives as well as our experience administering them.

A. Government-Wide Information Quality Guidelines

Section 515 of the Treasury and General Government Appropriations Act, 2001 (Pub. L. No. 106-554, 31 U.S.C. § 3516 note), commonly known as the "Information Quality Act" (IQA), requires OMB to develop government-wide standards "for ensuring and maximizing" the quality of information disseminated by Federal agencies.

To implement the IQA, OMB issued final government-wide guidelines on February 22, 2002 (67 FR 8452), and each Federal agency was charged with promulgating its own Information Quality Guidelines. OMB facilitated the development of these agency guidelines, working with the agencies to ensure consistency with the principles set forth in the government-wide guidelines. By October 1, 2002, almost all agencies had released their final guidelines, which became effective immediately. The OMB government-wide guidelines require agencies to submit a report annually to OMB providing information on the number and nature of complaints received by the agency and how such complaints were resolved.

In August 2004, the OIRA Administrator issued a memorandum to the President's Management Council requesting that agencies post all Information Quality correspondence on agency web pages to increase the transparency of the process.⁴⁹ In their FY 2004 Information Quality Reports to OMB, agencies provided OMB with the specific links to these web pages and OMB began providing this information to the public in our 2005 update on Information Quality.⁵⁰ This increase in transparency allows the public to view all correction requests, appeal requests, and agency responses to these requests. The web pages also allow the public to track the status of correction requests that may be of interest. An updated list of agency web pages is provided in Appendix C of this Report.

In our 2003 report, OMB presented a thorough discussion of the IQA and its implementation, including a discussion of perceptions and realities, legal developments, ways to improve transparency, suggestions for improving correction requests, and the release of the OMB Information Quality Bulletin for Peer Review.⁵¹

This section of the chapter provides a summary of the current status of correction requests received in FY 2007, as well as an update on the status of requests received in FY 2004, FY 2005 and FY 2006. An update on legal developments is also provided. Our discussion of the individual correction requests and agency responses is minimal because all correspondence between the public and the agencies regarding these requests is publicly available on the agencies' Information Quality web pages.

Request for Correction Process

1. New Correction Requests and Appeal Requests Received by the Agencies in FY 2007

Table 3-1 below lists the departments and agencies that received requests for corrections FY 2007. In FY 2007 a total of 21 requests for correction were sent to eight different

⁴⁹See http://www.whitehouse.gov/omb/inforeg/info_quality_posting_083004.pdf.

⁵⁰See *Validating Regulatory Analysis: 2005 Report to Congress on the Costs and Benefits of Federal Regulations and Unfunded Mandates on State, Local, and Tribal Entities*, http://www.whitehouse.gov/omb/inforeg/2005_cb/final_2005_cb_report.pdf.

⁵¹See *Information Quality, a Report to Congress FY 2003*, OMB, http://www.whitehouse.gov/omb/inforeg/fy03_info_quality_rpt.pdf, and *Validating Regulatory Analysis: 2005 Report to Congress on the Costs and Benefits of Federal Regulations and Unfunded Mandates on State, Local, and Tribal Entities*, http://www.whitehouse.gov/omb/inforeg/2005_cb/final_2005_cb_report.pdf.

departments and agencies. All of the departments and agencies listed below have received correction requests in the past. In addition, three appeals associated with these 21 requests were filed in FY 2007. One appeal was sent to the National Institute of Standards and Technology within the Department of Commerce (DOC) regarding a World Trade Center fire report, one appeal was sent to the Environmental Protection Agency (EPA) regarding sampling at a lead smelter, and one appeal was sent to the Federal Communications Commission regarding line charges. As some of the agency's 21 responses were sent at the end of FY 2007, or were still pending at the end of FY 2007, there is a possibility that additional appeals may be filed.

Table 3-1: Departments and Agencies that Received Information Quality Correction Requests in FY 2007

Agency	Number of FY07 Correction Requests
Department of Commerce	7
Department of Defense	1
Department of Energy	2
Department of Health and Human Services	1
Department of the Interior	3
Department of Labor	1
Environmental Protection Agency	3
Federal Communications Commission	3
Total	21

Further, as shown below in Table 3-2, there were an additional four appeals filed in FY 2007. These appeal requests were sent to the agencies following receipt of responses to correction requests that were initiated in FY 2006.

Table 3-2: Departments and Agencies that Received Information Quality Appeals Requests in FY 2007, Following Responses to Requests Initiated in FY 2006

Agency	Number of FY07 Appeals
Department of Defense	1
Department of Health and Human Services	2
Environmental Protection Agency	1
Total	4

Details concerning the 21 requests and seven appeals (three relating to FY 2007 requests and four relating to FY 2006 requests) can be found at the agencies' Information Quality websites (see Appendix C-A for a link to agency web pages). The correction requests received in FY 2007 were as diverse and interesting as those received in previous years.

For instance, the National Institute of Standards and Technology (NIST) within the Department of Commerce (DOC) received multiple requests from private individuals regarding the World Trade Center fire investigations reports and a report on the collapse of the towers; the Army Corps of Engineers, within the Department of Defense, received a correction request on behalf of the Home Builders Association of Northern California and the Bay Planning Coalition regarding the National List of Plant Species that Occur in Wetlands; the National Park Service, within the Department of the Interior, received a correction request from a law firm regarding information in a Point Reyes National Seashore news report; and the Environmental Protection Agency (EPA) received a correction request on behalf of the Efficacy Working Group regarding a Use-Dilution test methodology used by the EPA Office of Pesticide Programs Antimicrobial Division.

Figure 3-1 shows the status of the 21 FY 2007 correction requests. For details relating to the specific requests, including agency responses, readers are encouraged to visit agency Information Quality websites. As shown below, this year we are categorizing how agencies responded to requests in a more detailed manner. For instance, we are including the category of "other corrections." This category is used when the agency response does not provide the specific changes that were requested, but makes other changes instead. For example, a requester asked for revisions to the NIST reports relating to the World Trade Center collapse. NIST clarified information using an erratum, and this clarification has been classified in the "other corrections" category. OMB continues to use the "other processes/mechanisms" category to describe responses that were handled by other pre-existing processes at the agencies. For example, a request to the National Oceanic and Atmospheric Administration regarding information on the Monterey Bay National Marine Sanctuary was treated and considered as a public comment on a rulemaking undertaken by the Department of Commerce.

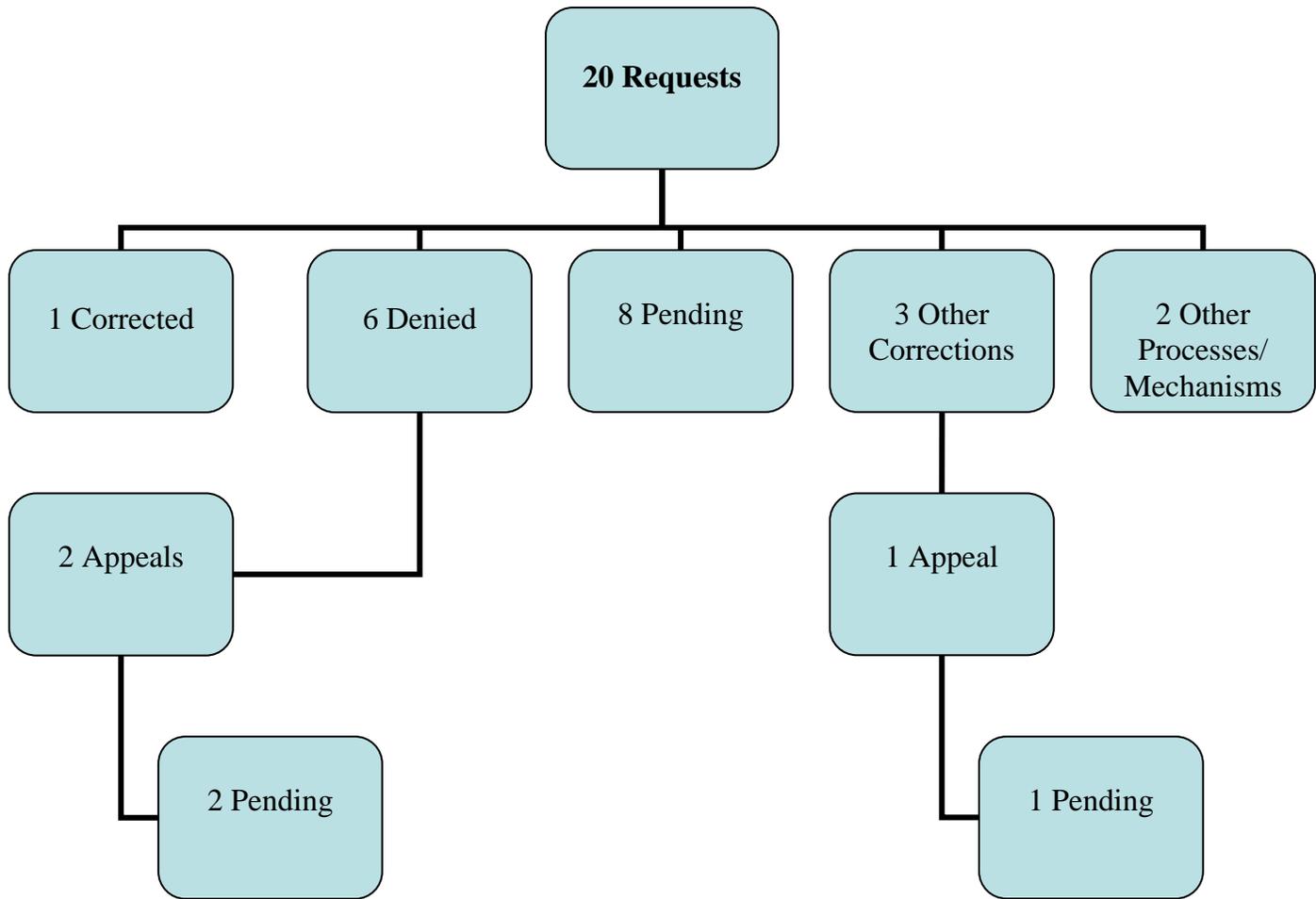


Figure 3-1: Status of IQ Correction Requests Received in FY 2007

As noted in the 2007 final Report,⁵² OMB cautions readers against drawing any conclusions about trends or year-to-year comparisons because agency procedures for classifying correction requests are still evolving. However, we note that in FY 2003 there were 48 correction requests, in FY 2004 there were 37 correction requests, in FY 2005 there were 24 correction requests, and in FY 2006 there were 22 correction requests.

2. Status of Outstanding Correction Requests Received by the Agencies in FY 2003-2006

At the close of FY 2006, 13 Information Quality correction request responses and two appeal responses were pending from the agencies. The pending correction requests were initiated in FY 2004, FY 2005, and FY 2006. Figure 3-2 shows the status of those outstanding correction request responses at the close of FY 2006. Agencies have responded to nine of these correction requests and were still working on responses to the remaining four at the end of FY 2007.

⁵² See 2007 Report to Congress on the Costs and Benefits of Federal Regulations and Unfunded Mandates on State, Local, and Tribal Entities, http://www.whitehouse.gov/omb/infoereg/2007_cb/2007_cb_final_report.pdf.

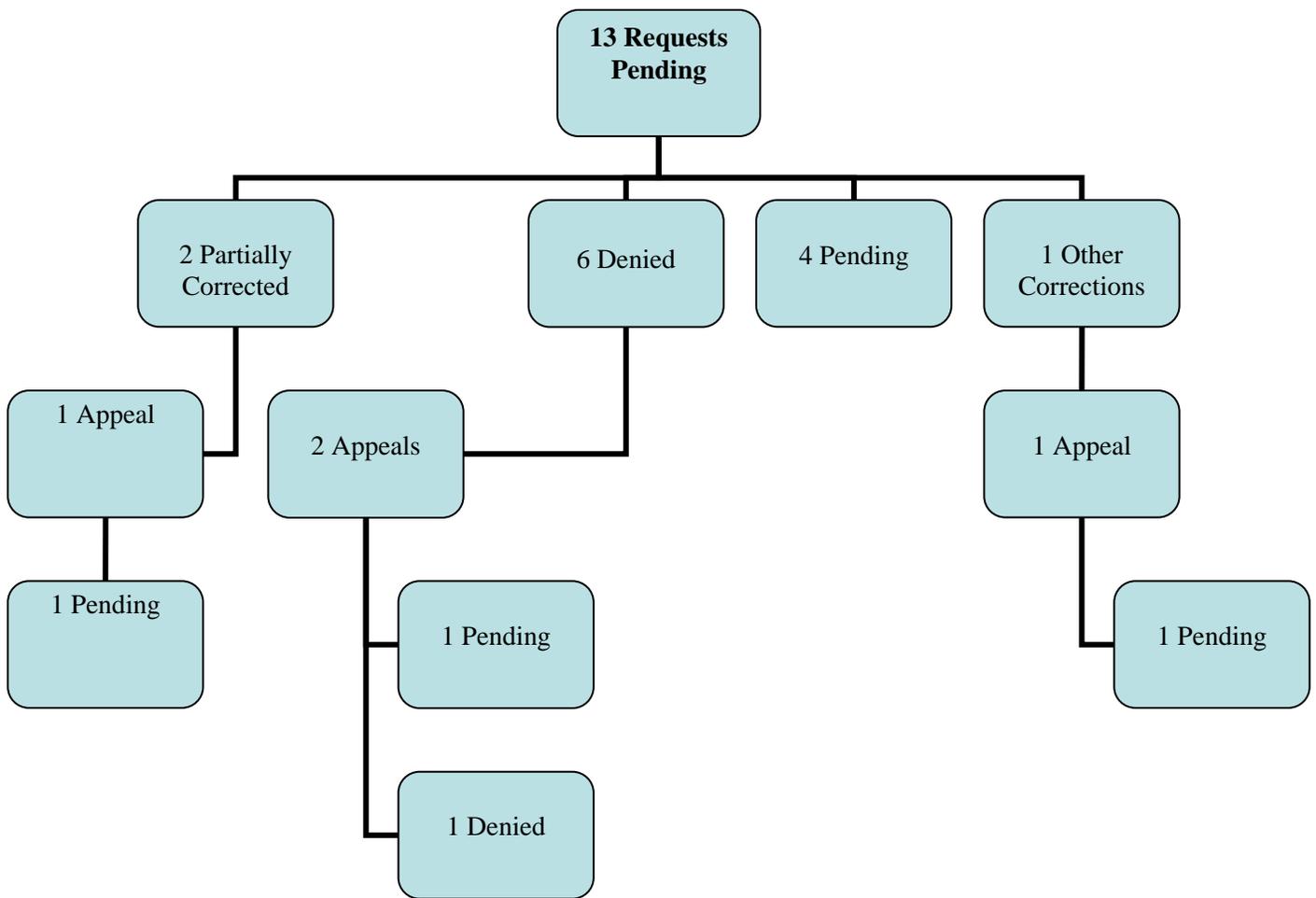


Figure 3-2: FY 2007 Status of Pending Correction Requests from FY 2004, FY 2005 and FY 2006

Figure 3-3 below gives the status of the two appeal requests pending at the close of FY 2006. The Department of Transportation responded to an appeal request it received in FY 2004 regarding the Federal Aviation Administration’s Age 60 rule, and the Environmental Protection Agency responded to an appeal request received in FY 2005 regarding environmental databases. In both these cases, the Agencies provided corrections other than those requested. Correspondence showing the agencies responses to these requests is publicly available on the agencies’ Information Quality web pages.

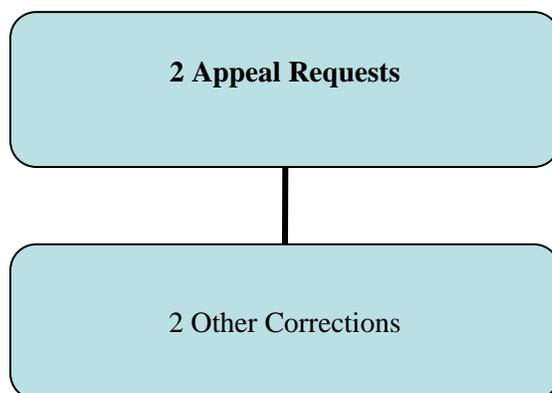


Figure 3-3: FY 2007 Status of Pending Appeal Requests from FY 2003 and FY 2006

Legal updates.

As we discussed in the final 2007 Report (page 51), litigation has arisen regarding the legal issue of whether agency responses to IQA requests for correction are subject to judicial review under the IQA and the Administrative Procedure Act (APA). In this litigation, the courts concluded that the agency responses in those cases were not subject to judicial review under the IQA and the APA. See *Salt Institute v. Leavitt*, 440 F.3d 156, 159 (4th Cir. 2006); *Americans for Safe Access v. United States Dep't of Health and Human Servs.*, No. C 07-01049 WHA, 2007 U.S. Dist. LEXIS 89257, at *11 (N.D. Cal. Nov. 20, 2007); *Americans for Safe Access v. United States Dep't of Health and Human Servs.*, No. C 07-01049 WHA, 2007 U.S. Dist. LEXIS 55597, at *14 (N.D. Cal. July 24, 2007); *In re Operation of the Missouri River System Litigation*, 363 F. Supp. 2d 1145, 1174-75 (D. Minn. 2004), *vacated in part and aff'd in part on other grounds*, 421 F.3d 618 (8th Cir. 2005). The district court's ruling in *Americans for Safe Access* is currently pending on appeal. *Americans for Safe Access v. United States Dep't of Health and Human Servs.*, No. 07-17388 (9th Cir.).

B. Information Quality Bulletin for Peer Review

In keeping with the goal of improving the quality of government information, on December 16, 2004, OMB issued the Final Information Quality Bulletin for Peer Review (the Peer Review Bulletin).⁵³ The Peer Review Bulletin requires executive agencies to ensure that all “influential scientific information” they disseminate after June 16, 2005 has been peer reviewed.

“Influential scientific information” is defined as “scientific information the agency reasonably can determine will have or does have a clear and substantial impact on important public policies or private sector decisions.”⁵⁴ In the term “influential scientific information,” the

⁵³ See <http://www.whitehouse.gov/omb/memoranda/fy2005/m05-03.pdf>

⁵⁴ The Bulletin notes that information dissemination can have a significant economic impact even if it is not part of a rulemaking. For instance, the economic viability of a technology can be influenced by the government's

term "influential" is to be interpreted consistently with OMB's government-wide Information Quality Guidelines and the information quality guidelines of each agency.

One type of scientific information is a scientific assessment. For the purposes of the Peer Review Bulletin, the term "scientific assessment" means an evaluation of a body of scientific or technical knowledge, which typically synthesizes multiple factual inputs, data, models, assumptions, and/or applies best professional judgment to bridge uncertainties in the available information.⁵⁵

The Peer Review Bulletin describes the factors that should be considered in choosing an appropriate peer review mechanism and stresses that the rigor of the review should be commensurate with how the information will be used. Agencies are directed to choose a peer review mechanism that is adequate, giving due consideration to the novelty and complexity of the science to be reviewed, the relevance of the information to decision making, the extent of prior peer reviews, and the expected benefits and costs of additional review. When deciding what type of peer review mechanism is appropriate for a specific information product, agencies will need to consider at least the following issues: individual versus panel review, timing, scope of the review, selection of reviewers, disclosure and attribution, public participation, disposition of reviewer comments, and adequacy of prior peer review.

The Peer Review Bulletin specifies the most rigorous peer review requirements for "highly influential scientific assessments," which are a subset of "influential scientific information." To ensure that implementation of the Peer Review Bulletin is not too costly, these requirements for more intensive peer review apply only to the more important scientific assessments disseminated by the Federal Government – those that could have a potential impact of more than \$500 million in any one year on either the public or private sector or are novel, controversial, or precedent-setting, or have significant interagency interest.

Under the Peer Review Bulletin, agencies are granted broad discretion to weigh the benefits and costs of using a particular peer review mechanism for a specific information product. In addition to the factors noted above, agencies also are provided with the option of employing "alternative processes" for meeting the peer review requirement (e.g., commissioning a National Academy of Sciences' panel). Moreover, to ensure that peer review does not unduly delay the release of urgent findings, time-sensitive health and safety determinations are exempted from the requirements of the Peer Review Bulletin. There are also specific exemptions for national security, individual agency adjudication or permit proceedings, routine statistical information, and financial information. The Peer Review Bulletin does not cover information disseminated in connection with routine rules that materially alter entitlements, grants, user fees, or loan programs, or the rights and obligations of recipients thereof.

characterization of its attributes. Alternatively, the Federal Government's assessment of risk can directly or indirectly influence the response actions of state and local agencies or international bodies.

⁵⁵ These assessments include, but are not limited to, state-of-science reports; technology assessments; weight-of-evidence analyses; meta-analyses; health, safety, or ecological risk assessments; toxicological characterizations of substances; integrated assessment models; hazard determinations; or exposure assessments.

The Peer Review Bulletin provides two mechanisms for monitoring the progress of the agencies in meeting these peer review requirements: a transparent peer review planning process and annual reporting, described below.

The good science and good government requirements of the Peer Review Bulletin should assist in improving the accuracy and transparency of agency science. Additionally, the peer review planning process described in the Peer Review Bulletin, which includes posting of plans on agency websites, will enhance the ability of the government and the public to track influential scientific disseminations made by agencies.

On June 16, 2005, the Peer Review Bulletin became effective for all influential scientific information, including highly influential scientific assessments. The peer review planning component of the Bulletin, discussed below, became fully effective on December 16, 2005. By the end of FY 2007, we have had two full years of implementation.

Peer Review Planning

The Peer Review Planning component of the Peer Review Bulletin (Section V) requires agencies to begin a systematic process of peer review planning for influential scientific information (including highly influential scientific assessments) that the agency plans to disseminate in the foreseeable future.

A key feature of the agency's peer review plan is a web-accessible listing (agenda) of forthcoming influential scientific disseminations that is updated on a regular basis. These postings are designed to allow the public to participate in the peer review process by providing data and comments to the sponsoring agencies as well as to external peer reviewers.

The agenda is designed to encourage planning for peer review early in the information generation process; thus, the agenda should cover all information subject to the Peer Review Bulletin that the agency plans to disseminate *in the foreseeable future*. For instance, once an agency has established a time line for the generation of a scientific report, the agency should include that report in its agenda. Thus, although the Peer Review Bulletin specifies that agencies should update their peer review agendas every six months, the agenda is not a six-month forecast (i.e., it should not be limited to information (documents) that the agency plans to peer review in the next six months).

By making these agendas publicly available, agencies increase the level of transparency in their peer review processes and also have a mechanism to gauge the extent of public interest in their proposed peer reviews.

Readers are encouraged to visit the agendas for agencies of interest. OMB asks agencies to ensure that there is an easily identifiable hyperlink to the peer review agenda from the agency's information quality home page. For cabinet-level departments that have a central information quality page but do not have a central peer review agenda, OMB requests that a

hyperlink to each agency agenda be provided. Appendix C-2 provides the URLs for most agencies' peer review agendas.

Cabinet level departments with processes in place for proactively identifying documents subject to the Bulletin include the Departments of Agriculture⁵⁶, Commerce⁵⁷, Health and Human Services⁵⁸, Interior⁵⁹, Labor, and Transportation, Housing and Urban Development, Justice, and State and the Environmental Protection Agency. Other agencies with processes in place for proactively identifying documents subject to the Peer Review Bulletin include the Consumer Product Safety Commission and the Federal Communications Commission.

There is another group of agencies that does, from time to time, produce or sponsor influential scientific information, but has not currently identified forthcoming information products subject to the Peer Review Bulletin. OMB is currently working with these agencies to ensure that they develop rigorous processes for determining which documents are subject to the Bulletin and to ensure that the peer review plans for those documents are listed on the agency's agenda in a timely manner. These agencies include the Departments of Defense, Education, Energy, Homeland Security, and Veterans Affairs, as well as the National Aeronautics and Space Administration, the Nuclear Regulatory Commission, the Small Business Administration, the Federal Trade Commission, and the Tennessee Valley Authority.

Several agencies do not think that they currently produce or sponsor information subject to the Peer Review Bulletin. Most of these agencies primarily produce financial information or routine statistical information for which the Bulletin provides specific exemptions. Others primarily engage in management, oversight, or granting activities. A list of these agencies can be found in Appendix C-3.

Although the Peer Review Planning section of the Bulletin lays out the specific items that should be included in each peer review plan, OMB does not specify the format that agencies should use, thereby giving agencies the flexibility to incorporate their agendas into existing e-government and science planning initiatives.⁶⁰ As such, some agencies house their peer review agendas within a research arm of the agency whereas others operate out of the office of the chief information officer or the policy and planning office. Some departments provide an integrated agenda across the agencies,⁶¹ while other departments have chosen to have individual agencies host their own agendas.⁶² Furthermore, some agencies have chosen to provide a single agenda

⁵⁶ The Animal and Plant Health Inspection Service and the Food Safety and Inspection Service have strong peer review programs, as does the Economic Research Service. Many of the other agencies have come into compliance this year. The Forest Service is making progress in coming into compliance.

⁵⁷ The National Oceanographic and Atmospheric Administration is the only agency within Commerce that has identified documents subject to the Bulletin; their peer review process is strong.

⁵⁸ The Food and Drug Administration, the Center for Disease Control and Prevention, and the National Toxicology Program are compliant with the Bulletin.

⁵⁹ The Fish and Wildlife Service has an exemplary peer review process. The U.S. Geological Survey and the Mineral Management Service are also compliant with the Bulletin. The DOI is working to incorporate peer review planning in the rest of its Bureaus.

⁶⁰ For instance, the Environmental Protection Agency's incorporation with its science inventory project

⁶¹ For instance, the agenda for the Department of Transportation

⁶² For instance, the agendas for the Department of Health and Human Services and the Department of the Interior

for both influential scientific information and highly influential scientific assessments,⁶³ while others provide two separate agendas.⁶⁴ The Peer Review Bulletin specifically requires that agencies provide a link from the agenda to each document made public pursuant to the Bulletin, including the completed peer review report. Although some agencies routinely provide such links,⁶⁵ agendas at other agencies do not yet have this capability. Agencies have advised us that provision of these links is not always straightforward when the peer review is nested within a more complicated preexisting public process.⁶⁶ OMB is currently working with all of the agencies to ensure that the required information is posted and that the web sites are easy to locate and navigate.

FY 2006 and FY 2007 Annual Reports of Agency Peer Reviews

The Annual Reports Section (Section VI) of the Peer Review Bulletin discusses the annual reporting requirement. This requirement is designed to provide OMB with a count of the peer reviews completed in the fiscal year as well as information about the use of waivers, deferrals, exemptions, alternative processes, and exceptions to the independence and conflict of interest criteria for choosing reviewers and the degree to which opportunities for public participation were provided.

FY 2007 constituted the second full year of implementation for the Peer Review Bulletin. Tables 3-3 a and b summarize the results of the annual data call for the first two years of implementation below so that the reader can explore trends.

For FY 2006, agencies reported that they conducted 159 peer reviews that fell within the scope of the Peer Review Bulletin's provisions. For FY 2007, agencies reported conducting 235 peer reviews that fell within the scope of the Bulletin's provisions. This number includes all such peer reviews that were conducted, regardless of whether the final peer review report has been completed. In FY 2006, 34 of the 159 peer reviews were of highly influential scientific assessments and in FY 2007, 40 of the 235 peer reviews were of highly influential scientific assessments.

Many of these reported peer reviews were part of preexisting processes, consistent with agencies' or programs' pre-Bulletin policies to conduct peer reviews of scientific information. Because OMB does not have baseline information of how many peer reviews were conducted during FY 2005 and prior years, it is not possible to draw inferences about how many of the peer reviews during FY 2006 or FY 2007 were conducted specifically as a result of the Peer Review Bulletin. However, the increase from FY 2006 and FY 2007 in the total number of peer reviews reported, as well as the increased number of agencies that reported conducting reviews pursuant to the Bulletin, suggests that more agencies are adopting rigorous pre-dissemination practices.

⁶³ For instance, the agenda for the Department of Commerce

⁶⁴ For instance, the agenda for the Department of Transportation

⁶⁵ For instance, agendas for the Department of Agriculture's Animal and Plant Health Inspection Service, the Department of Health and Human Services' Center for Disease Control, and the Environmental Protection Agency (See Appendix for URLs for these agencies' agendas.)

⁶⁶ For instance some National Oceanographic and Atmospheric Administration documents that are part of the Endangered Species Act process (e.g., <http://www.fakr.noaa.gov/protectedresources/stellers/section7.htm>)

Furthermore, even for those reviews that would have happened in the absence of the Peer Review Bulletin, discussion with agencies suggest that the Bulletin has encouraged additional rigor, strengthening the underlying peer review process.

In 2007, only one agency invoked a waiver, and none requested deferrals or exemptions. The waiver, issued annually by the Department of the Interior Fish and Wildlife Service (the Service), is for the information underlying its annual regulations for hunting migratory game birds.⁶⁷ The assessments underlying these decisions are subject to review and input from technical experts, but the Service determined that due to the extremely limited time between when data are collected and analyzed and decisions must be made regarding the hunting seasons, it was not possible to follow the requirements of the Peer Review Bulletin for these reviews.

OMB acknowledges that peer review as described in the Peer Review Bulletin is only one of the many procedures that agencies can employ to ensure an appropriate degree of pre-dissemination quality for influential scientific information. As such, the Peer Review Bulletin provides for the use of “alternative processes.” During FY 2006 only one “alternative process” was used – the Department of Commerce’s National Oceanic and Atmospheric Administration used a National Academy of Sciences (NAS) panel to review its study of temperature trends in the lower atmosphere.⁶⁸ No agencies reported relying on alternative processes in FY 2007.

Sections II (3) and III (3) of the Peer Review Bulletin lay out criteria for selection of peer reviewers, including expertise, balance, independence, and lack of conflict of interest. The Peer Review Bulletin suggests adopting or adapting the NAS policy for committee selection with respect to evaluating the potential for conflicts. The strictest standards for independence from the sponsoring agency apply to highly influential scientific assessments. In FY 2007, no agency reported the need to appoint peer reviewers pursuant to the exception in Section III (3)(c) regarding the use of scientists employed by the sponsoring agency for review of highly influential assessments. The infrequent need for this exemption, as seen in this first two years of implementation, should alleviate concerns raised by some public commenters that agencies would not be able to identify sufficient external reviewers.

Section V (3) of the Bulletin requires agencies to establish a mechanism for allowing the public to comment on the adequacy of agency peer review plans. Very few members of the public took advantage of the opportunity to provide comments on the several hundred peer review plans posted by Federal agencies over the last year. Agencies received a total of nine comments in FY 2006 and 28 in FY 2007. OMB is unsure whether this is because the public has not found it to be useful to comment on the peer review plans or perhaps because the public is largely unaware of the agendas or the opportunity to provide comment. Public input on this issue is welcome.

⁶⁷ <http://www.fws.gov/migratorybirds/MBPeerReviewWaiver.pdf>

⁶⁸ <http://www.cio.noaa.gov/itmanagement/prplans/ID22.html>

Table 3-3A: Peer Reviews Conducted Subject to the Peer Review Bulletin

Department/ Agency	Total Peer Reviews Completed		Reviews of Highly Influential Scientific Assessments		Waivers, Deferrals, or Exemptions		Potential Reviewer Conflicts		Reviews w/ Public Meetings		Public Comments on Agenda ⁶⁹	
	2006	2007	2006	2007	2006	2007	2006	2007	2006	2007	2006	2007
Department of Agriculture ⁷⁰	19	71	8	9	0	0	0	0	0	1	3	0
Department of Commerce ⁷¹	19	24	3	2	0	0	0	0	6 72	14	0	17
Department of Defense ⁷³	2		2		0		0		1		N/A	
Department of Energy ⁷⁴	1	2	1	2	0	0	0	0	1	1	0	2
Department of Health and Human Services ⁷⁵	31	32	6	7	0	0	0	0	3	24	1	0
Department of the Interior ⁷⁶	51	68	1	1	1	1	4	0	1	0	1	0
Department of Justice ⁷⁷	0	3	0	0	0	0	0	0	0	0	0	0
Department of Labor ⁷⁸	2	0	1	0	0	0	0	0	0	0	0	0
Department of Transportation ⁷⁹	12	14	5	10	0	0	0	0	0	1	1	3

⁶⁹ Section V (3) of the Bulletin requires agencies to establish a mechanism for allowing the public to comment on the adequacy of agency peer review *plans*.

⁷⁰ The Department of Agriculture agencies reporting peer reviews in FY 2006 were the Animal and Plant Health Inspection Service and the Food Safety Inspection Service. In FY 2007 the following agencies were added: Agricultural Research Service, Economic Research Service, Food and Nutrition Service, Grain Inspection, Packers and Stockyards Administration, and Office of the Chief Economist.

⁷¹ The Department of Commerce agency reporting peer reviews in FY 2006 was the National Oceanic and Atmospheric Administration.

⁷² Incomplete count (minimum number).

⁷³ The only Department of Defense agency reporting peer reviews in FY 2006 was the Army Corps of Engineers.

⁷⁴ The only Department of Energy peer reviews reported in FY 2006 and FY 2007 were associated with climate change science program.

⁷⁵ The Department of Health and Human Services agencies reporting peer reviews in FY 2006 were the Centers for Disease Control and Prevention, the Food and Drug Administration, and the National Toxicology Program at the National Institute for Environmental Health Sciences.

⁷⁶ The Department of the Interior agency reporting peer reviews in FY 2006 was the Fish and Wildlife Service, the Minerals Management Service, and the U.S. Geological Survey.

⁷⁷ The Department of Justice agency reporting in FY2007 was the Executive Office for U.S. Trustees.

⁷⁸ The Department of Labor agency reporting peer reviews in FY 2006 was Employee Benefits Security Administration.

⁷⁹ The Department of Transportation agencies reporting peer reviews in FY 2006 were the Federal Aviation Administration, National Transportation Safety Administration, Federal Highway Administration, and Federal Motor Carrier Safety Administration.

Department/ Agency	Total Peer Reviews Completed		Reviews of Highly Influential Scientific Assessments		Waivers, Deferrals or Exemptions		Potential Reviewer Conflicts		Reviews w/ Public Meetings		Public Comments on Agenda ⁶⁹	
	2006	2007	2006	2007	2006	2007	2006	2007	2006	2007	2006	2007
Consumer Product Safety Commission	4	0	3	0	0	0	0	0	0	0	0	0
Environmental Protection Agency	15	15	4	7	0	0	0	0	7	12	3	4
Federal Communications Commission	3	4	0	0	0	0	0	0	0	0	0	1
National Aeronautics and Space Administration ⁸⁰	0	2	0	2	N/A	0	N/A	0	N/A	1	0	1
Total	159	235	34	40	1	1	4	0	19	54	9	28

⁸⁰ The only National Aeronautics and Space Administration peer reviews reported in FY 2007 were associated with climate change science program; nothing was reported in FY2006.

Table 3-3B: Change in the Number of Peer Reviews Conducted Subject to the Peer Review Bulletin, from FY2006 to FY2007

Department/ Agency	Total Peer Reviews Completed	Reviews of Highly Influential Scientific Assessments	Waivers, Deferrals or Exemptions	Potential Reviewer Conflicts	Reviews w/ Public Meetings	Public Comments on Agenda
Department of Agriculture	52	1	0	0	1	-3
Department of Commerce	5	-1	0	0	8	17
Department of Defense	-2	-2	0	0	-1	N/A
Department of Energy	1	1	0	0	0	2
Department of Health and Human Services	1	1	0	0	21	-1
Department of the Interior	17	0	0	-4	-1	-1
Department of Justice	3	0	0	0	0	0
Department of Labor	-2	-1	0	0	0	0
Department of Transportation	2	5	0	0	1	2
Consumer Product Safety Commission	-4	-3	0	0	0	0
Environmental Protection Agency	0	3	0	0	5	1
Federal Communications Commission	1	0	0	0	0	1
National Aeronautics and Space Administration	2	N/A	N/A	N/A	N/A	N/A
Total Change	76	4	0	-4	34	18

C. Final Bulletin for Agency Good Guidance Practices

On January 18, 2007, the President issued Executive Order 13422,⁸¹ which amended Executive Order 12866 and clarified OMB's authority to coordinate interagency review of agencies' significant guidance documents.⁸² In connection with the issuance of this Executive Order, and after soliciting and responding to public and interagency comment, OMB issued a Final Bulletin for Agency Good Guidance Practices (the Good Guidance Practices Bulletin).⁸³ These documents were designed to lead to improvements in the way the Federal government does business – by increasing the quality, accountability, and transparency of agency guidance documents.

The impetus behind the Good Guidance Practices Bulletin is that while guidance documents do not have the force of law, they can nevertheless have a significant impact on American businesses, workers, consumers, and State, local and tribal governments. Well-designed guidance documents serve many important functions in regulatory programs, such as advising and assisting individuals, small businesses and other regulated entities in their compliance with agency regulations, as well as furthering consistency and fairness in an agency's enforcement of its regulations. However, agency guidance that has an impact on society equivalent to that of a regulation should be subject to an appropriate level of review, within an agency, by other agencies with related missions, and by the public. Many of those providing public comments on the draft bulletin expressed support for OMB's issuance of it.⁸⁴

To accomplish its goal, the Good Guidance Practices Bulletin established policies and procedures for the development, issuance, and use of significant guidance documents by Executive Branch departments and agencies, including the following:

- In each agency, appropriate officials will review and approve the agency's issuance of significant guidance documents.
- Agencies will maintain on their websites current lists of their significant guidance documents that are in effect, so that the public can know what guidance applies to them.
- Agencies will provide the public with access to and the opportunity to provide feedback on the significant guidance documents of the agency. Agencies will advertise on their websites a means for the public to submit comments electronically on these guidance documents.

⁸¹ Executive Order 13422 (January 23, 2007), *available at* http://www.whitehouse.gov/omb/inforeg/eo12866/fr_notice_eo12866_012307.pdf.

⁸² Section 9 of Executive Order 12866, as amended.

⁸³ OMB, Final Bulletin for Agency Good Guidance Practices (January 18, 2007), *available at* <http://www.whitehouse.gov/omb/memoranda/fy2007/m07-07.pdf>.

⁸⁴ See public comments on the draft Good Guidance Practices Bulletin, *available at* http://www.whitehouse.gov/omb/inforeg/good_guid/c-index.html.

- For those guidance documents that are economically significant, agencies will publish notices in the Federal Register announcing that the draft documents are available (on the internet or in hard copy), invite public comment on them, and post on their websites response-to-comments documents.

On April 25, 2007, OMB issued a memorandum to the agencies providing implementation assistance for both the amended Executive Order and the Good Guidance Practices Bulletin.⁸⁵ This memorandum was designed to respond to frequently-asked questions and guide the agencies to substantial compliance. As of July 2008, the agencies have been working for approximately 18 months to implement these documents. While full implementation may take another six months, much progress has been made.

Agency Websites for Significant Guidance Documents

One of the main reasons that OMB issued the Good Guidance Practices Bulletin, as its preamble makes clear, is that, while agency guidance documents serve many important functions – by providing guidance to the public on permissible and impermissible conduct while ensuring equal treatment of similarly situated parties, for example – guidance documents can be poorly or improperly implemented.⁸⁶ Additionally, prior to the issuance of the Good Guidance Practices Bulletin, it was not always easy for the public to track down and review agency guidance documents.

One of the ways that the Good Guidance Practices Bulletin sought to correct these problems is its requirement that agencies provide the public with access to and the opportunity to provide feedback on the agency's significant guidance documents.⁸⁷ The Good Guidance Practices Bulletin requires each agency to maintain on its website a current list of significant guidance documents in effect, the name of each significant guidance document, their issuance dates, and links to the guidance documents themselves.⁸⁸ Additionally, agencies are required to advertise on their websites a means for the public to submit comments on significant guidance documents; to request issuance, reconsideration, modification, or rescission of significant guidance documents; and the office designated to receive complaints that the agency is not following proper guidance procedures.⁸⁹

Agencies have substantially complied with these requirements by updating their websites. A notable example is the Environmental Protection Agency which has a webpage that outlines its compliance with Executive Order amendments and the Good Guidance Practices Bulletin, contains contact information as well as an electronic comment form for public comments about guidance documents, and provides links to significant guidance documents both by issuing office

⁸⁵ OMB, "Implementation of Executive Order 13422 (amending Executive Order 12866) and the OMB Bulletin on Good Guidance Practice," available at <http://www.whitehouse.gov/omb/memoranda/fy2007/m07-13.pdf>.

⁸⁶ Preamble to the Good Guidance Practices Bulletin.

⁸⁷ Section III of the Good Guidance Practices Bulletin.

⁸⁸ Section III(1)(a) of the Good Guidance Practices Bulletin.

⁸⁹ Section III(2) of the Good Guidance Practices Bulletin.

and environmental topic. The Department of Labor has also done a noteworthy job of making its guidance documents available to the public.

The following list provides links to the guidance document sections of agency websites:

Department of Agriculture: <http://www.usda.gov/guidance>
Department of Commerce: http://ocio.os.doc.gov/ITPolicyandPrograms/Information_Quality/PROD01_003167
Department of Defense: <http://www.dtic.mil/whs/directives/infomgt/regulatory/regulatory.htm>
Department of Education: <http://www.ed.gov/policy/gen/guid/significant-guidance.html>
Department of Energy: http://www.energy.gov/about/guidance_documents.htm
Department of Health & Human Services: <http://www.hhs.gov/about/significantguidance.html>
Department of Homeland Security: <http://www.dhs.gov/xabout/laws>
Department of Housing & Urban Development: <http://www.hud.gov/offices/ogc/regulations.cfm>
Department of the Interior: <http://www.doi.gov/initiatives/guidancedocuments.html>
Department of Justice: http://www.usdoj.gov/olp/doj_sig_guidance.htm
Department of Labor: <http://www.dol.gov/asp/guidance>
Department of State: <http://www.state.gov/m/a/dir/92111.htm>
Department of Transportation: <http://regs.dot.gov/Guidance>
Department of the Treasury: <http://www.treas.gov/offices/general-counsel/guidance>
Department of Veterans Affairs: <http://www1.va.gov/orpm>
Environmental Protection Agency: <http://www.epa.gov/regulations/guidance>

Agency Regulatory Policy Officers

In addition to clarifying OMB's role in the review of agency significant guidance documents, the amended Executive Order requires agency heads to designate⁹⁰ one of the agency's Presidential Appointees to be its Regulatory Policy Officer (RPO), to advise OMB of the designation, and to update OMB annually on the status of this designation.⁹¹ Regulatory Policy Officers are not new; in 1993, when President Clinton issued Executive Order 12866, he directed each agency head to designate an RPO. In 1993, it was determined that the Regulatory Policy Officer "shall be involved at each stage of the regulatory process to foster the development of effective, innovative, and least burdensome regulations and to further the principles set forth in this Executive Order [12866]."⁹²

⁹⁰ A Presidential Appointee is appointed by the President and should not be confused with "political appointees" appointed by the agency head. The amendments to the Executive Order place no restrictions on the agency head's discretion in choosing which Presidential Appointee within the agency to designate as the agency's Regulatory Policy Officer and do not change the fact that the Regulatory Policy Officer reports to the agency head.

⁹¹ Section 6(a)(2) of Executive Order 12866, as amended.

⁹² Section 6(a), Executive Order 12866.

The current list of agency Regulatory Policy Officers is as follows:⁹³

Agency/Department	RPO-Designated Position
Agriculture (USDA)	General Counsel
Commerce (DOC)	General Counsel
Defense (DOD)	General Counsel
Education (Ed)	General Counsel
Energy (DOE)	General Counsel
Health & Human Services (HHS)	Deputy Secretary
Homeland Security (DHS)	General Counsel
Housing & Urban Development (HUD)	General Counsel
Interior (DOI)	Deputy Secretary
Justice (DOJ)	Assistant Attorney General, Office of Legal Policy
Labor (DOL)	Assistant Secretary for Policy
State	Assistant Secretary for Administration
Transportation (DOT)	General Counsel
Treasury	General Counsel
Veterans Affairs (VA)	Deputy Secretary
Environmental Protection Agency (EPA)	Deputy Administrator
US Agency of International Development (USAID)	Deputy Administrator
Access Board (ATBCB)	Chair
Corporation for National & Community Service (CNCS)	Chief Executive Officer
Equal Employment Opportunity Commission (EEOC)	Vice Chair
General Services Administration (GSA)	Administrator
National Archives and Records Administration (NARA)	Archivist of the United States
National Aeronautics and Space Administration (NASA)	Deputy Administrator
National Capital Planning Commission (NCPC)	Chairman
Office of Federal Housing Enterprise Oversight (OFHEO)	Director
Office of Government Ethics (OGE)	Director
Office of Personnel Management (OPM)	Director
Small Business Administration (SBA)	Deputy Administrator
Social Security Administration (SSA)	Commissioner of Social Security

⁹³ The current list of agency Regulatory Policy Officers is on OMB's website, *available at:* http://www.whitehouse.gov/omb/info/regpol/agency_reg_policy_officers.pdf.

D. Updated Principles for Risk Analysis

Recognizing that risk analysis is the key tool used to evaluate health, safety, and environmental risks to inform policy-makers as to the extent to which different policy choices can reduce risks, in 1995 an interagency working group co-chaired by the Office of Management and Budget (OMB) and the Office of Science and Technology Policy (OSTP) developed a set of principles to guide policymakers in assessing, managing, and communicating policies to address environmental, health, and safety risks (the 1995 Principles).⁹⁴ In September, 2007, OMB and OSTP issued a joint memorandum to reinforce the 1995 Principles with reference to more recent guidance from the scientific community, the Congress, and the Executive Branch.⁹⁵ This Memorandum also benefits from feedback received on OMB's Proposed Risk Assessment Bulletin issued in 2006 (Proposed Risk Assessment Bulletin).⁹⁶

In releasing the updated risk principles, OMB and OSTP asked agencies to review their current risk analysis practices and guidelines to incorporate the updated principles as they develop, update, and issue risk analyses and guidelines. OMB and OSTP also committed to working with the Federal agencies to ensure consistency with the updated principles.

Agency Risk Analysis Guidance Documents

As part of our oversight and to help OMB and OSTP better understand where coordination efforts and future dialogue among federal agencies would be most useful, OMB requested that agencies provide a current list of documents produced by each agency that provides guidance relating to risk analysis practices. In addition, OMB also asked agencies to provide suggestions for risk analysis topic areas where further interagency coordination and dialogue would be useful.⁹⁷ As a result of this request to agencies, OMB and OSTP learned that

⁹⁴ U.S. Office of Mgmt. and Budget (OMB), Memorandum for the Regulatory Working Group, *Principles for Risk Analysis* (1995), available at http://www.whitehouse.gov/omb/inforeg/regpol/jan1995_risk_analysis_principles.pdf.

⁹⁵ OMB and OSTP, *Updated Principles for Risk Analysis* (2007), available at <http://www.whitehouse.gov/omb/memoranda/fy2007/m07-24.pdf>.

⁹⁶ OMB, *Proposed Risk Assessment Bulletin*, (2006) [hereinafter Proposed Risk Assessment Bulletin], available at http://www.whitehouse.gov/omb/inforeg/proposed_risk_assessment_bulletin_010906.pdf. In January 2006, OIRA, in consultation with OSTP, released the Proposed Risk Assessment Bulletin for public comment and asked the National Academy of Sciences (NAS) to conduct an expert peer review. The NAS issued its report on the Proposed Risk Assessment Bulletin in 2007 (National Research Council, National Academy of Sciences, *Scientific Review of the Proposed Risk Assessment Bulletin from the Office of Management and Budget*, 2007). While supportive of the goal of "increasing the quality and objectivity of risk assessment in the federal government," the NAS recommended an approach that would "outline goals and general principles of risk assessment." After carefully evaluating these constructive recommendations from the NAS, as well as feedback from a rigorous interagency review, and public comments, OMB and OSTP decided to issue an updated memorandum to reinforce generally-accepted principles for risk analysis upon which a wide consensus now exists.

⁹⁷ The 2007 NAS Report (National Research Council, National Academy of Sciences, *Scientific Review of the Proposed Risk Assessment Bulletin from the Office of Management and Budget*, 2007) on the Proposed Risk Assessment Bulletin identified areas where coordinated risk guidance would be helpful. Some of these areas include: inference options and defaults, uncertainty analysis and probabilistic risk assessment, presentation of risk results and ranges, variability, adversity of health effects, weight of evidence evaluations, and risk comparisons and presentation of this information to the public.

while some agencies have many publicly available guidance documents regarding their risk assessment practices, other agencies have more limited written guidance available. For instance, while the Environmental Protection Agency (EPA) has over 150 guidance documents available and about 30 additional documents in progress, the Department of Health and Human Services (HHS) (including FDA and CDC) identified less than 10 guidance documents related to the risk analyses that they conduct. Excluding their Information Quality Guidelines, the Department of Labor (DOL) identified only one written document providing guidance related to OSHA's general policy for identifying and classifying occupational carcinogens. The Department of Transportation reported that NHTSA has no written guidance on risk assessment but commented that they conduct probabilistic uncertainty analysis within the regulatory impact analyses of their regulations. The National Aeronautics and Space Administration (NASA) identified about 15 guidance documents, including guidance on probabilistic risk analysis. Interestingly all of the NASA documents have expiration dates to ensure that guidance is updated as appropriate.

As expected, the framing of the guidance produced by agencies is frequently specific to the types of analyses they conduct. However, as the NAS suggested, there are still areas where coordinated risk guidance would be helpful (see footnote 49), and OMB and OSTP continue to work with the agencies to facilitate a useful dialogue and coordination. For instance, the Consumer Products Safety Commission (CPSC) is working on guidelines for uncertainty and variability analysis and the Nuclear Regulatory Commission (NRC) is developing guidance on the treatment of uncertainties associated with probabilistic risk analyses in risk informed decision making. OMB will continue to work with agencies to ensure that guidance documents are coordinated and consistent to the extent feasible and practical. OMB welcomes input from the public on suggestions for areas where future coordination would be useful.

The Transatlantic Risk Dialogue

In November 2007, OMB and OSTP began conversations with the European Union (EU) and Canada to discuss facilitating an international dialogue on risk analysis. This dialogue was suggested by the EU-US High-Level Regulatory Cooperation Forum which works to strengthen cooperation and information exchange between the EU and US. Parties on both sides of the Atlantic agreed that every effort should be made to encourage cooperation at the technical and scientific level in order to reach a common understanding between the EU, Canadian and US regulatory authorities of how to measure risk in all areas of regulation and to use the same analytical tools for this purpose. Such a common understanding would not, of course, rule out policy differences between the EU, Canada and US approach in respect to risk management, but would help both sides to understand the scientific and risk management similarities and differences.

In February 2008, the Treasury Board of Canada hosted a meeting on Regulatory Risk Assessment in Ottawa. It was here that staff from OMB, OSTP, EU Health and Consumers Directorate General (DG-SANCO) and the EU Delegation began face to face talks regarding further meetings on risk analysis.

In July 2008, OMB and OSTP hosted over 60 participants for a day and a half of government-to-government discussions on risk analysis issues. Attendees included representatives of the European Commission, and the Canada Treasury Board, as well as experts from various US Departments and Agencies, from EU Scientific Committees and Panels, and from Canadian Departments and Agencies. The overall goal of the meeting was to launch the transatlantic risk assessment dialogue through an initial discussion among representatives of relevant departments and scientific experts on the role and organization of risk analysis in the US, EU, and Canadian regulatory systems, and to address a few methodological risk assessment issues and certain key aspects and challenges for risk assessment. Opening discussions familiarized participants with the relevant background, including governmental structure and regulatory realities and organization of risk assessment within the EU, US, and Canada, to set the stage for ensuing discussions. Sessions included: discussion on risk assessment terminology and how risk and uncertainty are expressed in the area of environmental and food toxins compared to the characterization of uncertainty by the Intergovernmental Panel on Climate Change; discussion of risk assessment methodologies including the margin of exposure approach as well as mode of action frameworks; discussion of advances in exposure assessment; challenges in bridging gaps at the risk assessment and risk management interface; and future challenges for the risk assessment community.

The presentations and discussions showed many similarities and for the future the group will consider a suggestion to develop a basic set of common transatlantic risk analysis principles. The meeting also set the stage for the First International Risk Assessment Conference planned for November 13th and 14th, 2008 in Brussels, which will include members of the public as well as governmental representatives. This meeting will build upon the July 2008 discussions and will be used to further exchange information and expertise as the participants begin to develop case studies that will help to further a useful and informative risk dialogue.

The EU will share scientific opinions with the US and Canadian governments in advance of the November meeting, and US, Canadian and EU staff will work collaboratively to develop a common set of risk analysis principles. These opinions, focused on thresholds of toxicological concern, risk assessment of genotoxic carcinogens, and nanotechnology in food, will provide a starting point for further discussion on these topics, including discussion at the November risk conference. Additionally, the risk dialogue will begin to focus on areas where the July Workshop participants expressed interest in the development of future methodologies and case studies. Of highest importance were the development of: a framework for exposure assessment (including probabilistic exposure assessment), a framework for defining adversity (particularly in the context of what to do with new endpoints and testing methodologies that will provide increased levels of information), and a framework for improving terminologies and methodologies used to characterize uncertainty. Case studies will be formulated and prepared for the November meeting to help further the development of such methodologies.

In addition to the efforts above, during the July workshop, among other topics, participants expressed a widespread interest in furthering discussions regarding how risk assessors, risk managers, and economists can work together more efficiently and more effectively. Participants also expressed interest in discussing (1) the acceptability of risk and (2)

risk communication challenges. Both these topics will be considered for future transatlantic risk dialogue activities.

APPENDIX A: CALCULATION OF BENEFITS AND COSTS

Chapter I presents estimates of the annual benefits and costs of selected major final regulations reviewed by OMB between October 1, 1996 and September 30, 2006. OMB presents more detailed explanation of these regulations in several documents.

- Rules from October 1, 1996 to September 30, 1997 appear in Table B-1 in Appendix B of this Report.
- Rules from October 1, 1995 to September 30, 1996 appear in Table B-1 in Appendix B of the 2007 Report.
- Rules from October 1, 1992 to September 30, 1995: Tables C-1 through C-3 in Appendix C of our 2006 Report.
- Rules from October 1, 1995 to March 31, 1999 can be found in Chapter IV of the 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 the 2006 Report
- Rules from October 1, 2005 to September 30, 2006: Tables 1-4 and A-1 of the 2007 Report.
- Rules from October 1, 2006 to September 30, 2007: Tables 1-4 and A-1 of this 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 Gross Domestic Product (GDP) deflator, available from the Bureau of Economic Analysis at the Department of Commerce.⁹⁸ 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 percent, unless the agency has already presented annualized, monetized results using a different explicit discount rate.

⁹⁸National Income and Product Accounts, available at <http://www.bea.gov>

OMB discusses, in this Report and in previous Reports, the difficulty of estimating and aggregating the benefits and costs 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, 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 practices" 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 benefits and costs we present in future Reports will become more comparable across agencies and programs. The 2006 Report was the first Report that included 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 ten major rules reviewed by OMB from October 1, 2005 through September 30, 2006, 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 I of this Report presents the adjusted impact estimates for the seven rules finalized in 2005-06 that were added to the Chapter I accounting statement totals.

Table A-1: Summary of Agency Estimates for Final Rules
 October 1, 2006 to September 30, 2007 (As of Date of Completion of OMB Review)

Rule [FR Cite]	Agency	Benefits	Costs	Other Information
Prohibition of the Use of Specified Risk Materials for Human Food and Requirements for the Disposition of Non-Ambulatory Disabled Cattle [72 FR 38700]	USDA/FSIS	Not estimated	\$87-221 million per year	<p>Benefits: USDA states that the main benefit of this proposed rule is the prevention of vCJD in the United States. While vCJD is considered a very rare condition, the interim final rule may have public health benefits if it contributes to the prevention of vCJD in the U.S. USDA also states that the rule may benefit the meat industry by helping to restore confidence in the domestic meat supply.</p> <p>Costs: In addition to the direct compliance costs of the rulemaking, FSIS may incur costs to increase inspection and compliance activities to ensure that the measures taken to prevent Specified Risk Materials from entering commerce are effective. Producers may receive lower prices from processors, and some of their stock may be condemned outright. The price consumers pay for meat may rise or fall due to this rulemaking, depending on how the discovery of BSE in the U.S. affects consumer demand for beef.</p> <p>The RIA is available online at: www.fsis.usda.gov/PDF/SRM_Impact_Analysis_03-025F.pdf</p>

Rule [FR Cite]	Agency	Benefits	Costs	Other Information
Bovine Spongiform Encephalopathy (BSE); Minimal-Risk Regions and Importation of Commodities [72 FR 53314]	USDA/ APHIS	\$169-340 million per year	\$98-194 million per year	<p>Benefits: According to an agricultural multi-sector analysis, USDA stated that rule will result in a decline in consumer expenditures of about 1% annually in the short term. In addition, U.S. buyers of certain ruminants and ruminant products allowed to enter from Canada by the rule (including sheep and goats, the meat of sheep and goats, cervids, camelids, and products such as bovine livers and tongues, gelatin, and tallow) will benefit from the additional source of supply.</p> <p>Costs: Include the program cost of monitoring the movement of feeder cattle imported from Canada, estimated to be an annualized cost over the 5-year period of about \$3.1 million. In addition, producers and suppliers of certain ruminants and ruminant products allowed to enter from Canada by the rule will face increased competition. According to the 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: USDA also conducted sensitivity analyses 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>The RIA is available online at: http://www.regulations.gov/fdmspublic/component/main?main=DocketDetail&d=APHIS-2006-0041</p>

Rule [FR Cite]	Agency	Benefits	Costs	Other Information
Energy Efficiency Standards for Electric Distribution Transformers [72 FR 58190]	DOE/ EERE	\$490-865 million per year	\$381-428 million per year	<p>Experience has shown that the choice of residential appliances and commercial equipment being purchased by both builders and building owners is generally based on the initial cost rather than on life-cycle cost. Thus, the law requires minimum energy efficiency standards for appliances to eliminate inefficient appliances and equipment from the market.</p> <p>The specific costs and benefits for this rulemaking have not been established because the final standard levels have not been determined. Nevertheless, existing analysis from the Notice of Proposed Rulemaking, 71 FR 44356, for energy conservation standards for distribution transformers projects savings of 2.4 quadrillion BTUs of energy from 2010 to 2038, with a national financial impact on the consumer in terms of national Net Present Value (NPV) up to 2.5 billion dollars.</p> <p>The RIA is available online at: http://www1.eere.energy.gov/buildings/appliance_standards/commercial/distribution_transformers.html</p>
Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Dietary Ingredients and Dietary Supplements [72 FR 34752]	HHS/ FDA	\$10-79 million per year	\$87-293 million per year	<p>Benefits: FDA states that the rule will help to ensure the safety and quality of dietary supplements. They estimate the regulation will reduce the number of sporadic human illnesses and rare catastrophic illnesses from contaminated products. FDA is aware of products that contain potentially harmful contaminants because of apparently inadequate manufacturing controls and quality control procedures. There also have been cases of misidentified ingredients harming consumers using dietary supplements. The Agency believes that a system of CGMPs is the most effective and efficient way to ensure the quality of dietary supplements.</p> <p>Costs: Include the value of resources devoted to increased sanitation, process monitoring and controls, testing, and written records. FDA also anticipates that small businesses will bear a proportionately larger cost than large businesses.</p> <p>Other details: FDA also performed an uncertainty analysis, varying the assumptions on the value of a statistical life, the amount of underreporting of illnesses during a recall, and on the characteristics of the manufacturing process such as the number of tests and batches needing testing and labor cost.</p> <p>The full RIA was published in the FR preamble to the final rule.</p>

Rule [FR Cite]	Agency	Benefits	Costs	Other Information
<p>Current Good Manufacturing Practice for Blood and Blood Components: Notification of Consignees and Transfusion Recipients Receiving Blood and Blood Components at Increased Risk of Transmitting HCV Infection [72 FR 48766]</p>	<p>HHS/ FDA</p>	<p>\$28-130 million per year</p>	<p>\$11 million per year</p>	<p>Benefits: The final rule will help ensure the continued safety of the blood supply. In this rulemaking, FDA requires that blood establishments prepare and follow written procedures for appropriate action when it is determined that blood and blood components pose an increased risk for transmitting hepatitis C virus (HCV) infection because they have been collected from a donor who, at a later date, tested reactive for evidence of HCV. Because 70 to 75 percent of HCV infections are asymptomatic, if recipients of such blood products become infected, most would not show any symptoms of the infection for several years and would not know to seek treatment in the early stages of the infection, which is much more effective and cost-effective.</p> <p>Costs: Are associated with the tracing of previous donations of donors, quarantining in-date products, identifying the recipients of previous blood donations, and notifying these recipients, as appropriate.</p> <p>Other details: Uncertainties in the estimates are primarily due to the fact that the particular FDA case studies of HCV look-back activities did not match the characteristics of the general population. FDA also studied the differences between a more general look-back versus the targeted look-back put in place by this rulemaking, and concluded that both approaches are relatively cost-effective.</p> <p>The full RIA was published in the FR preamble to the final rule.</p>
<p>Revision of the Form 5500 Series [72 FR 64731]</p>	<p>DOL/ EBSA</p>	<p>Not estimated</p>	<p>\$(83) million per year (cost savings)</p>	<p>Cost Savings: The revisions to the Form 5500 Annual Return/Report forms, including the new Short Form 5500, are intended to streamline the annual reporting process, reduce annual reporting burdens, especially for small businesses, update the annual reporting forms to reflect current issues and agency priorities, incorporate new reporting requirements contained in the Pension Protection Act of 2006, and facilitate electronic filing.</p> <p>Other details: DOL also studied the impacts of their program on small business, and decided the rule should exempt the vast majority of small plans from the requirement to file annual reports. ,</p> <p>The full RIA was published in the FR preamble to the final rule.</p>

Rule [FR Cite]	Agency	Benefits	Costs	Other Information
Emergency Mine Evacuation [71 FR 71430]	DOL/ MSHA	\$10 million per year	\$41 million per year	<p>Benefits: The rule provides miners with tools and training to successfully escape a serious mine accident that requires emergency evacuation of the mine. Benefits estimates are based on a study of 4 previous fatal mine accidents over the past 25 years that MSHA believes could have been mitigated if the requirements of this rule were in place.</p> <p>Costs: Are primarily planning, notification, training, and lifeline costs, as well as additional expense for the required purchase of self-contained self-rescue devices.</p> <p>Other details: Note that this rule is economically significant and major, due to the estimate first year compliance costs of \$147 million.</p> <p>The RIA is available online at: http://www.msha.gov/REGS/REA/06-9608EmerEvacETS.pdf</p>

Rule [FR Cite]	Agency	Benefits	Costs	Other Information
Electronic Stability Control (ESC) [72 FR 17235]	DOT/ NHTSA	\$5,987-11,282 million per year	\$913-917 million per year	<p>Benefits: The goal of this rulemaking is to reduce the serious risk of rollover crashes and the risk of death and serious injury in those crashes. Electronic Stability Control (ESC) systems use automatic computer-controlled braking of individual wheels to assist the driver in maintaining control in critical driving situations in which the vehicle is beginning to lose directional stability at the rear wheels (spin out) or directional control at the front wheels (plow out). Based on crash data studies, NHTSA estimates that the installation of ESC will reduce single-vehicle crashes of passenger cars by 34 percent and single vehicle crashes of sport utility vehicles (SUVs) by 59 percent, with a much greater reduction of rollover crashes. NHSTA estimates that the proposal would save 1,536 to 2,211 lives and prevent 50,594 to 69,630 MAIS 1-5 injuries annually once all passenger vehicles have ESC.</p> <p>Costs: The total incremental cost of the proposal includes the cost to install antilock brakes, electronic stability control, and malfunction lights. The average incremental cost per passenger vehicle is estimated to be \$58 (\$90 for the average passenger car and \$29 for the average light truck), a figure which reflects the fact that many baseline model year 2011 vehicles are projected to already come equipped with ESC components (particularly ABS).</p> <p>Other details: NHTSA also conducted a probabilistic uncertainty analysis. The major sources of uncertainty include the effectiveness of the rule in preventing a crash, the value of travel delays and property damage prevented, the lifetime fuel economic cost per vehicle, the number of vehicles affected, and the value of a statistical life.</p> <p>The RIA is available online at: http://www.regulations.gov/fdmspublic/component/main?main=DocketDetail&d=NHTSA-2007-27662</p>

Rule [FR Cite]	Agency	Benefits	Costs	Other Information
Side Impact Protection [72 FR 51907]	DOT/ NHTSA	\$736-1,058 million per year	\$401-1,051 million per year	<p>Benefits: the goal of the rule is to reduce the number of fatal and serious head injuries during side impact crashes. DOT estimated that the rule would benefit occupants in outboard seating positions in near-side crashes in vehicle-to-pole and vehicle-to-vehicle crashes. The agency has also found that the side air bags provide benefits to unbelted far-side occupants in side impacts, and for belted drivers riding alone in the front seat.</p> <p>Costs: Compliance costs are dependent upon the types of head and thorax side air bags chosen by the manufacturers and the number of sensors used in the system. The costs for installing new systems range from wide combination head/thorax side air bags with two sensors at \$126 per vehicle to wide window curtains and wide thorax side air bags with four sensors at a cost of \$280 per vehicle. The rule could potentially lead to other structural costs or padding costs that were not identified in testing.</p> <p>Other details: NHTSA also conducted a probabilistic uncertainty analysis. The major sources of uncertainty include the target population, the effectiveness of the rule in preventing the 4 major types of impacts and injuries affected by this rule, the number of vehicles affected, and the value of a statistical life.</p> <p>The RIA is available online at:</p> <p>http://www.regulations.gov/fdmspublic/component/main?main=DocketDetail&d=NHTSA-2007-29134</p>

Rule [FR Cite]	Agency	Benefits	Costs	Other Information
Control of Hazardous Air Pollutants From Mobile Sources [72 FR 8428]	EPA/ Air	\$2,310-2,983 million per year	\$298-346 million per year	<p>Motor vehicles are significant contributors to national emissions of several hazardous air pollutants. These pollutants are known or suspected to have serious health or environmental impacts. Reducing emissions of these pollutants will reduce risk to public health and welfare. The Clean Air Act requires EPA to periodically revise requirements to control emissions of these pollutants from mobile sources. EPA committed to this rulemaking in the preamble of the last rulemaking on this topic, promulgated on March 29, 2001.</p> <p>These controls would significantly reduce emissions of benzene and other mobile source air toxics such as 1,3-butadiene, formaldehyde, acetaldehyde, acrolein, and naphthalene. This proposal would result in additional substantial benefits to public health and welfare by significantly reducing emissions of particulate matter from passenger vehicles. We project annual nationwide benzene reductions of 35,000 tons in 2015, increasing to 65,000 tons by 2030. Total reductions in mobile source air toxics would be 147,000 tons in 2015 and over 350,000 tons in 2030. Passenger vehicles in 2030 would emit 45 percent less benzene. Gas cans meeting the new standards would emit almost 80 percent less benzene. Gasoline would have 37 percent less benzene overall. We estimate that these reductions would have an average cost of less than 1 cent per gallon of gasoline and less than \$1 per vehicle. The average cost for gas cans would be less than \$2 per can. The reduced evaporation from gas cans would result in significant fuel savings, which would more than offset the increased cost for the gas can.</p> <p>The RIA is available online at:</p> <p>http://www.regulations.gov/fdmspublic/component/main?main=DocketDetail&d=EPA-HQ-OAR-2005-0036</p>

Rule [FR Cite]	Agency	Benefits	Costs	Other Information
Clean Air Fine Particle Implementation [72 FR 20586]	EPA/ Air	\$18,833-167,408 million per year	\$7,324 million per year	<p>This rule is needed in order to provide guidance to State and local agencies in preparing State implementation plans (SIPs) designed to bring areas into attainment with the 1997 PM-2.5 standards. The implementation requirements for nonattainment areas are generally described in subpart 1 of section 172 of the Clean Air Act. This rule provides further interpretation of those requirements for the PM-2.5 standards.</p> <p>The RIA is available online at: http://www.regulations.gov/fdmspublic/component/main?main=DocketDetail&d=EPA-HQ-OAR-2003-0062</p>
Oil Pollution Prevention; Spill Prevention, Control, and Countermeasure (SPCC) Requirements— Amendments [71 FR 77266]	EPA/ SWER	Not estimated	\$(148)-(86) million per year (cost savings)	<p>This rulemaking will provide streamlined, alternative approaches for compliance with oil spill prevention requirements for certain entities, and to improve net welfare by reducing the costs of regulation and improving compliance, resulting in greater environmental protection.</p> <p>Considered separately and applying a 7 percent discount rate, today's proposed regulatory changes could yield annualized compliance cost savings, in 2005 dollars, of about \$38 million for the "Qualified Facility" option, \$39 to \$67 million for "Oil-Filled Equipment" option (assuming 25 to 75 percent of facilities with oil-filled equipment affected); \$1 million to \$5 million for the "Motive Power" exemption (assuming 10 to 50 percent of facilities with motive power containers affected); and \$17 million to \$51 million for the "Mobile Refuelers" exemption (assuming 25 to 75 percent of facilities with mobile refuelers affected). The main benefit of the rule is the reductions in compliance costs due to streamlined requirements. EPA does not believe that these cost reductions would be offset by any significant losses in environmental protection.</p> <p>The RIA is available online at: http://www.regulations.gov/fdmspublic/ContentViewer?objectId=09000064802ff9d5&disposition=attachment&contentType=pdf</p>

Rule [FR Cite]	Agency	Benefits	Costs	Other Information
Chemical Facility Anti-Terrorism Standards [72 FR 65396]	DHS/OS	Not estimated	\$835-1,535 million per year	<p>Benefits: The goal of this rule is to reduce the vulnerability of high-risk chemical facilities to a terrorist attack.</p> <p>Costs: DHS estimates approximately 50,000 facilities would undergo the "Top Screen," and of these facilities, 5,000 would be classified in one of the four risk tiers, which would trigger additional security planning and analysis requirements.</p> <p>Other details: DHS also performed a probabilistic uncertainty analysis. The major sources of uncertainty included the number of facilities undertaking the Top Screen, the number of facilities falling in each of the risk tiers, and the compliance costs associated with each risk tier.</p> <p>The RIA is available online at: http://www.regulations.gov/fdmspublic/component/main?main=DocketDetail&d=DHS-2006-0073</p>

Rule [FR Cite]	Agency	Benefits	Costs	Other Information
Passenger Manifest for Commercial Aircraft and Vessels Arriving In and Departing From the United States [72 FR 48320]	DHS/ CBP	Security Benefits Not quantified. Benefits of fewer diversions quantified at \$14 million per year.	\$94-134 million per year	<p>Benefits: The goal of the rule is to prevent high-risk passengers from boarding aircraft bound for or departing from the U.S., and to prevent such passengers and crew from departing on vessels leaving the U.S. DHS also estimated quantified benefits of \$14 million per year, primarily due to fewer diverted aircraft.</p> <p>Costs: Include costs to develop the systems to transmit passenger data to DHS, the value of the extra time passengers would need to submit the data and possibly arrive earlier at the airport, and the possibility of passengers missing connecting flights. For the high end of the range, DHS estimates that the rule will result in 1 percent of passengers on large carriers missing connecting flights and needing to be rerouted, with an average delay of 4 hours, and that 5 percent of originating passengers will need to arrive 15 minutes earlier than usual. For the low end, DHS assumes widespread use of the “interactive” system option, which leads to an estimate of 0.5 percent of passengers requiring rerouting on large carriers, and no earlier arrivals of passengers at the airport.</p> <p>Other details: DHS also performed a break-even analysis, which identified annual risk reductions required for the rule to breakeven for three attack scenarios.</p> <p>The RIA is available online at: http://www.regulations.gov/fdmspublic/component/main?main=DocketDetail&d=USCBP-2005-0003</p>

Rule [FR Cite]	Agency	Benefits	Costs	Other Information
Documents Required for Travel Within the Western Hemisphere [71 FR 68411]	DHS/ CBP	Not estimated	\$131-664 million per year	<p>Benefits: The goal of this rule is to increase security in the air environment by requiring a passport at all air ports of entry. The rule addresses a vulnerability of the U. S. to entry by terrorists or other persons by false documents or fraud under the previous documentary exemptions for travel within the Western Hemisphere. These vulnerabilities have been noted extensively by Congress and others.</p> <p>Costs: Include both the direct costs of the rule (for travelers to obtain new passports and continue traveling) and the indirect cost of the rule (for travelers foregoing travel in lieu of obtaining a new passport).</p> <p>Other details: DHS also performed a probabilistic uncertainty analysis. The major sources of uncertainty were the elasticity of travel demand, the time cost to obtain a passport, and the total cost of trips to the Western Hemisphere impacted by this rule.</p> <p>The RIA is available online at: http://www.regulations.gov/fdmspublic/component/main?main=DocketDetail&d=USCBP-2006-0097</p>
Transportation Worker Identification Credential (TWIC) Implementation in the Maritime Sector [72 FR 55043]	DHS/ TSA	Not estimated	\$88-415 million per year	<p>Benefits: The goal of the rule is to increase the security of the maritime transportation sector by reducing the number of high-risk individuals with access to secure areas in vessels and facilities.</p> <p>Costs: major categories of costs include the direct compliance cost for facilities and vessels, which are primarily costs associated with controlling access and providing escorts to unauthorized individuals, and the opportunity costs of the time needed for issuance and enrollment of TWIC cards.</p> <p>The RIA is available online at: http://www.regulations.gov/fdmspublic/component/main?main=DocketDetail&d=TSA-2006-24191</p>

Rule [FR Cite]	Agency	Benefits	Costs	Other Information
Migratory Bird Hunting; 2007 to 2008 Migratory Game Bird Hunting Regulations: Early Season [72 FR 49622]	DOI/FWS	\$291 million	Not estimated	<p>Benefits: The listed benefits represent estimated “consumer surplus.” Consumer surplus in this instance essentially measures the net gains to hunters stemming from the right to hunt, which this rule grants. Those net gains are the difference between what it costs to hunt (including gear, travel, and time spent hunting) and the satisfaction hunters get from taking part in this activity. Data to estimate “producers’ surplus” (the net gains to producers of hunting gear and to the providers of other services hunters use) 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 used by DOI 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 and made some updates for the 2007-2008 season. 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 available online at: http://www.fws.gov/migratorybirds/reports/SpecialTopics/EconomicAnalysis-2007Update.pdf</p>
Migratory Bird Hunting; 2007 to 2008 Migratory Game Bird Hunting Regulations: Late season [72 FR 53882]	DOI/FWS	\$291 million	Not estimated	<p>See “early season” regulation above.</p> <p>The RIA is available online at: http://www.fws.gov/migratorybirds/reports/SpecialTopics/EconomicAnalysis-2007Update.pdf</p>

APPENDIX B: THE BENEFITS AND COSTS OF 1996-1997 MAJOR RULES

Table B-1 lists the rules that were omitted from the ten-year running totals presented in Chapter 1 of our Reports to Congress. It consists of the annualized, monetized benefits and costs of rules for which OMB concluded review between October 1, 1996 and September 30, 1997. These rules were included in Chapter 1 of the 2007 Report as part of the ten-year totals, but are not included in the 2008 Report.

We continue to believe that the ten-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 benefits and costs 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 ten years.

**Table B-1: Estimates of Annual Benefits and Costs of Twelve Major Federal Rules
October 1, 1996 to September 30, 1997**
(millions of 2001 dollars)

REGULATION	AGENCY	BENEFITS	COSTS	EXPLANATION
Conservation Reserve Program	USDA/NRCS	2,400	1,058	No adjustment to agency estimate
Environmental Quality Incentives Program	USDA/NRCS	316	218	We amortized the agency's present value estimates over 25 years.
Energy Conservation Standards for Refrigerators and Freezers	DOE/EERE	764-829	284	We amortized the agency's present value estimates over 30 years.
Energy Conservation Standards for Room Air Conditioners	DOE/EERE	87	22	We amortized the agency's present value estimates over 30 years.
Quality Mammography Standards	HHS/FDA	218-305	44	No adjustment to agency estimate
Exposure to Methylene Chloride	DOL/OSHA	98	120	We monetized OSHA's estimated benefits of 31 cases of cancer and 3 deaths avoided per year using a VSL of \$5 million. We also assume that the reduction in cancer deaths starts in year 2017, based on an average 20 year lag from exposure to death from cancer.
Airbag Depowering	DOT/NHTSA	185-295	120-546	We amortized and monetized NHTSA's estimated fatalities and injuries avoided over lifetime of one full model-year's vehicles.
Roadway Worker Protection	DOT/FHWA	44	44	We amortized the agency's present value estimates over 10 years.
Acid Rain Nitrogen Oxide Emission Controls	EPA-Air	433-4,446	297	We valued annual NO _x emissions reductions using the values in Appendix B of the 2006 Report to Congress.
Acid Rain Nitrogen Oxide Phase II Emission Controls	EPA-Air	329-3,382	223	We valued annual NO _x emissions reductions using the values in Appendix B of the 2006 Report to Congress.

APPENDIX C: INFORMATION ON THE REGULATORY ANALYSES FOR MAJOR RULES BY INDEPENDENT AGENCIES

**Table C-1: Total Number of Rules Promulgated by Independent Agencies
October 1, 1997 to September 30, 2007**

Agency	1998	1999	2000	2001	2002	2003	2004	2005	2006	2007
Consumer Product Safety Commission (CPSC)	0	0	0	0	0	0	0	0	1	0
Federal Communications Commission (FCC)	19	7	8	2	4	0	1	4	2	2
Federal Energy Regulatory Commission (FERC)	0	0	2	0	0	0	0	0	0	0
Federal Reserve System	0	0	1	0	0	1	1	0	0	0
Federal Trade Commission (FTC)	0	0	1	0	0	0	0	1	0	0
National Credit Union Administration (NCUA)	0	1	0	0	0	0	0	0	0	0
Nuclear Regulatory Commission (NRC)	2	1	2	1	1	1	1	1	1	1
Pension Benefit Guaranty Corporation (PBGC)	0	1	0	0	0	0	0	0	0	0
Securities and Exchange Commission (SEC)	5	4	6	3	3	5	1	5	0	7
Total	26	14	20	6	8	7	4	11	4	10

**Table C-2: Total Number of Rules with Some Information on Benefits or Costs⁹⁹
Promulgated by Independent Agencies
October 1, 1997 to September 30, 2007**

Agency	1998	1999	2000	2001	2002	2003	2004	2005	2006	2007
Consumer Product Safety Commission (CPSC)	--	--	--	--	--	--	--	--	1	--
Federal Communications Commission (FCC)	5	0	1	0	0	0	1	0	0	0
Federal Energy Regulatory Commission (FERC)	--	--	2	--	--	--	--	--	--	--
Federal Reserve System	--	--	0	--	--	0	1	--	--	--
Federal Trade Commission (FTC)	--	--	1	--	--	--	--	0	--	--
National Credit Union Administration (NCUA)	--	0	--	--	--	--	--	--	--	--
Nuclear Regulatory Commission (NRC)	0	--	1	--	--	--	--	--	--	--
Pension Benefit Guaranty Corporation (PBGC)	--	1	--	--	--	--	--	--	--	--
Securities and Exchange Commission (SEC)	4	4	6	3	3	5	1	5	--	7
Total	9	5	11	3	3	5	3	5	1	7

⁹⁹ Tables 1-9 through 1-11 exclude all fee assessment rules promulgated by independent agencies. FCC promulgated six fee assessment rules from 1997 through 2002. NRC promulgated statutorily mandated ten fee assessment rules from 1997 through 2007.

**Table C-3: Percent of Rules with Monetized Benefits
Promulgated by Independent Agencies
October 1, 1997 to September 30, 2007**

Agency	1998	1999	2000	2001	2002	2003	2004	2005	2006	2007
Consumer Product Safety Commission (CPSC)	--	--	--	--	--	--	--	--	100	--
Federal Communications Commission (FCC)	0	0	0	0	0	--	0	0	0	0
Federal Energy Regulatory Commission (FERC)	--	--	50	--	--	--	--	--	--	--
Federal Reserve System	--	--	0	--	--	0	0	--	--	--
Federal Trade Commission (FTC)	--	--	0	--	--	--	--	0	--	--
National Credit Union Administration (NCUA)	--	0	--	--	--	--	--	--	--	--
Nuclear Regulatory Commission (NRC)	0	--	100	--	--	--	--	--	--	--
Pension Benefit Guaranty Corporation (PBGC)	--	0	--	--	--	--	--	--	--	--
Securities and Exchange Commission (SEC)	0	0	0	66	33	20	100	40	--	43

**Table C-4: Percent of Rules with Monetized Costs
Promulgated by Independent Agencies
October 1, 1997 to September 30, 2007**

Agency	1998	1999	2000	2001	2002	2003	2004	2005	2006	2007
Consumer Product Safety Commission (CPSC)	--	--	--	--	--	--	--	--	100	--
Federal Communications Commission (FCC)	6	0	0	0	0	--	100	0	0	0
Federal Energy Regulatory Commission (FERC)	--	--	0	--	--	--	--	--	--	--
Federal Reserve System	--	--	0	--	--	0	0	--	--	--
Federal Trade Commission (FTC)	--	--	0	--	--	--	--	0	--	--
National Credit Union Administration (NCUA)	--	0	--	--	--	--	--	--	--	--
Nuclear Regulatory Commission (NRC)	0	--	100	--	--	--	--	--	--	--
Pension Benefit Guaranty Corporation (PBGC)	--	0	--	--	--	--	--	--	--	--
Securities and Exchange Commission (SEC)	40	25	33	100	100	80	100	100	--	43

APPENDIX D: INFORMATION QUALITY AND PEER REVIEW

A. Links for Agency Information Quality Correspondence

Links to Agencies that Received Correction Requests in FY 2007:

Department of Commerce:

http://ocio.os.doc.gov/ITPolicyandPrograms/Information_Quality/index.htm

Department of Defense, Army Corps of Engineers:

<http://www.hq.usace.army.mil/ceci/informationqualityact>

Department of Energy: <http://www.cio.energy.gov/infoquality.htm>

Department of Health and Human Services: <http://aspe.hhs.gov/infoquality/requests.shtml>

Department of the Interior, Fish and Wildlife Service: <http://www.fws.gov/informationquality>

Department of the Interior, National Park Service:

<http://www.nps.gov/policy/infoqualcorrect.htm>

Department of the Interior, U.S. Geological Survey: http://www.usgs.gov/info_qual

Department of Labor: <http://www.dol.gov/cio/programs/InfoGuidelines/IQCR.htm>

Environmental Protection Agency: <http://epa.gov/quality/informationguidelines/iqg-list.html>

Federal Communications Commission: <http://www.fcc.gov/omd/dataquality/welcome.html>

Links to All Agencies' IQ Correspondence Web Pages:

Access Board: <http://www.access-board.gov/about/policies/infoquality.htm>

Chemical Safety and Hazard Investigation Board:

http://www.csb.gov/index.cfm?folder=legal_affairs&page=index

Commodity Futures Trading Commission:

<http://www.cftc.gov/webpolicy/index.htm#information>

Consumer Product Safety Commission:

<http://www.cpsc.gov/library/correction/correction.html>

Corporation for National and Community Service:

http://www.nationalservice.gov/home/site_information/quality.asp

Defense Nuclear Facilities Safety Board:

http://www.dnfsb.gov/about/information_quality.html

Department of Agriculture, Forest Service: <http://www.fs.fed.us/qoi/disclosure.shtml>

Department of Agriculture: http://www.ocio.usda.gov/qi_guide

Department of Commerce:

http://ocio.os.doc.gov/ITPolicyandPrograms/Information_Quality/index.htm

Department of Defense, Army Corps of Engineers:

<http://www.hq.usace.army.mil/ceci/informationqualityact>

Department of Defense: <http://www.defenselink.mil/pubs/dodiqguidelines.html>

Department of Education: <http://www.ed.gov/policy/gen/guid/infoqualguide.html>

Department of Energy: <http://www.cio.energy.gov/infoquality.htm>
Department of Health and Human Services: <http://aspe.hhs.gov/infoquality/requests.shtml>
Department of Housing and Urban Development:
<http://www.hud.gov/offices/adm/grants/qualityinfo/qualityinfo.cfm>
Department of Justice: http://www.usdoj.gov/iqpr/iqpr_disclaimer.html
Department of Labor: <http://www.dol.gov/cio/programs/InfoGuidelines/IQCR.htm>
Department of State: <http://www.state.gov/misc/49492.htm>
Department of the Interior, Bureau of Land Management:
http://www.blm.gov/wo/st/en/national_page/Notices_used_in_Footer/data_quality.html
Department of the Interior, Fish and Wildlife Service:
<http://www.fws.gov/informationquality>
Department of the Interior, National Park Service:
<http://www.nps.gov/policy/infoqualcorrect.htm>
Department of the Interior: <http://www.doi.gov/ocio/iq>
Department of Transportation, Surface Transportation Board:
<http://www.stb.dot.gov/stb/InformationQualityGuidelines.htm>
Department of Transportation: <http://www.dot.gov/infoquality.htm>
Department of Veteran Affairs: http://www.rms.oit.va.gov/Information_Quality.asp
Environmental Protection Agency: <http://epa.gov/quality/informationguidelines/iqg-list.html>
Equal Employment Opportunity Commission:
<http://www.eeoc.gov/policy/guidelines/index.html>
Farm Credit Administration: http://www.fca.gov/FCA-Web/fca%20new%20site/home/info_quality.html
Federal Communications Commission: <http://www.fcc.gov/omd/dataquality/welcome.html>
Federal Deposit Insurance Corporation: <http://www.fdic.gov/about/policies/#information>
Federal Energy Regulatory Commission: <http://www.ferc.gov/help/filing-guide/file-correct.asp>
Federal Maritime Commission:
<http://www.fmc.gov/reading/IntroInformationQualityGuidelines.asp?PRINT=Y>
Federal Reserve Board: http://www.federalreserve.gov/iq_correction.htm
Federal Trade Commission: <http://www.ftc.gov/ogc/sec515/index.htm>
General Services Administration:
http://www.gsa.gov/Portal/gsa/ep/contentView.do?contentId=12667&contentType=GSA_OVIEW
Institute of Museum and Library Services: <http://www.imls.gov/about/guidelines.shtm>
Internal Revenue Service: <http://www.irs.gov/irs/article/0,,id=131585,00.html>
Merit Systems Protection Board:
<http://www.mspb.gov/netsearch/viewdocs.aspx?docnumber=251846&version=252119&application=ACROBAT>
National Aeronautics and Space Administration: <http://www.sti.nasa.gov/qualinfo.html>
National Archives: <http://www.archives.gov/about/info-qual/requests/index.html>
National Credit Union Administration: <http://www.ncua.gov/data/InfoQuality/InfoQuality.htm>
National Endowment for the Arts: <http://www.arts.gov/about/infoquality.html>
National Endowment for the Humanities: <http://www.neh.gov/whoweare/dissemination.html>
National Labor Relations Board:
http://www.nlr.gov/about_us/public_notices/information_on_quality_guidelines.aspx

National Science Foundation: <http://www.nsf.gov/policies/infoqual.jsp>
National Transportation Safety Board: <http://www.nts.gov/info/quality.htm>
Nuclear Regulatory Commission: <http://www.nrc.gov/public-involve/info-quality.html>
Nuclear Waste Technical Review Board: <http://www.nwtrb.gov/plans/plans.html>
Occupational Safety & Health Review Commission:
<http://www.oshrc.gov/infoquality/infoquality.html>
Office of Federal Housing Enterprise Oversight:
<http://www.ofheo.gov/PublicInformation.aspx?Nav=105>
Office of Government Ethics: http://www.usoge.gov/pages/about_oge/info_quality.html
Office of Management and Budget:
http://www.whitehouse.gov/omb/inforeg/info_quality/information_quality.html
Office of Personnel Management: <http://www.opm.gov/policy/webpolicy/index.asp>
Office of Special Counsel: <http://www.osc.gov/InfoQuality.htm>
Overseas Private Investment Corporation:
<http://www.opic.gov/pubs/qualityguidelines/index.asp>
Peace Corps: <http://www.peacecorps.gov/index.cfm?shell=pchq.policies.docs>
Pension Benefit Guaranty Corporation: <http://www.pbgc.gov/media/key-resources-for-the-press/content/page5274.html>
Small Business Administration: <http://www.sba.gov/information/index.html>
Social Security Administration: <http://www.ssa.gov/515/requests.htm>
Tennessee Valley Authority: <http://www.tva.gov/infoquality/>
U.S. International Trade Commission: http://www.usitc.gov/policies/info_quality.htm
USAID: http://www.usaid.gov/policy/info_quality/

B. Links for Agency Peer Review Agendas

Cabinet-Level Departments

Department of Agriculture: http://www.ocio.usda.gov/qi_guide/qoi_officer_1st.html
Agricultural Research Service: <http://www.ars.usda.gov/Main/docs.htm?docid=8040>
Animal and Plant Health Inspection Service:
http://www.aphis.usda.gov/peer_review/peer_review_agenda.shtml
Economic Research Service: <http://www.ers.usda.gov/AboutERS/peerreview.htm>
Food Safety Inspection Service:
http://www.fsis.usda.gov/Information_Quality/Peer_Review/index.asp
Forest Service: <http://www.fs.fed.us/qoi/peerreview.shtml>
Grain Inspection, Packers, and Stockyard Inspection Administration:
<http://www.gipsa.usda.gov/GIPSA/webapp?area=home&subject=iq&topic=pr>
Office of the Chief Economist: http://www.usda.gov/occe/peer_review
Department of Commerce:
http://ocio.os.doc.gov/ITPolicyandPrograms/Information_Quality/index.htm
National Oceanic and Atmospheric Administration:
<http://www.cio.noaa.gov/itmanagement/prplans/PRsummaries.html>

Department of Defense: <http://www.defenselink.mil/pubs/dodiqguidelines.html>
Army Corps of Engineers: <http://www.hq.usace.army.mil/ceci/informationqualityact>

Department of Education: <http://www.ed.gov/policy/gen/guid/iq/peerreview.html>

Department of Energy: <http://cio.energy.gov/infoquality.htm>

Department of Health and Human Services: <http://aspe.hhs.gov/infoquality/peer.shtml>
Center for Disease Control: <http://www2a.cdc.gov/od/peer/peer.asp>
Food and Drug Administration: <http://www.fda.gov/oc/peerreview>
National Toxicology Program: <http://fmp-8.cit.nih.gov/sif/agenda.php>
Office of Public Health and Science:
<http://aspe.hhs.gov/infoquality/guidelines/ophspeer.html>

Department of Homeland Security: no website

Department of Housing and Urban Development:
http://www.huduser.org/about/pdr_peer_review.html

Department of the Interior: http://www.doi.gov/ocio/iq_1.html
Bureau of Land Management:
http://www.blm.gov/wo/st/en/national_page/Notices_used_in_Footer/data_quality.print.html
Bureau of Reclamation: <http://www.usbr.gov/main/qoi/peeragenda.html>
Fish and Wildlife Service:
http://www.fws.gov/informationquality/peer_review/index.html
Mineral Management Service: <http://www.mms.gov/qualityinfo/PeerReviewAgenda.htm>
National Park Service: <http://www.nps.gov/policy/peerreview.htm>
Office of Surface Mining: <http://www.osmre.gov/Peerreview.htm>
U.S. Geological Society: http://www.usgs.gov/peer_review

Department of Justice: http://www.usdoj.gov/iqpr/iqpr_disclaimer.html

Department of Labor: <http://www.dol.gov/asp/peer-review/index.htm>
Employee Benefits Security Administration:
<http://www.dol.gov/ebsa/regs/peerreview.html>
Occupational Safety and Health Administration:
http://www.osha.gov/dsg/peer_review/peer_agenda.html

Department of State: <http://www.state.gov/misc/49492.htm>

Department of Transportation: <http://www.dot.gov/peerrt.htm>

Department of Veterans Affairs: http://www.va.gov/oit/egov/rms/info_peer.asp

Other Agencies

Consumer Product Safety Commission: <http://www.cpsc.gov/library/peer.html>

Environmental Protection Agency: <http://www.epa.gov/quality/informationguidelines>

Federal Communications Commission: <http://www.fcc.gov/omd/dataquality/peer-agenda.html>

Federal Energy Regulatory Commission: <http://www.ferc.gov/help/filing-guide/file-correct.asp>

Federal Trade Commission: <http://www.ftc.gov/ogc/sec515/>

National Aeronautics and Space Administration: http://www.sti.nasa.gov/peer_review.html

Nuclear Regulatory Commission: <http://www.nrc.gov/public-involve/info-quality/peer-review.html>

Office of Management and Budget:

http://www.whitehouse.gov/omb/inforeg/info_quality/information_quality.html

Small Business Administration: <http://www.sba.gov/information/index.html>

Tennessee Valley Authority: <http://www.tva.gov/infoquality>

C. Agencies that Do Not Produce or Sponsor Information Subject to the Bulletin

See website links in section A of this Appendix.

Agency for International Development
Corporation for National and Community Service
Council on Environmental Quality
Defense Nuclear Facilities Safety Board
Department of the Treasury
Equal Employment Opportunity Commission
Farm Credit Association
Federal Maritime Commission
Federal Reserve
General Services Administration
Institute of Museum and Library Services
International Trade Commission
Merit Systems Protection Board
National Archives
National Credit Union Administration
National Endowment for the Arts
National Endowment for the Humanities
National Labor Relations Board
National Science Foundation
Nuclear Waste Technical Review Board
Office of Federal Housing Enterprise Oversight
Office of Government Ethics
Office of Personnel Management
Overseas Private Investment Corporation
Patent and Trade Office
Peace Corps
Pension Benefit Guaranty Corporation
Railroad Board
Securities and Exchange Commission
Selective Services System
Social Security Administration
Surface Transportation Board
US Occupational Safety and Health Review Commission

APPENDIX E: UPDATE ON 2004 REGULATORY REFORM NOMINATIONS

The Regulatory Right-to-Know Act requires OMB to publish “recommendations for reform” (Pub. L. No. 106-554, App. C, § 624(a)(3)). During the Bush Administration, OMB has responded to this requirement by requesting that the public identify candidates for reform. We solicited nominations for reform in 2001, 2002, and 2004. In previous Reports, OMB has provided periodic updates on these important regulatory reform initiatives. We are doing so again in this Final Report.

In OMB’s 2004 draft Report to Congress on the Costs and Benefits of Federal Regulations, we asked the public to suggest specific reforms to regulations, guidance documents or paperwork requirements that would improve manufacturing regulation. In response to the solicitation, OMB received 189 nominations. OMB and the agencies evaluated the nominations, and in March 2005, OMB issued the Regulatory Reform of the U.S. Manufacturing Sector Report.¹⁰⁰ In this report, we determined that 76 of the 189 nominations should be priorities, and also identified milestones and deadlines.

OMB continues to work closely with the regulatory agencies responsible for each of these reforms, and the agencies continue to make progress. Table E-4 below provides a further item-by-item update of the status of the regulatory reforms. The table indicates that 60 of the 76 reform items are now complete as of July 2008.

Table E-1: 2004 Manufacturing Regulatory Reform Nomination Status						
#	Reform Name	Nominator	Agency	Promised Action	Date	Status
4	Coastal Zone Management Act Federal Consistency Regulations	National Association of Manufacturers (9)	DOC NOAA	Final Rule	Anytime 2005	Complete. Final rule published on January 5, 2006 (71 FR 787)

¹⁰⁰This report is available at: http://www.whitehouse.gov/omb/inforeg/reports/manufacturing_initiative.pdf

Table E-1: 2004 Manufacturing Regulatory Reform Nomination Status

#	Reform Name	Nominator	Agency	Promised Action	Date	Status
6	North American Free Trade Agreement (NAFTA) Certificates of Origin	Motor & Equipment Manufacturers Association (41); Recreational Vehicle Industry Association (25)	DHS and Treasury	Report to OMB	May-05	Complete. Report submitted to OMB in May 2005. The reported summarized NAFTA activities and other electronic facilitation of Certificates of Origin. The report also noted that Rules of Origin are part of a trilateral agreement between U.S., Canada, and Mexico & cannot be changed unilaterally by the U.S. The USG has undertaken many initiatives to simplify NAFTA requirements. The United States Trade Representative (USTR) is leading an initiative to further simplify NAFTA requirements under the Strategy for Peace and Prosperity, a cooperative effort of the Governments of the U.S., Canada, and Mexico.
7	Maritime Security	American Shipbuilding Association (44)	DHS Coast Guard	Report to OMB	May-05	Complete. Report submitted to OMB in May, 2005. The report noted that Department of Defense (DOD) security plan requirements may not be sufficient for the purposes of the Maritime Transportation Security Act (MTSA) regulations for shipyards, because DOD plans generally do not cover non-DOD work at a facility. The report also noted, however, that the Coast Guard will consider waiving MTSA requirements in cases where the DOD plan is found to be equivalent to a plan required under MTSA. The Navy and the Coast Guard will continue to work together to ensure that effective security measures are in place for protecting shipyards that do not impose unnecessary or duplicative burdens on the affected Federal and private sector parties.

Table E-1: 2004 Manufacturing Regulatory Reform Nomination Status

#	Reform Name	Nominator	Agency	Promised Action	Date	Status
12	Motor Vehicle Brakes	National Association of Manufacturers (9); National Marine Manufacturers Association (38)	DOT FMCSA	Proposed Rule	Sep-05	Complete. Proposed rule published on October 7, 2005 (70 FR 58657)
12	Motor Vehicle Brakes	National Association of Manufacturers (9); National Marine Manufacturers Association (38)	DOT FMCSA	Final Rule	Sep-06	Complete. Final rule published on March 6, 2007. (72 FR 9855)
14	Hours of Service	SBA Office of Advocacy (39)	DOT FMCSA	Final Rule	Aug-05	Complete: Final rule published on August 25, 2005 (70 FR 49977)
16	Lighting & Reflective Devices	National Association of Manufacturers (9); Motor & Equipment Manufacturers Association (41)	DOT NHTSA	Proposed Rule	Dec-05	Complete: Proposed rule published on December 30, 2005 (70 FR 77453)
16	Lighting & Reflective Devices	National Association of Manufacturers (9); Motor & Equipment Manufacturers Association (41)	DOT NHTSA	Final Rule	Oct-07	Complete: Final rule published on December 4, 2007 (72 FR 68234).
18	Occupant Ejection Safety Standard	Public Citizen (2)	DOT NHTSA	Proposed Rule	Dec-06	Complete: Side impact proposal published on May 17, 2004 (69 FR 27989). Door retention proposal published on December 15, 2004 (69 FR 75020)
18	Occupant Ejection Safety Standard	Public Citizen (2)	DOT NHTSA	Final Rule	Feb-07	Complete: Final rule on door locks and other door retention devices published on February 6, 2007 (72 FR 5385)
22	Vehicle Compatibility Standard	Public Citizen (2)	DOT NHTSA	Report to OMB	Jun-05	Complete: Report submitted to OMB in June 2005. The report summarized current and projected future NHTSA research into vehicle compatibility.

Table E-1: 2004 Manufacturing Regulatory Reform Nomination Status

#	Reform Name	Nominator	Agency	Promised Action	Date	Status
26	EEO-1	U.S. Chamber of Commerce (19)	EEOC	Final Notice	Jun-05	Complete: Final EEO-1 report posted on January 27, 2006, and is available at http://www.eeoc.gov/eo1/index.html .
28	Document AP-42: "Coke Production" Emission Factors	American Coke and Coal Chemicals Institute (3)	EPA	Model software	Jun-05	Complete: Software modeled by September 30, 2005.
28	Document AP-42: "Coke Production" Emission Factors	American Coke and Coal Chemicals Institute (3)	EPA	Revise EF development process	Sep-05	Complete: Emission factor development process revised by September 30, 2005.
28	Document AP-42: "Coke Production" Emission Factors	American Coke and Coal Chemicals Institute (3)	EPA	Report on EF uncertainty assessment	Sep-05	Complete: Report on emission factors uncertainty completed in February 2007.
30	Document AP-42: Science and Site-Specific Conditions	National Association of Manufacturers (9)	EPA	Model software	Jun-05	Complete: Software modeled by September 30, 2005.
30	Document AP-42: Science and Site-Specific Conditions	National Association of Manufacturers (9)	EPA	Revise EF development process	Sep-05	Complete: Emission factor development process revised by September 30, 2005.
30	Document AP-42: Science and Site-Specific Conditions	National Association of Manufacturers (9)	EPA	Report on EF uncertainty assessment	Sep-05	Complete: Report on emission factors uncertainty completed in February 2007.
33	Clean Up Standards for PCBs	Motor and Equipment Manufacturers Association (41)	EPA	Report to OMB	Sep-05	Complete: EPA conducted an internal review in the first half of 2005. Stakeholder consultations occurred in May and June of 2005. EPA submitted a plan to OMB in September 2005 detailing the issue and outlining next steps.

Table E-1: 2004 Manufacturing Regulatory Reform Nomination Status

#	Reform Name	Nominator	Agency	Promised Action	Date	Status
34	Common Company Identification Number in EPA Databases	Deere & Company (1)	EPA	Ensure Underground Injections and Institutional Controls database utilizes the Facility Registration System identification number	Sep-05	Complete: EPA completed study to ensure that the Underground Injections and Institutional Controls database utilizes the Facility Registration System identification number by September, 2005.
34	Common Company Identification Number in EPA Databases	Deere & Company (1)	EPA	Work with remaining States as the States are ready to accept the common unique identification number	Anytime 2006	Complete: EPA is working with the States as they are ready to accept the unique Facility Registration System identification number. This is an ongoing project initiated in December, 2005. EPA continues to work with states to develop a common framework for information sharing.
35	ECHO Website	American Iron and Steel Institute (34)	EPA	Improve text explanations	Jun-05	Complete: EPA has improved the ECHO text explanations in order to guard against misinterpretation. This task was completed in June, 2005.
36	Electronic Formats for Agency Forms	National Association of Manufacturers (9)	EPA	Identify what existing regulatory form formats are currently available	Jul-05	Complete: EPA has identified what existing regulatory form formats are currently available in July, 2005.
36	Electronic Formats for Agency Forms	National Association of Manufacturers (9)	EPA	Determine if it is reasonable to assume most regulated entities have access to needed software	Oct-05	Complete: see final entry for #36 below
36	Electronic Formats for Agency Forms	National Association of Manufacturers (9)	EPA	Determine value and cost of offering form in additional format	Dec-05	Complete: see final entry for #36 below

Table E-1: 2004 Manufacturing Regulatory Reform Nomination Status

#	Reform Name	Nominator	Agency	Promised Action	Date	Status
36	Electronic Formats for Agency Forms	National Association of Manufacturers (9)	EPA	For those forms where conversion to other formats is warranted, make form available in new format	Feb-06	Complete: EPA determined that the best solution for a common format is to make public use forms available in Portable Document Format (PDF), which is non-proprietary and widely-used. Of the 197 forms EPA determined were being used to collect information from the public, 96% are currently being made available to the public in PDF. EPA determined that it was not necessary to offer the remaining forms in electronic format, because hardcopy is the more appropriate means for these collections. These forms include such things as forms that are mailed to EPA along with physical samples, and forms used by Agency interviewers. EPA continues to work with states and other stakeholders to ease the burden of electronic reporting through initiatives such as EPA's central data exchange and SBA's e-government.
38	Expand the Comparable Fuels Exclusion (CFE) under RCRA	National Association of Manufacturers (9); American Chemistry Council (31)	EPA	Discuss and Receive input from stakeholders	Jan-06	Complete: EPA discussed and received input on this nomination from stakeholders in December, 2005.
38	Expand the Comparable Fuels Exclusion (CFE) under RCRA	National Association of Manufacturers (9); American Chemistry Council (31)	EPA	Proposed Rule	Sep-06	Complete. Proposed rule published on June 15, 2007 (72 FR 33283)
38	Expand the Comparable Fuels Exclusion (CFE) under RCRA	National Association of Manufacturers (9); American Chemistry Council (31)	EPA	Final Rule	Nov-07	Overdue: Final Rule expected October, 2008

Table E-1: 2004 Manufacturing Regulatory Reform Nomination Status

#	Reform Name	Nominator	Agency	Promised Action	Date	Status
39	Export Notification Requirements	National Association of Manufacturers (9); American Chemistry Council (31)	EPA	Proposed Rule	Jan-06	Complete: Proposed rule published on February 9, 2006 (71 FR 6733). Final rule published on November 14, 2006 (71 FR 66234).
42	Hazardous Waste Rules Should Be Amended to Encourage Recycling (Definition of Solid Waste)	National Association of Manufacturers (9); American Petroleum Institute (12); Synthetic Organic Chemical Manufacturers Association (17); National Paint and Coatings Association (18); U.S. Chamber of Commerce (19); Alliance of Automobile Manufacturers (23); Specialty Graphic Imaging Association (27); American Chemistry Council (31); IPC - The Association Connecting Electronics Industries (32); SBA Office of Advocacy (39)	EPA	Final Rule or Re-proposal (which would be due in Winter of 2008)	Nov-06	Complete: Supplementary Proposed rule published on March 26, 2007 (72 FR 14171). Final rule expected September, 2008

Table E-1: 2004 Manufacturing Regulatory Reform Nomination Status

#	Reform Name	Nominator	Agency	Promised Action	Date	Status
43	Lead Reporting Burdens Under the Toxic Release Inventory	National Federal of Independent Business (8); National Association of Manufacturers (9); Synthetic Organic Chemical Manufacturers Association (17); National Paint and Coatings Association (18); The Policy Group (28); IPC - The Association Connecting Electronics Industries (32); The Copper and Brass Fabricators Council (45)	EPA	Report to OMB on the status of applying the metals framework to lead and lead compounds	Sep-05	Complete: EPA reviewed the Framework documents in accordance with the recommendations made by the SAB, and reported to OMB in 2007. EPA has decided not to pursue rulemaking on lead reporting thresholds.
44	Maximum Achievable Control Technology (MACT) standard for Chromium Emissions	The Policy Group (28)	EPA	Final Rule	No Deadline	Complete: Final rule published on July 19, 2004 (69 FR 42885)
45	PCB Remediation Wastes	Utility Solid Waste Activities Group (7)	EPA	Internal Review and Stakeholder Consultations	May-05	Complete: EPA conducted an internal review in the first half of 2005. Stakeholder consultations occurred in May and June of 2005. EPA submitted a plan to OMB in September 2005 detailing the issue and outlining next steps. Currently OMB and EPA are discussing the details of the plan and information that has been submitted by stakeholders.
45	PCB Remediation Wastes	Utility Solid Waste Activities Group (7)	EPA	Report to OMB	Sep-05	Complete: Report submitted to OMB in September 2005.

Table E-1: 2004 Manufacturing Regulatory Reform Nomination Status

#	Reform Name	Nominator	Agency	Promised Action	Date	Status
46	Permit Use of New Technology to Monitor Leaks of Volatile Air Pollutants	National Association of Manufacturers (9); U.S. Chamber of Commerce (19)	EPA	Proposed Rule or Guidance	Mar-06	Complete: Proposed rule published on April 6, 2006 (71 FR 17401)
46	Permit Use of New Technology to Monitor Leaks of Volatile Air Pollutants	National Association of Manufacturers (9); U.S. Chamber of Commerce (19)	EPA	Final Rule or Guidance	Mar-07	Overdue: In progress. Final rule is expected to be complete in December, 2008.
47	Pretreatment Streamlining Rule	The Policy Group (28); SBA Office of Advocacy (39); Motor and Equipment Manufacturers Association (41)	EPA	Final Rule	Jun-05	Complete: Final rule published on October 14, 2005 (70 FR 60133)
48	Provide More Flexibility in the Management of Wastewater Treatment Sludge to Encourage Recycling	The Policy Group (28); IPC - The Association Connecting Electronics Industries (32); SBA Office of Advocacy (39)	EPA	Proposed Rule	Dec-05	Complete: Proposed rule published on March 26, 2007 (72 FR 14171)
48	Provide More Flexibility in the Management of Wastewater Treatment Sludge to Encourage Recycling	The Policy Group (28); IPC - The Association Connecting Electronics Industries (32); SBA Office of Advocacy (39)	EPA	Final Rule	Jun-06	Overdue. Final rule expected December, 2008
51	Remove Regulatory Disincentive to Recycle Spent Hydrotreating and Hydrorefining Catalysts	American Petroleum Institute (12)	EPA	Respond to Petition	Dec-05	Complete: EPA concluded that there is sufficient data to support a rulemaking that addresses the issues raised by the petitioner (a catalyst recycler) and the commenter. EPA is proceeding with developing this rulemaking, but has not yet set estimated dates for the proposed and final rule.

Table E-1: 2004 Manufacturing Regulatory Reform Nomination Status

#	Reform Name	Nominator	Agency	Promised Action	Date	Status
52	Reporting and Paperwork Burden in the Toxic Release Inventory	Deere & Company (1); National Association of Manufacturers (9); American Petroleum Institute (12); National Small Business Association (24); Specialty Graphic Imaging Association (27); Society of Glass and Ceramic Decorators (33); SBA Office of Advocacy (39)	EPA	Final Rule (forms modification)	Jun-05	Complete: Final Rule published on July 12, 2005 (70 FR 39931)
52	Reporting and Paperwork Burden in the Toxic Release Inventory	See above	EPA	Proposed Rule (burden reduction)	Aug-05	Complete: Proposed rule published on October 4, 2005 (70 FR 57822)
52	Reporting and Paperwork Burden in the Toxic Release Inventory	See above	EPA	Final Rule (burden reduction)	Dec-06	Complete: Final rule published on December 22, 2006 (71 FR 76932).

Table E-1: 2004 Manufacturing Regulatory Reform Nomination Status

#	Reform Name	Nominator	Agency	Promised Action	Date	Status
54-58	Spill Prevention Control and Counter-measures (SPCC) Rule	Utility Solid Waste Activities Group (7); National Association of Manufacturers (9); Synthetic Organic Chemicals Manufacturing Association (17); National Paint and Coatings Association (18); General Electronic Company (26); American Furniture Manufacturers Association (35); SBA Office of Advocacy (39); American Public Power Association (42); Copper and Brass Fabricators Council (45)	EPA	Guidance to Inspectors	Jul-05	Complete: Guidance document released in October, 2005. The guidance is available at http://www.epa.gov/oilspill/guidance.htm
54-58	Spill Prevention Control and Counter-measures (SPCC) Rule	See above	EPA	Proposed Rule (related to NODA)	Aug-05	Complete: Proposed rule published on December 12, 2005 (70 FR 73523)
54-58	Spill Prevention Control and Counter-measures (SPCC) Rule	See above	EPA	Final Rule (related to NODA)	Feb-06	Complete: Final rule published on December 26, 2006 (71 FR 77266).
54-58	Spill Prevention Control and Counter-measures (SPCC) Rule	See above	EPA	Proposed Rule for Regulatory Modifications	Jun-06	Complete: Proposed rule published on October 15, 2007 (72 FR 58377).

Table E-1: 2004 Manufacturing Regulatory Reform Nomination Status

#	Reform Name	Nominator	Agency	Promised Action	Date	Status
54-58	Spill Prevention Control and Counter-measures (SPCC) Rule	See above	EPA	Final Rule for Regulatory Modifications	Jun-07	Final rule expected in October, 2008
59	Water Permit Rules (mass-based standards, direct dischargers)	National Association of Manufacturers (9); American Chemistry Council (31)	EPA	Review as part of biennial plan	Aug-05	Complete: Published the 2006 Effluent Guidelines Program [304(m)] plan in August, 2005. The plan is available at http://www.epa.gov/waterscience/guide/plan.html . The final plan published in Fall 2006.
61	Annual Reporting of Pesticide Information	National Association of Manufacturers (9)	EPA	Post revised policy on website	Mar-05	Complete: EPA posted their revised reporting policy in February, 2005: http://www.epa.gov/compliance/monitoring/programs/fifra/establishments.html
68	Cooling Water Intake Structures, Phase III	American Public Power Association (42)	EPA	Final Rule	May-06	Complete: Published final rule on June 16, 2006 (71 FR 35005)
75	Electronic Filing by Manufacturing Firms	American Furniture Manufacturers Association (35)	EPA	Report to OMB	Dec-05	Complete: Report submitted to OMB in December, 2005. EPA has concluded that this action cannot be implemented at the present time. EPA will continue to monitor the situation to gauge the interest in developing common forms for use by this industry and, where applicable, promote the use of central data exchange-type networks as the basis for reporting and document management.
83	Leak-Detection and Repair Regulatory Programs	National Association of Manufacturers (9)	EPA	Proposed Rule	Mar-06	See item #46 above.
83	Leak-Detection and Repair Regulatory Programs	National Association of Manufacturers (9)	EPA	Final Rule	Mar-07	See item #46 above

Table E-1: 2004 Manufacturing Regulatory Reform Nomination Status

#	Reform Name	Nominator	Agency	Promised Action	Date	Status
86	Method of Detection Limit/Minimum Level Procedure under the Clean Water Act	National Association of Manufacturers (9); Inter-Industry Analytic Group (14); Alliance of Automobile Manufacturers (23)	EPA	Complete FACA Process	Sep-06	Complete: The Federal Advisory Committee (FACA) issued a final report in December, 2007
86	Method of Detection Limit/Minimum Level Procedure under the Clean Water Act	See above	EPA	Conclude Pilot Project	Nov-06	Complete: concluded FACA pilot project in January, 2007. Because the final method recommended by the FACA was not included in the first pilot study, EPA will conduct a new pilot, closing in Fall, 2008.
86	Method of Detection Limit/Minimum Level Procedure under the Clean Water Act	See above	EPA	Proposed Rule	Jun-07	Overdue: currently scheduled for December, 2009.
86	Method of Detection Limit/Minimum Level Procedure under the Clean Water Act	See above	EPA	Final Rule	Jun-08	Overdue: Awaiting issuance of proposed rule.
87	Operating Permits Under the Clean Air Act	National Association of Manufacturers (9)	EPA	Final Report on whether to change Title V	Dec-05	Complete: Final report to the Clean Air Advisory Committee on Title V published in April 2006. EPA responded in September 2006 with plans to develop best practice and guidance documents, improve EPA processes, and to pursue program changes through rulemaking. EPA proposed the Flexible Air Permits Rule in September 2007. Reports, recommendations and EPA response available at http://www.epa.gov/air/oaqps/permits/taskforce.html .

Table E-1: 2004 Manufacturing Regulatory Reform Nomination Status

#	Reform Name	Nominator	Agency	Promised Action	Date	Status
88	Potential to Emit (PTE) Test	Deere & Company (1); Motor and Equipment Manufacturers Association (41)	EPA	Proposed Rule	Jan-06	Overdue: Proposed rule expected in December 2008.
88	Potential to Emit (PTE) Test	Deere & Company (1); Motor and Equipment Manufacturers Association (41)	EPA	Final Rule	Jan-07	Overdue: Awaiting issuance of proposed rule.
90	Prohibit Use of Mercury in Automobile Manufacturing	American Iron and Steel Institute (34)	EPA	Conduct Preliminary Analysis	Jun-05	Complete: EPA finished its preliminary analysis in June, 2005
90	Prohibit Use of Mercury in Automobile Manufacturing	American Iron and Steel Institute (34)	EPA	Discuss Regulatory options with stakeholders	Sep-05	Complete: EPA finished its discussions with stakeholders by June, 2005
90	Prohibit Use of Mercury in Automobile Manufacturing	American Iron and Steel Institute (34)	EPA	Make determination on appropriate regulatory or voluntary approach	Nov-05	Complete: Proposed rule published on July 11, 2006 (71 FR 39035)
92	Reduce the Inspection Frequency from Weekly to Monthly for Selected RCRA Facilities	Deere & Company (1)	EPA	Final Rule	Nov-05	Complete: Final rule published on April 4, 2006 (71 FR 16861)
97	Reportable Quantity (RQ) Threshold for Nitrogen Oxide and Dioxide at Combustion Sources	National Association of Manufacturers (9); American Chemistry Council (31)	EPA	Proposed Rule	Sep-05	Complete: Proposed rule published on October 4, 2005 (70 FR 57813)
97	Reportable Quantity (RQ) Threshold for Nitrogen Oxide and Dioxide at Combustion Sources	National Association of Manufacturers (9); American Chemistry Council (31)	EPA	Final Rule	Sep-06	Complete: Final rule published on October 4, 2006 (70 FR 58525)

Table E-1: 2004 Manufacturing Regulatory Reform Nomination Status

#	Reform Name	Nominator	Agency	Promised Action	Date	Status
101	Sulfur and Nitrogen Monitoring at Stationary Gas-Fired Turbines	National Association of Manufacturers (9)	EPA	Report to OMB on the status of discussions with Commenter to determine whether rule promulgated April 2004 addresses commenter's concerns	May-05	Complete: Report submitted to OMB in May, 2005. The report stated that the 2004 rule on sulfur and nitrogen monitoring satisfied the reform nomination. EPA subsequently checked with commenter (NAM) which agreed the 2004 rule was responsive to the reform nomination.
103	Systematic Program for Developing and Validating Analytic Methods	Inter-Industry Analytic Group (14); American Public Power Association (42)	EPA	Form a Federal Advisory Committee	Sep-06	Complete: FACA issued a final report in December, 2007. Please see item #86 above.
103	Systematic Program for Developing and Validating Analytic Methods	See above	EPA	Conclude Pilot Project	Nov-06	Complete: concluded pilot project in January, 2007. New pilot scheduled for Fall, 2008. Please see item #86 above.
103	Systematic Program for Developing and Validating Analytic Methods	See above	EPA	Proposed Rule	Jun-07	Currently scheduled for December, 2009.
103	Systematic Program for Developing and Validating Analytic Methods	See above	EPA	Final Rule	Jun-08	Overdue: Awaiting issuance of proposed rule.
108	Deferral of Duplicative Federal Permitting	The Policy Group (28)	EPA	Proposed Rule	Mar-05	Complete: Proposed rule published on March 25, 2005 (70 FR 15250)
108	Deferral of Duplicative Federal Permitting	The Policy Group (28)	EPA	Final Rule	Aug-05	Complete: Final rule published on December 19, 2005 (70 FR 75319)

Table E-1: 2004 Manufacturing Regulatory Reform Nomination Status

#	Reform Name	Nominator	Agency	Promised Action	Date	Status
110	SARA Title 312, 313 Programs	American Iron and Steel Institute (34)	EPA	Final Rule (TRI forms modification)	Jun-05	Complete: Final Rule published on July 12, 2005 (70 FR 39931)
110	SARA Title 312, 313 Programs	See above	EPA	Proposed Rule (TRI burden reduction)	Aug-05	Complete: Proposed rule published on October 4, 2005 (70 FR 57822)
110	SARA Title 312, 313 Programs	See above	EPA	Final Rule (TRI burden reduction)	Dec-06	Complete: Final rule published on December 22, 2006 (71 FR 76932).
112	Vapor Recovery at Gasoline Stations	American Petroleum Institute (12)	EPA	Report to OMB on cost-effectiveness	Sep-05	Complete: Report submitted to OMB September 2005. The report examines the cost-effectiveness of maintaining Stage II control at the gasoline pump under various assumptions on the penetration of onboard recovery controls in the mobile source fleet.
116	Publicly Owned Treatment Work (POTW) removal credits	Copper and Brass Fabricators Council (45)	EPA	Internal Issue Paper	Mar-05	Complete: EPA developed an internal issue paper in March, 2005.
117	Categorical Wastewater Sampling and Testing	Copper and Brass Fabricators Council (45)	EPA	Final Rule	Jun-05	Complete: Part of Pretreatment Streamlining final rule, published on October 14, 2005 (70 FR 60133)
118	Definition of Volatile Organic Compound	Copper and Brass Fabricators Council (45)	EPA	Advance Notice of Proposed Rulemaking (ANPRM)	May-05	Complete: On September 13, 2005 (70 FR 54046), EPA issued guidance, as an alternative to issuing an ANPRM, on State implementation plans designed to meet the national ambient air quality standard for ozone. This guidance summarizes recent scientific findings, provides examples of innovative applications of reactivity information in the development of Volatile Organic Compound (VOC) control measures, and clarifies the relationship between innovative reactivity-based policies and EPA's current definition of VOC.

Table E-1: 2004 Manufacturing Regulatory Reform Nomination Status

#	Reform Name	Nominator	Agency	Promised Action	Date	Status
119	Thermal Treatment of Hazardous Waste Guidance	Copper and Brass Fabricators Council (45)	EPA	Report to OMB	Feb-06	Complete: Report submitted to OMB in February 2006. The report reviewed the risks and benefits of the reform nomination.
121	Do Not Fax Rule	National Federal of Independent Business (8); National Association of Manufacturers (9); U.S. Chamber of Commerce (19); National Small Business Association (24); SBA Office of Advocacy (39)	FCC	Resolution of petition for reconsideration of rulemaking. July 2005 is the effective date for the final rule	Jul-05	Complete: Proposed rule published on December 19, 2005 (70 FR 75102)
122	Broadband	Heritage Foundation (5)	FCC	Resolution of Rule following Supreme Court decision	Jul-05	Complete: Final rule published on October 17, 2005 (70 FR 60222)
125	HIPAA	Motor & Equipment Manufacturers Association (41)	HHS CMS	Proposed Rule	Dec-05	Overdue: In progress.
125	HIPAA	Motor & Equipment Manufacturers Association (41)	HHS CMS	Final Rule	Dec-06	Overdue: Awaiting issuance of proposed rule.

Table E-1: 2004 Manufacturing Regulatory Reform Nomination Status

#	Reform Name	Nominator	Agency	Promised Action	Date	Status
134 135 136 137 139 141 142 143 144	FMLA	FMLA Technical Corrections Coalition (4); Heritage Foundation (5); National Federation of Independent Business (8); National Association of Manufacturers (9); U.S. Chamber of Commerce (19); American Furniture Manufacturers Association (35); Motor & Equipment Manufacturers Association (41); Society for Human Resource Management (46)	DOL ESA	Proposed Rule	Anytime 2005	Complete: OMB Conclude review on FMLA proposed rule on January 31, 2008.
145	Permanent Labor Certification	U.S. Chamber of Commerce (19)	DOL	Final Rule	No Deadline; rule already issued	Complete: Final rule published on December 27, 2004 (69 FR 77325)

Table E-1: 2004 Manufacturing Regulatory Reform Nomination Status

#	Reform Name	Nominator	Agency	Promised Action	Date	Status
151	Annual Training Requirements for Separate Standards	American Furniture Manufacturers Association (35)	DOL OSHA	Report to OMB	May-05	Complete: Report submitted to OMB in May, 2005. The report noted that OSHA does not require separate training programs for each standard that requires training. The report also noted that OSHA has sought to avoid duplication of EPA's training requirements on subjects where both agencies have jurisdiction. OSHA plans to revise and update its publication, Training Requirements in OSHA Standards and Training Guidelines, to clarify training requirements, and will add training consideration to its Standards Improvement Project Phase III. OSHA published an ANPRM on the Standards Improvement Project on December 21, 2006. The comment period closed on Feb. 20, 2007 and OSHA is analyzing the comments.
152	Coke Oven Emissions	American Coke and Coal Chemicals Institute (3); American Iron and Steel Institute (34)	DOL OSHA	Final Rule	No Deadline; rule already issued	Complete: Final rule published on January 5, 2005 (70 FR 1111)

Table E-1: 2004 Manufacturing Regulatory Reform Nomination Status

#	Reform Name	Nominator	Agency	Promised Action	Date	Status
153	Flammable Liquids	National Association of Manufacturers (9); National Marine Manufacturers Association (38)	DOL OSHA	Rulemaking	No Deadline	In progress: OSHA published an ANPRM for the Standards Improvement Project, Phase III (SIP III) on December 21, 2006. The ANPRM sought public comment on, the recommendation to replace several of the National Fire Protection Association (NFPA) consensus standards referenced in the OSHA standards regulating flammable liquids with the most recent editions of these NFPA standards. Comments received in response to the ANPRM did not provide sufficient information to propose updating OSHA's flammable-liquid standards as recommended. Accordingly, the proposed SIP III rule, which is due for publication in November, 2008, will solicit additional public comment on the recommendations.
155	Hazard Communication Training	National Association of Manufacturers (9)	DOL OSHA	Final Guidance	Anytime 2005	In Progress: The Hazard Communication Training guide is undergoing final Department of Labor review. The completion of this training project has been delayed because of the Agency's work on the Hazard Communication/Globally Harmonized System rulemaking, which has a proposed rule due for publication in October 2008.
156	Hazard Communication Material Safety Data Sheets	Deere & Company (1); National Association of Manufacturers (9); American Furniture Manufacturers Association (35)	DOL OSHA	Proposed Guidance	Anytime 2005	Complete.

Table E-1: 2004 Manufacturing Regulatory Reform Nomination Status

#	Reform Name	Nominator	Agency	Promised Action	Date	Status
156	Hazard Communication Material Safety Data Sheets	See above	DOL OSHA	Final Guidance	Feb-06	Complete: OSHA issued the guidance document "Guidance on Hazard Determination" in June 2007. It is on OSHA's web site at http://www.osha.gov/dsg/hazcom/ghd053107.html .
157	Hexavalent Chromium	The Policy Group (28); SBA Office of Advocacy (39)	DOL OSHA	Final Rule	Jan-06	Complete: Final rule published on February 28, 2006 (70 FR 10100)
159	Sling Standard	U.S. Chamber of Commerce (19); Associated Wire Rope Fabricators (42)	DOL OSHA	Guidance, with rulemaking considered at a later date	Feb-06	Complete. Guidance issued on September 7, 2007. It is on OSHA's web site at http://www.osha.gov/dsg/guidance/slings/index.html .
160	Guardrails Around Stacks of Steel	American Iron and Steel Institute (34)	DOL OSHA	Report to OMB	May-05	Complete: Report submitted to OMB in May, 2005. This report noted that OSHA is currently conducting a rulemaking on its Walking and Working Surfaces standard, and will consider the guardrail requirement as part of that rulemaking. It also stated that the agency had contacted the commenter to discuss OSHA's plans and that the commenter supported addressing the issue in the Walking and Working Surfaces rulemaking. OSHA plans to publish this proposed rule in April, 2008.
169	Walking and Working Surfaces	Copper and Brass Fabricators Council (45)	DOL OSHA	Report to OMB	May-05	Complete: Report submitted to OMB in May, 2005. This report noted that OSHA is currently conducting a rulemaking on its Walking and Working Surfaces standard, and will consider the allowance of ship stairs in certain circumstances as part of that rulemaking. It also stated that the agency had contacted the commenter and that the commenter supported including a flexible policy for ship stairs in the final rule.

Table E-1: 2004 Manufacturing Regulatory Reform Nomination Status

#	Reform Name	Nominator	Agency	Promised Action	Date	Status
175	Duty Drawback	National Association of Manufacturers (9)	Treasury Customs	Incorporate drawback simplification into the ACE project	No Deadline	Complete: Customs is working with the trade to streamline and simplify drawback as part of the Automated Commercial Environment (ACE) project. As of April, 2007, Electronic Manifests are not operational and required at all southern land ports. More information on ACE is available at http://www.cbp.gov/xp/cgov/too/box/about/modernization/
178	Election to Expense Certain Depreciable Business Assets	SBA Office of Advocacy (39)	Treasury IRS	Support legislation making the \$100,000 expensing limit permanent	No Deadline	Complete: On May 17, 2006, the President signed into law the Tax Increase Prevention and Reconciliation Act of 2005. The Act extends through 2009 the ability of small businesses to expense up to \$100,000 (indexed for inflation) of investments in depreciable assets under section 179 of the Internal Revenue Code.
188	Ready to Eat Meat Establishments to Control for Listeria	National Association of Manufacturers (9); SBA Office of Advocacy (39); William Russell & Associates, Inc. (30)	USDA FSIS	Final Rule	Jun-05	Overdue: In progress.

The agency contact information provided in Table E-5 is intended to allow interested members of the public to inquire about the status of regulatory reforms that remain underway.

Table E-2: Agency Contact Information for Further Updates

Agency	Person/Office	Phone Number	E-Mail Address/URL
Agriculture	Mike Poe	202-720-3257	poe@opba.usda.gov
HHS	John Gallivan	202-205-9165	john.gallivan@hhs.gov
DHS	Mary Kate Whalen	202-282-9160	marykate.whalen@dhs.gov
Interior	Office of Executive Secretariat and Regulatory Affairs	202-208-3181	fay_iudicello@ios.doi.gov
Labor	Susan Howe	202-693-5959	howe.susan@dol.gov
Transportation	Office of Asst. General Counsel for Regulation	202-366-4723	dot.regulation@dot.gov
Treasury	Office of the Executive Secretary	202-622-2000	http://www.treas.gov/education/execsec/contact-us.shtml
EEOC	Office of Legal Counsel	202-663-4645	carol.miaskoff@eoc.gov

Table E-2: Agency Contact Information for Further Updates			
Agency	Person/Office	Phone Number	E-Mail Address/URL
EPA	Nicole Owens	202-564-1550	Owens.Nicole@epamail.epa.gov
Federal Reserve	Financial Reports Section of the Federal Reserve Board	202-452-3829	RSMA-FinancialReports@frb.gov
FCC	Office of the Managing Director	202-418-2910	Karen.Wheeless@fcc.gov
FTC	Richard Gold	202 326-3355	rgold@ftc.gov
SBA	Martin Conrey	202-619-0638	Martin.Conrey@sba.com
SEC	Anne Sullivan	202-551-5019	sullivan@sec.gov
Army Corps	Katherine Trott	202-761-5542	Katherine.L.Trott@hq02.usace.army.mil

APPENDIX F: ANALYZING INTERNATIONAL EFFECTS OF REGULATION

A. Analyzing the Effect of Regulation on International Trade and Investment

As tariffs and other explicit barriers to international trade fall in an increasingly global marketplace, domestic policies are more likely to affect trading partners. Accordingly, OMB and the Secretariat General of the European Commission recently finalized a report on how our respective Regulatory Impact Analysis guidelines take into account the potential international effects of regulation, and are considering whether our respective regulatory analysis approaches should be modified to better incorporate international trade effects into the analysis of regulation.¹⁰¹ Knowing how regulation affects trade may help to ensure that regulatory policy does not become a tool for establishing (whether deliberately or not) unnecessary barriers to trade.

OIRA is considering brief guidance to agencies on considering the effect of draft regulations on international trade and investment. We would welcome comments on the following draft guidance.

Recent studies demonstrate the correlation between better business regulations and economic growth.¹⁰² This research suggests that a regulatory regime that offers transparent rules based on technical requirements promotes investment, which in turn leads to economic growth and an increase in consumer well-being.

The need for open markets may also lead to regulatory reforms as nations strive for efficiency and productivity to stay competitive in global markets. Generally, flexible labor and product markets that can quickly adapt to change contribute to efficiency gains. If there are unnecessary regulatory barriers among countries, firms may face a high cost of entry into a new market. Reports from the Organization for Economic Cooperation and Development (OECD), for example, found that differences in services market regulation have a large negative impact on market entry, which also lead to negative impacts on trade flows. Ultimately, local services sectors' export performance will suffer due to a lack of competition, and consumers will be worse off.

Regulations that correct market failures or government failures (including trade barriers) have the potential to improve market performance, both by generating social benefits and lowering or avoiding trade barriers. In addition to increasing productivity and flexibility in labor and products markets, performance- and market-based regulatory systems that are flexible and preserve liberal trade lead to higher employment, improvement in social indicators, and innovation. All of these advantages to flexible economies and open markets should be considered when designing new regulatory approaches to emerging issues.

¹⁰¹ The final report, draft report, and public comments are available at <http://www.whitehouse.gov/omb/inforeg/regpol.html#opp>

¹⁰² Please see Chapter 1, Section F of this draft Report for a discussion of this research.

Section B is a discussion of issues to consider when incorporating international trade and investment effects into the Regulatory Impact Analysis required by OMB Circular A-4. It was originally published for comment in the draft joint OMB-EC paper.

B. Incorporating Trade Impacts into Benefit-Cost Analysis

OMB Circular A-4 states that benefit-cost analysis is the primary tool used for regulatory analysis, as it provides decision makers with a clear indication of the regulatory alternative that generates the largest net benefits to society. Even if economic efficiency is not the only or primary public policy objective, an understanding of the benefits and costs of a regulatory action is important for decision makers and the public.

Further, EO 12866 states regulatory policies should recognize that “the private sector and private markets are the best engine for economic growth.” Although regulations typically impose limitations on the functioning of the private market, a subset of those regulations may affect international trade. International trade is simply a private market where economic exchange takes place across national boundaries. Therefore, in the absence of a market failure, trade itself presumptively increases the net benefits to each nation involved in the trading, in the same way trade increases welfare when taking place between individual private parties.

Just as a regulation may impose costs on private domestic markets, a regulation may have the effect of interfering with, and shrinking, the level of international trade. Since this aspect of regulation is presumptively harmful to overall economic welfare in each nation, the size of this harmful effect should be considered in regulatory analysis and compared, along with other regulatory costs, to the benefits generated by the regulation to determine whether regulations maximize the net benefits to society. It is important to emphasize: this discussion is not meant to convey that a regulation with such a trade impact cannot have net benefits. It merely points to a cost that should be assessed and compared with the estimated benefits of a regulation.

How might this cost be considered? Circular A-4 states that the analysis “should focus on benefits and costs that accrue to citizens and residents of the United States.” An example of how a trade impact could lead to an impact on U.S. citizens is the following. A regulation is introduced which leads the United States to stop or restrict the import of a particular product. U.S. citizens that used to consume this product now turn to a substitute product, which is produced domestically. To simplify, suppose the two products are identical, but the production of the domestically produced product uses more resources than the imported product and sells at a higher price. One effect of this regulation, therefore, is to induce a pure uncompensated cost, which is roughly equal to the average of the pre- and post-regulation quantity consumed multiplied by the price increase.

There is another possible cost. Since the regulation may reduce the number of competing suppliers of the product that was imported before the regulation, a benefit-cost analysis may also need to assess whether or not market-power-based price increases will occur as a result of the regulation. In this case, it may be difficult to estimate both the size of the price increase and the fraction of the market-power-based price increase which constitutes a net cost to a country, as

opposed to a simple wealth transfer from consumers to producers within that country. As Circular A-4 states, “distinguishing between real costs and transfer payments is an important, but sometimes difficult, problem in cost estimation.” Nevertheless, benefit and cost estimates should reflect real resource use.

Using this approach, regulators may more easily distinguish a regulation affecting trade which benefits the producers in their country at the expense of the consumers in their country, from a regulation that retains welfare-enhancing trade where possible and only restricts trade, either indirectly or directly, in cases where the benefits outweigh the costs.

The Role of Regulation: Just as domestic markets can fail to work properly, international markets can fail as well. Externalities, public goods, market power, and informational imperfections know no national boundaries. Consequently, the benefits and costs enjoyed by engaging in unregulated trade between nations may be enhanced through regulation in certain situations. For example, international trade certainly includes products traded in the presence of information asymmetry; products may suffer from negative attributes that may be unknown or unknowable at the time of purchase. Of course, the existence of information asymmetry itself does not establish a need for regulation. In private markets for these types of products, firms often invest substantial sums to develop a strong brand reputation to convey that their products contain positive attributes, such as safety for food. The products being imported into a country, however, may suffer greater information asymmetries than those products that are domestically produced, especially if such products do not carry strong brands. In addition, common property resources such as fisheries may not be able to be managed under a single jurisdiction. International regulatory mechanisms may be the most efficient approach to managing such resources.

**PART II: THIRTEENTH ANNUAL REPORT TO CONGRESS ON
AGENCY COMPLIANCE WITH THE UNFUNDED MANDATES REFORM ACT**

INTRODUCTION

This report represents OMB's thirteenth annual submission to Congress on agency compliance with the Unfunded Mandates Reform Act of 1995 (UMRA). It details agency actions to involve State, local, and tribal governments in regulatory decisions that affect them, including expanded efforts to involve them in agency decision-making processes. This report on agency compliance with the Act covers the period of October of 2006 through September of 2007 (rules published before October of 2006 were described in last year's report).

In recent years, this report has been included along with our final Report to Congress on the Costs and Benefits of Federal Regulations. This is done because the two reports together address many of the same issues and both highlight the need for regulating in a responsible manner that accounts for the benefits and costs of rules and takes into consideration the interests of our intergovernmental partners. This year, we are again publishing the UMRA report with the Report to Congress on the Benefits and Costs of Federal Regulations.

State and local governments have a vital constitutional role in providing government services. They have the major role in providing domestic public services, such as public education, law enforcement, road building and maintenance, water supply, and sewage treatment. The Federal Government contributes to that role by promoting a healthy economy and by providing grants, loans, and tax subsidies to State and local governments. However, over the past two decades, State, local, and tribal governments increasingly have expressed concerns about the difficulty of complying with Federal mandates without additional Federal resources. In response, Congress passed the Unfunded Mandates Reform Act of 1995 (the Act).

Title I of the Act focuses on the Legislative Branch, addressing the processes Congress should follow before enactment of any statutory unfunded mandates. Title II addresses the Executive Branch. It begins with a general directive for agencies to assess, unless otherwise prohibited by law, the effects of their rules on the other levels of government and on the private sector (Section 201). Title II also describes specific analyses and consultations that agencies must undertake for rules that may result in expenditures of over \$100 million (adjusted annually for inflation) in any year by State, local, and tribal governments in the aggregate, or by the private sector. Specifically, Section 202 requires an agency to prepare a written statement for intergovernmental mandates that describes in detail the required analyses and consultations on the unfunded mandate. Section 205 requires that for all rules subject to Section 202, agencies must identify and consider a reasonable number of regulatory alternatives, and then generally select from among them the least costly, most cost-effective, or least burdensome option that achieves the objectives of the rule. Exceptions require the agency head to explain in the final rule why such a selection was not made or why such a selection would be inconsistent with law.

Title II requires agencies to "develop an effective process" for obtaining "meaningful and timely input" from State, local and tribal governments in developing rules that contain significant intergovernmental mandates (Section 204). Title II also singles out small governments for particular attention (Section 203). OMB's guidelines assist Federal agencies in complying with the Act and are based upon the following general principles:

- intergovernmental consultations should take place as early as possible, beginning before issuance of a proposed rule and continuing through the final rule stage, and be integrated explicitly into the rulemaking process;
- agencies should consult with a wide variety of State, local, and tribal officials;
- agencies should estimate direct benefits and costs to assist with these consultations;
- the scope of consultation should reflect the cost and significance of the mandate being considered;
- effective consultation requires trust and significant and sustained attention so that all who participate can enjoy frank discussion and focus on key priorities; and
- agencies should seek out State, local, and tribal views on costs, benefits, risks, and alternative methods of compliance, and whether the Federal rule will harmonize with and not duplicate similar laws in other levels of government.

Federal agencies have been actively consulting with States, localities, and tribal governments in order to ensure that regulatory activities were conducted consistent with the requirements of the Act. Examples of agency consultation activities will be included in our final report.

The remainder of this report discusses the results of agency actions in response to the Act between October 1, 2006 and September 30, 2007. Not all agencies take many significant actions that affect other levels of government; therefore this report focuses on the agencies that have regular and substantive interactions on regulatory matters that involve States, localities, and tribes, as well as the private sector. This report also lists and briefly discusses the regulations meeting the Title II threshold and the specific requirements of Sections 202 and 205 of the Act. Eight rules have met this threshold, all for their impacts on the private sector. The appendix to this report discusses agency consultation efforts. These include both those efforts required under the Act and the many actions conducted by agencies above and beyond these requirements.

CHAPTER IV: REVIEW OF SIGNIFICANT REGULATORY MANDATES

In FY2007, Federal Agencies issued eight final rules that were subject to Sections 202 and 205 of the Unfunded Mandate Reform Act of 1995 (UMRA) because they require expenditures in any year by State, local or tribal governments, in the aggregate, or by the private sector, of at least \$100 million in any one year (adjusted annually for inflation). Four of these rules were issued by the Department of Homeland Security (DHS), two were issued by the Department of Transportation (DOT), and one was issued by each of the Departments of Labor (DOL), Health and Human Services (HHS), and the Environmental Protection Agency (EPA).

OMB worked with the agencies to ensure that the selection of the regulatory options for these rules fully complied with the requirements of Title II of the Act. Descriptions of the rules in addition to agency statements regarding compliance with the Act are included in the following section.

A. Department of Homeland Security

Documents Required for Travel Within the Western Hemisphere (WHTI) (71 FR 68411)
This rule requires travelers in the Western Hemisphere to present a passport or other secure document that establishes the bearer's identity and citizenship to enter or re-enter the United States via an air port of entry. This rule is applicable to United States citizens and nonimmigrant aliens from Canada, Bermuda, and Mexico who were previously exempt from presenting a passport upon arrival at U.S. air ports-of-entry.

DHS's primary estimate of the cost of this rule is \$206M annually. This burden is borne primarily by individuals and businesses that support the traveling public. If some travelers do not obtain passports because of the cost or inconvenience and forgo travel to Western Hemisphere destinations, certain industries would incur the indirect consequences of the forgone foreign travel. This rule will not impose a significant cost or uniquely affect small governments. The rule does have an effect on the private sector of \$100 million or more.

Passenger Manifest for Commercial Aircraft Arriving In and Departing From the United States; Passengers and Crew Manifests for Commercial Vessels Departing From the United States (72 FR 48319) This rule requires the electronic transmission of manifest information relating to passengers on arriving and departing aircraft and for passengers and crew on departing vessels prior to the departure of the vessels or aircraft.

DHS estimates that this rule will cost \$126.8M annually. This final rule would not impose any cost on small governments or significantly or uniquely affect small governments. However, CBP has determined that the rule would result in the expenditure by the private sector of \$100 million or more (adjusted annually for inflation) in any one year and thus would constitute a significant regulatory action. Consequently, the provisions of this rule constitute a private sector mandate under the UMRA.

Transportation Worker Identification Credential (TWIC) Implementation in the Maritime Sector; Hazardous Materials Endorsement for a Commercial Driver's License (72 FR 3492) This final rule establishes a standard biometric Transportation Worker Identity Credential (TWIC), including procedures for enrollment, issuance, and appeals and waivers. This rule requires all persons with unescorted access to secure areas of ports to possess a TWIC. The rule will also require random spot checks that will electronically verify the identity of the card holder. This rule will be of interest to port workers unions, trucker unions, and the shipping industry.

DHS estimates that this rule will cost \$1.75B over 10 years. This final rule would not impose any cost on small governments or significantly or uniquely affect small governments. However, DHS has determined that the rule would result in the expenditure by the private sector of \$100 million or more (adjusted annually for inflation) in any one year. Consequently, the provisions of this rule constitute a private sector mandate under the UMRA.

B. Department of Transportation

Electronic Stability Control (ESC) (72 FR 17235) This rulemaking established a new Federal motor vehicle safety standard to require electronic stability control (ESC) systems on all newly manufactured passenger cars and light trucks. The vast majority of rollovers occur in single-vehicle crashes involving loss of control. Crash data studies by NHTSA and other organizations worldwide show that ESC causes a dramatic reduction in single-vehicle crashes by assisting drivers in maintaining control in critical driving situations. NHTSA studies show a reduction in single-vehicle crashes of 34 percent to 59 percent and a reduction in single-vehicle crashes with rollover of over 70 percent. The requirement of ESC on cars and trucks could save thousands of lives annually.

This final rule is not expected to result in the expenditure by State, local, or tribal governments, in the aggregate, of more than \$122 million annually, but it will result in the expenditure of that magnitude by vehicle manufacturers and/or their suppliers. Therefore this rulemaking constitutes a private sector mandate under UMRA.

Side Impact Protection Upgrade--FMVSS No. 214 (72 FR 51907) This rulemaking would require in FMVSS No. 214 a vehicle-to-pole oblique impact test to reduce the number of fatal and serious head injuries, which are not addressed in FMVSS No. 201. Two Federal motor vehicle safety standards (FMVSS)--No. 201, "Occupant Protection in Interior Impact" and No. 214, "Side Impact Protection"--specify requirements for side impact protection. At present, FMVSS No. 214 specifies a moving deformable barrier (MDB) test addressing mainly the chest injury problem. The head injury reduction is partially addressed in FMVSS No. 201.

The agency's data show that the majority of side air bag systems are currently equipped with two side impact sensors. The total annual incremental cost for the most likely air bag system (curtain and thorax bag two-sensor countermeasure) would be about \$560 million. This is a private sector mandate under UMRA.

C. Department of Labor

Emergency Mine Evacuation (71 FR 71429) The Mine Safety and Health Administration (MSHA) published an emergency temporary standard on March 9, 2006. Under section 101(b) of the Federal Mine Safety and Health Act of 1977 (Mine Act) the emergency temporary standard was effective immediately. MSHA published a final rule on December 8, 2006 in accordance with section 101(b) of the Mine Act. In addition, the final rule incorporates relevant requirements of the Mine Improvement and Emergency Response Act (MINER Act). This final rule includes requirements for immediate accident notification applicable to all underground and surface mines. In addition, this final rule addresses requirements for self-contained self-rescuer storage and use; emergency evacuation and self-rescuer training and drills; and the installation and maintenance of lifelines that are applicable to all underground coal mines.

For purposes of the Unfunded Mandates Reform Act, this final rule includes a Federal mandate that will increase private sector expenditures by more than \$100 million in any one year. It will not result in increased expenditures by State, local, or tribal governments; nor will it significantly or uniquely affect small governments.

D. Department of Health and Human Services

Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Dietary Ingredients and Dietary Supplements (72 FR 34572) The Food and Drug Administration published a final rule in the Federal Register of June 25, 2007, on current good manufacturing practice (CGMP) regulations for dietary supplements. The final rule (the CGMP rule) was published to establish the minimum CGMPs necessary to ensure that, if firms engage in activities related to manufacturing, packaging, labeling or holding dietary supplements, they do so in a manner that will ensure the quality of the dietary supplements – i.e., to ensure that the dietary supplement consistently meets the established specifications for identity, purity, strength, and composition, and limits on contaminants, and has been manufactured, packaged, labeled, and held under conditions to prevent adulteration under section 402(a)(1), (a)(2), (a)(3), and (a)(4) of the act. FDA also published an interim final rule (IFR) in the June 25, 2007 Federal Register (72 FR 34959) that sets forth a procedure for requesting an exemption from the requirement in the final rule described above that the manufacturer conduct at least one appropriate test or examination to verify the identity of any component that is a dietary ingredient. This IFR allows for submission to, and review by, FDA of an alternative to the required 100 percent identity testing of components that are dietary ingredients, provided certain conditions are met. This IFR also establishes a requirement for retention of records relating to the FDA's response to an exemption request.

HHS estimates that this rule will have an annual cost of \$140M. This final rule would not impose any cost on small governments or significantly or uniquely affect small governments. However, HHS has determined that the rule would result in the expenditure by the private sector of \$100 million or more (adjusted annually for inflation) in any one year. Consequently, the provisions of this rule constitute a private sector mandate under the UMRA.

E. Environmental Protection Agency

Control of Hazardous Air Pollutants From Mobile Sources (72 FR 8428) This rule addresses the need for additional requirements, beyond those associated with existing programs and other forthcoming rules, to control hazardous air pollutants ("air toxics") from motor vehicles, non-road engines and vehicles, and their fuels. Previous mobile source programs for highway and non-road sources and fuels have already reduced air toxics significantly and will provide substantial further reductions in coming years as new standards and programs are phased in. This mobile-source air toxics rule will provide an overview of these mobile source programs and associated toxics emissions reductions. The rule addresses potential changes to gasoline fuel parameters to reduce toxics such as benzene and the potential for additional vehicle controls.

The EPA estimates that this rule will have an annual cost of \$400M. This final rule would not impose any cost on small governments or significantly or uniquely affect small governments. However, the EPA has determined that the rule would result in the expenditure by the private sector of \$100 million or more (adjusted annually for inflation) in any one year. Consequently, the provisions of this rule constitute a private sector mandate under the UMRA.

**APPENDIX G: AGENCY CONSULTATION ACTIVITIES
UNDER THE UNFUNDED MANDATES REFORM ACT OF 1995**

Sections 203 and 204 of the Act require agencies to seek input from State, local and tribal governments on new Federal regulations imposing significant intergovernmental mandates. On June 20th, 2008 OMB requested agency input regarding consultation activities with affected State, local and tribal governments. Examples of consultation activities that involved State, local and tribal governments will be included in the final report.