

**2008 Report to Congress
on the Benefits and Costs of
Federal Regulations
and Unfunded Mandates on
State, Local, and Tribal Entities**



2008

**Office of Management and Budget
Office of Information and Regulatory Affairs**

**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 the benefits and costs 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.

The reader should be mindful that there are still significant data gaps in the information available on regulatory benefits and costs.

We also 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 estimated average annual costs of major regulations reviewed by OMB and issued over the last seven years is about \$4.1 billion, which is about 24% less than the estimated annual average costs of \$5.5 billion 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 estimated benefits of major regulations issued over the last seven years exceed the costs by more than seven fold.

This 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; and d) implementation status of the Memorandum on the Principles of Risk Analysis.

Chapter IV discusses analyzing international trade effects of domestic regulation, recognizing that as tariff and other explicit barriers to international trade fall in an increasingly global marketplace, domestic policies are more likely to affect trading partners. The chapter considers analytical issues when incorporating international trade and investment effects into the Regulatory Impact Analysis required by OMB Circular A-4.

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 conduct a cost-benefit analysis and select the least costly, most cost-effective, or least burdensome alternative 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. Each agency must also seek input from State, local, and tribal governments.

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 broadly define major rules to include 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

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." According to OMB guidance issued in 1996: "The CRA's definition of 'major' is similar, but not identical, to the standard set forth in Section 3(f)(1) of Executive Order 12866 for identifying 'economically significant rules.' The main difference is that some additional rules may be captured by the CRA definition that are not considered 'economically significant' under Executive Order 12866, notably those rules that would have a significant adverse effect 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."

1997 and September 2007 with several important caveats.⁴ 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, Chapter IV considers analytical issues when incorporating international trade and investment effects into the Regulatory Impact Analysis required by OMB Circular A-4, and Chapter V summarizes agency compliance with UMRA.

The reader should be mindful that there are still significant data gaps in the information available on regulatory benefits and costs provided by agencies. In addition, this Report focuses on the benefits and costs of major regulations reviewed by OMB. It does not provide aggregate estimates of the benefits and cost of non-major rules, or regulations promulgated by independent agencies.

This final 2008 Report responds to comments received on the draft Report, both from the public and also from three peer reviewers.

⁴ For example, not all major rules include monetary benefits and costs. Further, the information on major rules issued by independent agencies relies on reports these agencies submitted to GAO. In addition, this Report aggregates the costs and benefits from Regulatory Impact Analyses that depend on somewhat different modeling conventions and assumption, and thus are not strictly comparable. This Report provides further discussion of these limitations.

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, 2007.⁵ 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 agency estimates of benefits and costs, or transparent modifications of agency information performed by OMB.⁶ This chapter includes a discussion of major rules issued by independent regulatory agencies, although OMB does not review these rules under Executive Order 12866.⁷ This discussion is based solely on data provided by these agencies to the Government Accountability Office (GAO) under the Congressional Review Act.

While aggregating benefit and cost estimates of individual regulations—to the extent they can be combined—provides some insight as to the magnitude of the effect of regulations, the resulting estimates cannot be considered precise or complete. Individual regulatory impact analyses vary in rigor and rely on different assumptions, including baseline scenarios, methods, and data, thus summing across estimates involves the aggregation of analytical results that are not strictly comparable.

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:⁸ (1) each rule was estimated to generate benefits or costs of at least \$100 million in

⁵All previous Reports are available at: http://www.whitehouse.gov/omb/inforeg/regpol-reports_congress.html.

⁶OMB 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.

⁷Section 3(b) of Executive Order 12866 excludes "independent regulatory agencies as defined in 44 U.S.C. 3502(10)."

⁸OMB 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

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 a complete accounting of all the benefits and costs of all regulations issued by the Federal Government during this period.⁹ 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 - 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 ¹⁰	40	83,298-592,567	32,252-35,058
Total	93	122,190-655,556	46,219-53,894

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.

⁹ In 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.

¹⁰ These totals include EPA's March 2005 final "Clean Air Interstate Rule." On July 11, 2008, the D.C. Circuit vacated this rule; however, in response to EPA's petition, the Court on December 23, 2008, remanded the rule without vacatur, which keeps it in effect while EPA conducts further proceedings consistent with the Court's July 11 opinion

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 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 10 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: 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.¹¹
- 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

¹¹ EPA cites the Clean Air Scientific Advisory Committee (CASAC) advice as the basis for use of these assumptions in regulatory impact analyses. For example, see Regulatory Impact Analysis, 2006 National Ambient Air Quality Standard for Particle Pollution, Chapter 5, pp. 6-7.
<http://www.epa.gov/ttn/ecas/regdata/RIAs/Chapter%205--Benefits.pdf>

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.¹²

- 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.

EPA is working with OMB to improve methods to quantify the degree of technical uncertainty in benefits estimates and to make other improvements to EPA's Regulatory Impact Analyses.¹³

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 40 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.¹⁵

Of the 40 rules, 18 are "social regulations," which may require substantial additional private expenditures as well as provide new social benefits.¹⁵ 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 are not able to present estimates of both costs and benefits are rules designed to improve homeland security. The benefits of improved security are very difficult to quantify and

¹² *Ibid.*

¹³ For example, a committee of the National Research Council/National Academy of Sciences, released the study *Estimating the Public Health Benefits of Proposed Air Pollution Regulations*, National Academy of Sciences (2003), which recommends improvements to EPA benefits estimates. In addition, we continue to work with EPA to incorporate recommendations from recent NRC reports *Valuing Health for Regulatory Cost-Effectiveness Analysis* (2006), and *Estimating Mortality Risk Reduction and Economic Benefits from Controlling Air Pollution* (2008).

¹⁴ We 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.

¹⁵ The *Federal Register* citations for these rules and links to available RIAs appear in Table A-1 in Appendix A.

monetize; however, the Department of Homeland Security did estimate the cost of all of these rules, which are summarized in Table 1-5.¹⁶ The Department of the Interior did not estimate costs for two other final rules setting conditions for migratory bird hunting. We do 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 estimates the value that the rule provides to hunters. We summarize the available information on the non-monetized impacts, and provide links to such information for all 18 of these rules in the “other information” column of Table A-1, where available.

The remaining 22 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 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 40 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 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 applies a uniform format for the presentation to make agency estimates more closely comparable with each other (for example, annualizing benefit and cost estimates). OMB monetizes quantitative estimates where the agency did not do 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 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 presents other qualitative information as reported by the agencies on the 18 social regulations reviewed by OMB in the time period covered by this Report.

¹⁶See Chapter 4 in the 2003 Report (pp. 64-80) for a more detailed discussion of this issue.

Table 1-3: Estimates, by Agency, of the Total Annual Benefits and Costs of Major Rules, October 1, 2006 - 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, October 1, 2006 - 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.

Rule	Agency	Benefits	Costs	Explanation of OMB Calculations
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 four 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. Available information on how the agency forecasts how the rule will improve security or otherwise prevent or mitigate the consequences of a terrorist attack is also summarized.

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 US, and to prevent such passengers and crew from departing on vessels leaving the US. 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.

Rule	Agency	Benefits	Costs	Other Information
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 unescorted 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 for which agencies have provided 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.¹⁷

C. Regulations Implementing or Adjusting Federal Budgetary Programs

Of the 40 economically significant rules reviewed by OMB, 22 implement or adjust Federal budgetary programs. Of these, one rule is issued by the Department of Homeland Security (DHS), two by the Department of Commerce (DOC), one by the Department of Labor (DOL), two by the Department of Agriculture (USDA), two by the Department of Education (ED), 12 by the Department of Health and Human Services (HHS), one by the Department of 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.

¹⁷ 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.

Table 1-6: Agency Rules Implementing or Adjusting Federal Budgetary Programs, October 1, 2006 - September 30, 2007¹⁸

Rule [FR Cite]	Agency	Estimated Budget Expenditure or Savings	Description
Adjustment of the Immigration Benefit Application/Petition and Biometric Fee Schedule [72 FR 29851]	DHS	\$569 million Applicants for certain immigration benefits to Federal Government	This rule proposes to adjust the immigration benefit application and petition fee schedule and increases the biometric fee. The fees that fund the IEFA were last updated on October 26, 2005.
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.
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.

¹⁸ 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 OMB 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	Estimated Budget Expenditure or Savings	Description
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.
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."

Rule [FR Cite]	Agency	Estimated Budget Expenditure or Savings	Description
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.
Revised Payment System for Services Furnished in Ambulatory Surgical Centers (ASCs) Effective January 1, 2008 (CMS-1517-F) [72 FR 42470]	HHS	Zero net effect; An increase in Medicare payments to ASCs for CY 2008 compared to CY 2007 of approximately \$308 million; Reduced Medicare spending in HOPDs and physicians' offices on services that migrate from these settings to ASCs that offset the increase payments to ASCs; 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.	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	\$150 million in 2008 Federal Government to Medicare providers	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	\$690 million in 2008 Federal Government to nursing facilities	This final rule updates the payment rates used under the prospective payment system (PPS) for skilled nursing facilities (SNFs) for fiscal year (FY) 2008.

Rule [FR Cite]	Agency	Estimated Budget Expenditure or Savings	Description
Changes to the Hospital Inpatient Prospective Payment Systems and FY 2008 Rates (CMS-1533-P) [72 FR 47130]	HHS	\$3837 million in 2008 Federal Government to Medicare providers	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	\$20 million in 2008 Federal Government to home health agencies	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.
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.

Rule [FR Cite]	Agency	Estimated Budget Expenditure or Savings	Description
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).¹⁹

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 10 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, as OMB does not review rules from these agencies.

¹⁹ Council of Economic Advisers (2008). *Economic Report of the President*, p. 116.

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 are presented 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 may therefore not match the number of rules presented here. Information is also presented on the extent to which the independent agencies reported benefit and cost information for these rules in Tables C-2 through C-4.

Table 1-7: Major Rules Issued by Independent Regulatory Agencies, October 1, 2006 - 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

Agency	Rule	Information on Benefits or Costs	Monetized Benefits	Monetized Costs
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 previous Reports have 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 OMB Circular A-94. Their recommendations include:

- Developing a minimum scorecard based on OMB guidance (e.g., OMB Circular A-4, OMB Circular A-94);
- 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 which OMB would summarize and present in a user-friendly format; and
- 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). In our draft 2008 Report, we have sought 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 the 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?

As noted in OMB Circular A-4, 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.²⁰

Due to concerns that scorecards may inadvertently introduce incentives for agencies to attempt to apply a cookbook-approach to regulatory analyses, we have sought comment on the usefulness of the scorecard concept, particularly through 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?

Response to Peer Reviews on Scorecard

OMB has received no public comments on these issues; however, all three peer reviewers express support for the concept of scorecard.

1. General Peer Reviewer Comments:

Peer Reviewer (1) notes that the usefulness of reporting aggregate information on whether agencies comply with OMB guidance through scorecards is showing whether there are systematic strengths and weaknesses in how analyses are conducted in each agency. Peer Reviewer (1) further notes that OMB is already providing an “abbreviated scorecard” for independent agencies.

Peer Reviewer (2) suggests that OMB separate the discussion into two distinct types of scorecards: a scorecard for evaluating regulatory analyses and a scorecard for evaluating

²⁰ OMB Circular A-4, p. 3. <http://www.whitehouse.gov/omb/circulars/a004/a-4.pdf>

regulations. In this vein, Peer Reviewer (2) raises some fundamental questions that OMB should consider before adopting a scorecard in this Report. The Reviewer asks:

- How will scorecards be used in regulatory analyses and in the rulemaking process?
- Who will prepare scorecards? Would a regulating agency prepare scorecards and submit it along with the regulatory analyses and the proposed and final rules? Would OMB prepare scorecards for regulatory analyses for proposed and final rules as part of the OMB review process?
- If an agency fails to meet an acceptable score on a regulatory analysis, would the proposed or final rule be returned to the agency for reconsideration? Would a scorecard be used as a screening tool?
- If not a screening tool, would OMB use a scorecard an evaluative tool after OMB regulatory review?
- “Is there any evidence that doing well on a regulatory scorecard is associated with ‘better’ RIA?”

OMB notes that the peer reviewers offered comments on both types of scorecards.

2. Peer Reviewer Comments on the Possible Scorecard Questions

The peer reviewers generally express support for the possible scorecard questions proposed in the draft report. They state that many of the proposed scorecard questions, including whether an RIA included a market failure argument, used the required discount rates, and analyzed reasonable regulatory alternatives, are useful. OMB notes that these metrics are consistent with the requirements of Executive Order 12866 and OMB Circular A-4. Peer reviewers provide further comment on a few of the proposed questions, which are discussed below.

3. Does the analysis quantify and monetize benefits and costs of proposed action? Peer Reviewer (1) suggests that a scorecard show the number and percentage of final regulations that pass or fail a benefit-cost test based strictly on quantified and monetized benefits and costs. The reviewer further suggests that if a regulation fails this benefit-cost test, using reasonable assumptions, OMB should either state why the regulation is implemented or argue for reform or elimination. OMB believes agency RIAs and this Report are already somewhat consistent with this recommendation. Agencies should always identify a need for the regulation, which should include whether or not the agency faces statutory direction towards a particular regulatory approach. Agencies should also identify whether they are allowed to use benefit-cost analysis to make regulatory decisions, and other reasons why a regulation is issued while having negative monetized net benefits. In addition, OMB Circular A-4 requires agencies to identify significant qualitative benefits and costs that were important inputs into agency decisions. We have attempted to capture such qualitative impacts in Table A-1 of this Report.

Peer Reviewer (2) cautions that scorecards should treat quantification and monetization equally. The Reviewer suggests that agencies adopt tables in the regulatory analyses that itemize “effects of the proposed regulation by category, separated into those categories that are quantifiable and monetizable, those that are only quantifiable but not monetizable, and those that

are not quantifiable, if there are any” (p. 2). OMB notes that this suggestion is consistent with the OMB Circular A-4 requirement for agencies to provide an “accounting statement” that contains monetized, quantified, and qualitative benefits, costs, and transfers.

6. For public health and safety regulations, does the analysis include cost-effectiveness analysis? Peer Reviewer (2) questions why cost-effectiveness analyses are restricted to public health and safety regulations. The Reviewer states that the information burden associated with conducting cost-effectiveness analyses is not different than for benefit-cost analysis. OMB agrees with this comment in part, in that we feel cost-effectiveness analysis is a useful tool that should be widely used. We also note that OMB Circular A-4 does not restrict agencies from providing a cost-effectiveness analysis for all of their regulations; however, OMB Circular A-4 only requires such an analysis for public health and safety regulations. We agree that if a quantifiable benefit exists for such regulations, a cost-effectiveness analysis would still be useful.

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? Peer Reviewer (3) advises that this metric is important. Peer Reviewer (1) suggests that OMB provide further guidance to agencies on ascertaining uncertainty around the benefit and cost estimates, including guidance on how to determine the high and low range for these estimates. We feel that OMB Circular A-4 does provide sufficient guidance for agencies to conduct the required formal uncertainty analysis; however, OMB is open to considering providing further uncertainty guidance in the future.

9. Is a break-even analysis presented for rules with substantial unquantifiable benefits? Peer Reviewer (2) states that this metric exemplifies OMB’s confusion regarding the emphasis put on monetization, which the Reviewer states depends critically on the quantification of the physical units of benefits. The Reviewer questions how an agency could conduct a break-even analysis if benefits are unquantifiable. OMB agrees in part that the question was not clearly worded. The “break-even” analysis we had in mind would be similar to those performed by DHS, which attempt to define what a regulation would need to achieve, in terms of reducing the probability of one or more types of terrorist attack, in order for the benefits of the regulation to outweigh its costs. In such analysis, the agencies would be able to monetize the particular scenarios under investigation, such as a 9/11- type attack, but would not be able to assign an objective probability to such an attack.

3. Peer Reviewer Comments on the Specific Questions

The peer reviewers also offer advice and suggestions on the specific questions asked regarding the usefulness of the scorecard concept in the draft Report. Because the reviewers offered substantive comment on each of the questions, we reproduce the questions and comments below.

1. Are the metrics objective? Peer Reviewer (3) notes that the metrics are generally good and reasonably objective, but expresses concerns about the quality of the responses to the metrics. OMB also shares the goal of ensuring that any responses to the metrics we propose are consistent and of high quality.

2. Are there other objective measures that indicate compliance with OMB guidance?

Peer Reviewer (1) notes that Hahn and Sunstein²¹ proposed a scorecard that can be adopted by agencies to evaluate regulatory impact analyses. The Reviewer suggests that this scorecard may provide useful information. In particular, the Reviewer states that any OMB scorecard should adopt aspects of the Hahn-Sunstein scorecard, and that we should add key issues such as whether an agency identified and considered alternatives. The Reviewer also suggests that OMB should assemble this information and present it in a user friendly format, similar to the way we presented the results of independent agency RIAs in Appendix C of the 2008 draft Report. OMB notes that question 4 of our proposed scorecard does address whether an analysis quantified and monetized benefits and costs of main alternative approaches. Our proposed question differs from the scorecard suggested by Peer Reviewer (1), however, which also calls for agencies to explain alternatives and describe why some were rejected, or to explain why no alternatives were analyzed. OMB believes all this information is useful and should be provided by an RIA, and is interested in whether such information could be summarized in a way that would facilitate easy comparison across agency scorecards.

Peer Reviewer (2) suggests that *ex post* analyses of regulatory impacts are important to regulatory quality, and lays out a research agenda to assess if “better [*ex post*] benefit cost estimates result from better RIAs” (p. 1) as a way of identifying whether a “high quality” RIA as identified by a scorecard may lead to more accurate impact estimates. OMB agrees that evaluating whether “better” RIAs produce “better” estimates of benefits and costs is important. On a related matter, OMB has discussed the validation analysis literature in the 2005 Report. In 2005, we compared the projected benefits and costs of 47 final regulations with benefit and cost information obtained after implementation. Our results indicated that analyses in our sample tended to overestimate both benefits and costs, but they had a significantly greater tendency to overestimate benefits than costs. We encourage researchers to assess whether “better” RIAs produce “better” benefit and cost estimates.

Peer Reviewer (2) also advocates for the inclusion of baseline information into a scorecard, especially baseline information on the physical quantities a regulation affects. The Reviewer states that “because good things tend to gain in value as they become more scarce, the change relative to the baseline matters,” (p. 2) and this information may be useful to decision makers. The example the Reviewer used to demonstrate this concept is a regulation that reduces fish mortality: “if billions of fish are dying each year, doesn’t it matter whether you have billions or trillions to start with” (p. 2)? The Reviewer believes that knowing such information “can provide a sense of perspective that can aid in assessing the credibility of the estimated changes in outcomes” (p. 2). OMB believes this concept has merit for inclusion in a scorecard, and notes that OMB Circular A-4 does require a sufficient description of the baseline against which agencies compare regulatory proposals and alternatives.

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

²¹ Hahn, Robert W., and Cass R. Sunstein (2002). “A New Executive Order for Improving Federal Regulation? Deeper and Wider Cost Benefit Analysis.” *University of Pennsylvania Law Review*, 150, p. 1489.

to address critical elements of regulatory analysis? Peer Reviewer (3) advocates for a small number of metrics rather than expanding the list of metrics, while acknowledging that a small number may lead to such a perverse effect. According to the reviewer, scorecards will trade-off the likelihood of perverse effects with the “do-ability” of scorecards, with the ultimate goal of encouraging agencies to improve regulatory impact analyses to aid decision-making, rather than “creating a perfect RIA.” OMB agrees that such a trade-off is important, and that the ultimate goal of an RIA is to be a useful aid for agency decision making.

Peer Reviewer (2) cautions against overly strict scorecard requirements that may encourage agencies to spend resources analyzing effects that are trivial in order to check boxes. The Reviewer also identifies that RIAs should be judged by their economic importance, and that all aspects of a scorecard may not be equally valuable to decision making in all cases, stating:

The literature on scorecards generally contends that RIAs as a group score pretty badly, omitting essential information, making inconsistent assumptions that are often difficult to find, etc. However, such analyses tend to treat all RIAs the same. The results might have been different if the RIAs had been weighted by a measure of the economic importance--such as the expected costs or benefits--of the rule. (p. 1)

4. Should the agencies report the extent to which they comply with relevant OMB guidance? Peer Reviewer (3) expresses a concern that such a report could potentially lead to a “cookbook response” from agencies on each of the scorecard items. The Reviewer suggests that agencies instead could provide a separate statement to OMB on why they did or did not undertake analysis identified as significant items in a scorecard. Peer Reviewer (1) suggests that OMB should request within the scorecard that agencies report on the extent to which they comply with OMB guidance. The scorecard example suggested by this reviewer, however, also asks for a narrative response to this question and does not suggest a check-box response.

OMB finds these comments very useful, and believes that the scorecard concept has merit. However, designing and implementing a scorecard will likely require careful deliberations, as demonstrated by the technical issues raised by the peer reviewers. As a result, OMB is not prepared to implement a scorecard in this Report; however, we encourage further research on the concept.

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).²²

- *EPA's National Primary Drinking Water Regulations: Disinfectants and Disinfection Byproducts* (1998): This rule promulgates health-based maximum contaminant level goals (MCLGs) and enforceable maximum contaminant levels (MCLs) for about a dozen disinfectants and byproducts that result from the interaction of these disinfectants with organic compounds in drinking water. The rule will require additional treatment at about 14,000 of the estimated 75,000 covered water systems nationwide. The costs of the rule are estimated at \$700 million annually. The quantified benefits estimates range from zero to 9,300 avoided bladder cancer cases annually, with an estimated monetized value of \$0 to \$4 billion per year. Possible reductions in rectal and colon cancer and adverse reproductive and developmental effects are 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 estimates 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 billion 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 has 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

²²We 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.

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 million to \$198 million per year. EPA has 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 million 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).²³ 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 by State, local, and tribal governments, and the private sector, of \$100 million or more 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 these costs out 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

²³ 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).

with this rule, DHS estimates that there are 1,500 to 6,500 covered chemical facilities. DHS also assumes that this rule may require certain municipalities that own and/or operate power generating facilities to purchase security enhancements. Although DHS is 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, it has been included in this list for the sake of completeness.

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. For example, many rules have monetary impacts lower than the \$100 million threshold, and agencies are also required to consider the Federalism implications of rulemakings under Executive Order 13132.

Impact on Small Business

Consistent with the direction in the Regulatory Right-to-Know Act to consider small business impacts, the need to be sensitive to the impact of regulations and paperwork on small business is 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 states 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.²⁴ The most recent study, published in 2005, has 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) is 45 percent greater per employee for firms with fewer than 20 employees compared to firms with over 500 employees. OMB 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 help

²⁴Crain, W.M. 2005. “The Impact of Regulatory Costs on Small Firms.” Report prepared for the Office of Advocacy, US 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.

America's small businesses comply with regulatory and reporting requirements.

Because of this relatively large impact of regulations on small businesses, President Bush has 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.

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

The Office of Advocacy works to improve the analysis of small business impacts and persuade agencies to afford relief to small businesses, and reports annually on the overall performance of agency compliance with the RFA and Executive Order 13272. 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 assist agencies and small business stakeholders to better understand and benefit from section 610 reviews of existing rules, and to give interested small entities the opportunity to nominate existing agency rules for review and potential reform.

In its first year of implementation, the r3 initiative consists of two related activities. First, after a process in which more than 80 nominations were received, the Office of Advocacy has identified the top 10 rules to be put forward for agency review in 2008. Four of the reforms recommended are similar to nominations that OMB received in the 2004 manufacturing initiative and previous reform nomination cycles: DOL's Mine Safety and Health Administration's explosives standards; EPA's rules on community drinking water systems; spill prevention control and countermeasure requirements; and recycling solid waste.²⁵ More information about the r3 initiative can be found at <http://www.sba.gov/advo/r3/>.

²⁵ Please see Appendix D for an update to the 2004 OMB manufacturing regulatory reform nominations.

Second, in the fall of 2007, the Office of Advocacy released a revised best practice guidance that is more comprehensive on section 610 analysis. This guidance is available at http://www.sba.gov/advo/r3/r3_section610.html. The Office of 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 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, 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 as part of their requests for OMB approval of an information collection, agencies certify 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 reinforces 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 outlines 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 amends 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, OMB has seen government-wide paperwork burdens increase over time, which are documented in the annual Information Collection Budget Report (ICB) submitted to Congress pursuant to the PRA. The 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 is 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 has 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 are 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 estimates 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 use regularly, 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 reduce their search time. The information available through Business.gov is 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: (i) What laws and regulations apply to me?; (ii) How do I comply?; and (iii) 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 "wages" are defined 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 "wages" are defined 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.²⁶

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.²⁷ Although wages may reflect the cost of compliance with health and safety rules, the job safety and other benefits of such regulation can compensate for the monetary loss. Workers, as consumers benefiting from safer products and a cleaner environment, may also come out ahead if regulation produces significant net benefits for society.

2. *Economic Regulation*

For economic regulation, defined as rules designed to set prices or conditions of entry for specific sectors, the effects on wages may be positive or negative.²⁸ 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 the cost of 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.²⁹

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.

²⁶From Ehrenberg, R. and R. Smith 1991. *Modern Labor Economics*, 4th Edition. HarperCollins, p. 279.

²⁷Based 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).

²⁸ Historical examples of economic regulation were the Federal regulations on the airline and trucking industries before these markets were deregulated.

²⁹Clifford 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.

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.³⁰

Several groups of researchers have developed indicators of economic freedom to rank countries and compare their economic performance. Since 1995, the Heritage Foundation and the *Wall Street Journal* have published jointly a yearly index of economic freedom. For 2008 it includes 162 countries.³¹ 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 are 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.³² 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

³⁰A 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.

³¹The latest version of this Report is *The 2008 Index of Economic Freedom*. (Heritage Foundation/WallStreet Journal).

³²The latest version of this Report is James Gwartney and Robert Lawson, *Economic Freedom of the World: 2007 Annual Report*. Fraser Institute, Vancouver, BC.

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. *Doing Business in 2004, Understanding Regulation* examines five fundamental aspects of a firm's life cycle: starting a business, hiring and firing workers, enforcing contracts, obtaining credit, and closing a business.³³ *Doing Business in 2005, Removing Obstacles to Growth* updates these measures and adds data about registering property and protecting investors.³⁴ *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.³⁵ *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 2004 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, but poor countries do not.

The 2005 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; and
- The payoffs from reform appear large.

The 2006 volume added a new conclusion: that a higher ranking on the ease of doing business metrics is associated with job creation. The 2007 and 2008 volumes refine the methodology and

³³World Bank. *Doing Business in 2004: Understanding Regulation*. Oxford Press. Washington, DC.

³⁴World Bank. *Doing Business in 2005: Removing Obstacles to Growth*. Oxford Press. Washington, DC.

³⁵World Bank. *Doing Business in 2006: Creating Jobs*. Washington, DC.

data, and reinforce these findings.

The World Bank finds that rich countries regulate less in all respects covered in the report, and common law and Nordic countries regulated less than countries whose legal systems are based on socialist principles. The World Bank study finds that both labor productivity and employment were positively correlated with less regulation. The study finds that heavier regulation was associated with greater inefficiency of public institutions and more corruption. The resulting regulation often has a perverse effect on the people it was meant to protect. Overly stringent regulation of business creates strong incentives for businesses to operate in the underground or informal economy. The study estimates that if the countries in the bottom three quartiles were able to move up to the top quartile in the “doing business” indicator rankings, they would be able to realize a 2 percentage point increase in annual economic growth.

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

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

In 2008, the top ten countries ranked on the ease of doing business based on the ten indicators are (in increasing order): Singapore, New Zealand, the United States, Hong Kong (China), Denmark, the United Kingdom, Canada, Ireland, Australia, and Iceland.³⁶

Also in 2008, the Independent Evaluation Group (IEG), an independent unit within the World Bank, issued the report *Doing Business: An Independent Evaluation*, which finds that the *Doing Business* report has been highly effective in measuring and drawing attention to the burdens of business regulation. It also offers recommendations to make the indicators more transparent and useful, and warns that policy should not be based just on indicators that can be easily measured. In the same report, the World Bank Group management concurs with the broad thrust of the conclusions and pledges to continue to refine and improve the indicators, as well as more fully utilize the expertise of World Bank country and regional units.³⁷

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 major work on this subject underway. A report by Giuseppe Nicoletti summarizes the findings of the OECD work as follows:

³⁶See *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.

³⁷ See IEG, *Doing Business: An Independent Evaluation*, 2008.

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.³⁸

According to the OECD's database of objective measures assembled in 2001, the OECD countries with least restrictive regulation are (in increasing order): the United States, the United Kingdom, Canada, Ireland, and New Zealand. The five with the most restrictive regulation are (in increasing order): Portugal, Greece, Italy, Spain, and France.³⁹ 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, as compared to the 1980s. Those countries also tended to show both the largest increase in the number of new small and medium-sized firms, and in the rate of investment in research and development in manufacturing. These factors are thought to be important in increasing the growth rate of productivity and per capita income.

The major efforts to determine the effect of regulatory policies on economic performance use different indicators of regulatory quality and examine different types of regulation, yet they reach very similar conclusions. Giuseppe Nicoletti and Frederic Pryor have 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 finds statistically significant correlations among the three indices, despite the differences in coverage and methodologies.⁴⁰ A second group of researchers, who have done work for the World Bank, also finds a strong correlation between regulation of entry into markets and the regulation of labor. They attribute this to their finding that the legal origin of regulation explains regulatory style. As they put it ... "countries have regulatory styles that are pervasive across activities and shaped by the origin of their laws."⁴¹ Thus, countries with good records on entry regulation (which they point out includes some environmental regulation) also have good records on labor regulation.⁴² 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.⁴³ 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 resent, thereby reducing

³⁸Giuseppe 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).

³⁹See 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.

⁴⁰*Ibid.*

⁴¹Juan Botero, Simeon Djankov, Rafael La Porta, Florencio Lopez-de-Salinas, and Andrei Shleifer, "The Regulation of Labor," *The Quarterly Journal Of Economics* (2004).

⁴²*Ibid.*

⁴³ See Philippe Aghion, Yann Algan, Piere Cahac, and Andrei Shlifer, "Regulation and Distrust" Harvard Economic Department Papers (July 3, 2008).

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.⁴⁴ 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 have a presumption against price and entry controls in competitive markets and thus deregulation is often appropriate.⁴⁵ For social regulation, OMB 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.⁴⁶

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

eRulemaking is a cross-agency program that facilitates *Regulations.gov* and is 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 knowing 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

⁴⁴Note 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.

⁴⁵Although 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.

⁴⁶ See Bruce Yandle, “Bootleggers and Baptists: the Education of a Regulatory Economist” *Regulation* 7, no.3 (1983):12.

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). In addition, eRulemaking publishes 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.

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 to quantify alternatives that would provide the public with the ability to participate in the regulatory process via the Internet. This benefit-cost analysis assessed the estimated costs for agencies to operate strictly paper-based processes without offering electronic access to the public, and found that the Federal government is likely to expend more than \$30 million over five years using a paper-based system rather than an electronic system. This estimate does not include additional benefits associated with centralized electronic access provided by *Regulations.gov*. In addition to the paper-based option, the analysis also compared two other alternatives, each providing electronic access and similar services currently provided by *Regulations.gov*. One alternative is for all agencies serviced by *Regulations.gov* to create their own systems, and the other alternative is for larger departments to each create a system that its sub-agencies could use. The analysis found that the first alternative is estimated to cost an additional \$129 million and the second alternative, \$106 million respectively, as compared to the centralized access that *Regulations.gov* provides to all federal entities.

To further examine the eRulemaking program, the Administrative Law & Regulatory Practice section of the American Bar Association has sponsored the Committee on the Status and Future of Federal e-Rulemaking, which produced a report entitled, *Achieving the Potential, The Future of Federal e-Rulemaking*. The mission of this Committee is to assess the current state of the Federal government's eRulemaking program and to provide future recommendations. In its report, the Committee recognizes the great effort and considerable progress made over the last five years to construct a single Federal eRulemaking portal. However, the Committee also finds that much work remains, and has provided detailed recommendations aimed to help the program meet its enormous potential. OIRA shares the Committee's vision to better leverage technology to transform public participation in, and transparency of, the regulatory process.

H. Response to Peer Reviews and Public Comments on the Accounting Statement

This chapter of the Report benefits from input OMB received from peer reviewers and commenters who responded to OMB's request for comments on the draft Report. These public and peer review comments are available in their entirety on <http://www.Regulations.gov> and http://www.whitehouse.gov/omb/inforeg/regpol-reports_congress.html. They are summarized by topic, below.

Scope of the Report

Commenter (C) has submitted public comments and a formal 'request for correction' regarding OMB's decision to include only major rules in the benefit and cost totals, on the grounds that this selection provides incomplete information on the aggregate benefits and costs of Federal regulation. This Commenter expresses particular concern over: (i) the lack of inclusion of non-major rules; (ii) a selection bias against accounting for economic regulations; and (iii) the lack of inclusion of independent agency regulations. To illustrate, he cites the number of major rules as a percentage of all final rules reviewed by OMB, and the total number of final rules published in the *Federal Register*: approximately 13 percent of the 296 rules reviewed by OMB and one percent of 3552 final rules published in the *Federal Register*. OMB notes that comments regarding the exclusion of non-major rules, the lack of thorough review of economic regulations, and the exclusion of independent agency regulations from the totals have been raised in the previous Reports.

Regarding the emphasis on major rules, OMB acknowledges in this and previous Reports that the focus on major rules reviewed by OMB provides an incomplete picture; however, we also believe that the aggregate estimates capture the "vast majority of the total costs and benefits of all rules subject to OMB review."⁴⁷ A more detailed discussion of this point can be found in past Reports (e.g., see 2004 Report).

With respect to economic regulations, OMB notes that although 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 has 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. Although the Commenter presents one example of an economic regulation he believes was misclassified as non-major, OMB disagrees with the Commenter that OMB devotes inappropriately low resources to the review of economic regulations subject to OMB review under Executive Order 12866.

In regards to independent agency regulations, OMB recognizes that the exclusion of these regulations in the accounting statement section of the Report leads to an incomplete accounting of benefits and costs of Federal regulation. However, we have explained in this Report, and past Reports the basis for excluding these estimates. In short, the Commenter acknowledges that

⁴⁷ Progress in Regulatory Reform: 2004 Report to Congress on the Costs and Benefits of Federal Regulations and Unfunded Mandates on State, Local, and Tribal Entities (2004), p. 26.

these analyses are outside the scope of OMB review under Executive Order 12866. OMB agrees, however, that it is important to assess the benefits and costs of independent agency regulatory actions, and we encourage independent agencies to conduct benefit-cost analyses that conform to our regulatory analysis guidance.

OMB traditionally includes the available information on the benefits and costs of major independent agency regulations, based on GAO reports, in a separate table. Since 2007, OMB also includes in the Report a more in depth presentation of the available information on all major regulations issued by independent agencies from 1996. By presenting available information on these regulations, readers are free to examine and analyze them as they see fit.⁴⁸

Agency vs. External Estimates

Commenter (C) has submitted public comments and a formal ‘request for correction’ regarding OMB’s reliance upon data provided by the agencies. He is concerned that the benefit and cost estimates presented in this Report cannot be considered objective in the absence of an independent analysis. He also worries about the implied precision of the estimates presented in the Report. This criticism is not new, and OMB responded extensively on this issue in the 2006 Report. In summary, we have concluded that “since most agency impact analyses present estimates with a precision of \$1 million, OMB presents estimates to that precision.”⁴⁹

Commenter (C) also criticizes OMB for aggregating estimated benefits and costs that were derived using different analytic procedures and assumptions. Although OMB has acknowledged this limitation in the past Reports, and has added additional caveats regarding this limitation to this Report, we believe these aggregations continue to have merit. In particular, we believe an aggregation of estimated benefits and costs from regulatory impact analyses following the guidance of OMB Circular A-4 provide the public with a meaningful estimate of the magnitude of the impact of regulations reviewed by OMB.

Commenter (C) recommends that OMB take the following steps to address these concerns: (i) solicit third-party estimates for benefits and costs of major rules; (ii) set up procedures to solicit third-party estimates and announce such procedures in this final Report; (iii) use third-party estimates for benefits and costs of major rules if they are superior to agency estimates upon reviewing them in lieu of agency estimates; (iv) seek peer review for the third-party estimates when the draft Report to Congress is reviewed by peer reviewers; and (v) seek public comment for the third-party estimates for benefits and costs of major rules. While OMB appreciates the value of competing analyses, and would encourage third-party efforts to develop independent estimates, it is beyond the scope of this Report to undertake such analyses.

⁴⁸ Rules promulgated by independent agencies such as the Securities and Exchange Commission and the Federal Reserve System are not subject to the OMB review. OMB relies on GAO reports for estimates of benefits and costs of independent agency rules.

⁴⁹ 2006 Report to Congress on the Costs and Benefits of Federal Regulations and Unfunded Mandates on State, Local, and Tribal Entities (2006), p. 17.

Technical Note

We realize that the differences in perspective on the scope of the Report and the approach used led Commenter (C) to suggest that OMB did not follow its Information Quality Guidelines, including the Information Quality Bulletin for Peer Review. Information quality is determined within the context of the stated purpose, the transparency of the methods used, the clarity with which assumptions are stated, and the specificity of the limitations presented.

It is OMB's view that submission of a proposed regulation to rigorous benefit-cost analysis and public comment operates to moderate any agency bias in estimating benefits and costs. In addition, OMB has already undertaken efforts to address the issue of validating agency estimates. OMB is aware that estimates are inherently uncertain, with *ex-ante* benefit and cost estimates being both under- and over-estimated. OMB has included a discussion on this topic in the 2005 Report, *Validating Regulatory Analysis*.

Furthermore, our original review of each agency regulatory impact analysis includes close attention to transparency and reproducibility. In this Report, we have provided additional links to the individual RIAs to improve transparency and assure reproducibility. We continue to highlight the key assumptions underlying the analyses and have strengthened the caveats provided. We acknowledge that it is difficult to provide quantitative assessment on the significance of these caveats; we have clarified this by strengthening the disclaimers in this Report. Overall, we think that the transparency of the methods used to generate each of the benefit and cost estimates provided, including the clear citation to the sources of that information, allows for reproducibility.

Finally, OMB uses external, independent scientific experts to review the draft Report each year, consistent with both the guidance provided in the OMB Bulletin and the requirements 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. We thank Commenter (C) for pointing out that we did not use the disclaimer recommended in OMB's Information Quality Bulletin on Peer Review; in the future OMB will apply the more extensive disclaimer for its draft Reports to Congress.

Other Issues

Peer Reviewer (1) urges OMB to report on the extent to which regulations under consideration maximized net benefits. Under the Executive Order 12866, "agencies should select those approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity), unless a statute requires another regulatory approach." To ensure and demonstrate that the agency is maximizing net benefits, OMB Circular A-4 states that an RIA should consider appropriate alternatives to a standard, and should evaluate incremental benefits on a continuum of stringency (pp. 16-7). OMB urges continued agency compliance with this directive, and provides links to individual RIAs below in Table A-1.

Peer Reviewer (2) suggests that physical effects of regulations or outcomes measures be presented along with the monetized benefit estimates. OMB agrees in part, and points out that OMB Circular A-4 “encourages agencies to report results with multiple measures of effectiveness that offer different insights and perspectives” (p. 13). On this point, OMB has provided links to individual RIAs for the reader in Table A-1, including (i) significant non-monetized benefits that agencies report to OMB, and (ii) a summary of the sources of the benefits agencies have monetized. For example, NHTSA’s Electronic Stability Control regulation, as reported in Table A-1, “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.” OMB will work to ensure that the physical outcome measures on which monetized estimates are based are clear in Table A-1.

Peer Reviewer (1) suggests that OMB facilitate the use of prediction markets for public purposes. In particular, the Reviewer asks OMB to urge Congress and the Commodity Futures Trading Commission to lower regulatory barriers to starting these new markets through a prompt letter. OMB agrees that information markets are an interesting new area of research, and encourages the Commenter to keep us apprised of relevant new findings.

Peer Reviewer (1) suggests that OMB (i) include a discussion of the costs and benefits of antitrust activities in the Report, and (ii) publish a guidance for analyzing benefits and costs of antitrust activities. The Reviewer notes that data from the Federal Trade Commission would be helpful in discussing antitrust activities, and urged the Congress to require the agencies to submit reports on antitrust activities to OMB. OMB feels that a discussion and guidance on analyzing benefits and costs of antitrust activities are beyond the scope of this Report.

Peer Reviewer (1) suggests that OMB provide guidelines for the analysis of anti-terrorism and homeland security regulation. OMB encourages DHS and any other agency with a substantial focus on security to develop more systematic ways of judging the efficacy of their regulations. As mentioned in previous Reports, and most prominently in a chapter dedicated to homeland security regulations in our 2003 Report, monetizing the benefits of homeland security regulations is exceedingly difficult, as it requires an estimate of the probability and consequences of a terrorist attack. In several recent rulemakings, DHS has instead conducted “break-even” analyses, which attempt to define what a regulation would need to achieve, in terms of reducing the probability of one or more types of terrorist attack, in order for the benefits of the regulation to outweigh its costs. We will continue to encourage DHS and other agencies regulating homeland security to develop this methodology in order to adopt, as much as possible, a type of benefit-cost analysis framework as a basis for evaluating their regulatory actions.

Recommendations to Congress

Peer Reviewer (1) and Commenter (C) recommend actions by Congress regarding regulatory analysis and this Report. Peer Reviewer (1) recommends that Congress should require agencies to comply with OMB Circular A-4, and restrict agencies’ abilities to move forward with regulatory actions in the absence of compliant regulatory impact analyses. In the absence of congressional action, Peer Reviewer (1) recommends that the President draft a new

executive order requiring agencies to comply with the Circular. Likewise, Commenter (C) notes that “without enforcing the RIA requirement, it is almost impossible for OMB to fulfill its statutory duty to provide an accounting statement that has utility for Congress or the public.” Instead of suggesting that Congress require compliance with OMB Circular A-4, the Commenter asks OMB to request a repeal of the law requiring OMB to produce Reports to Congress. OMB will consider these suggestions in the future; however, we feel the Report continues to provide a useful summary to Congress and other interested parties of agency estimates of benefits and costs of regulation.

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 have been reviewed by OMB under Executive Order 12866 or its predecessor, Executive Order 12291. Of these OMB-reviewed rules, 1,231 are 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. 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, are presented below. In addition, the cost estimates are extended back to 1981, the beginning of the regulatory review program at OMB, and include those regulations with cost, but not benefit, estimates.⁵⁰

While exploring the impact of rulemaking on the economy in the early 1980s, we find that several important deregulatory actions resulted in a net decrease in compliance costs. The net cost savings generated by these regulations are included 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, the 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 2001.⁵¹ Another important change is the

⁵⁰To 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.

⁵¹We 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.

inclusion of DOT's 1993 air bag rule, which had been left out of our calculations in 1993 because Congress had mandated the rule.⁵² We have made this change to be consistent with OMB Circular A-4, Regulatory Analysis, issued in September 2003. OMB 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 has estimated that the actions necessary to meet the revised standards would yield benefits ranging from \$20 billion to \$120 billion per year, and would impose costs of \$10 billion 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, our 2002 Report notes that in developing aggregate estimates of regulatory benefits and costs, estimates for the 1997 revisions of the ozone and fine PM NAAQS would be excluded, and estimates associated with the several "implementing" rules promulgated in subsequent years would be used instead. 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 the 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.⁵³

⁵²Our 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.

⁵³Note that this trend would have been 7 percent if the ergonomics rule were not included.

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

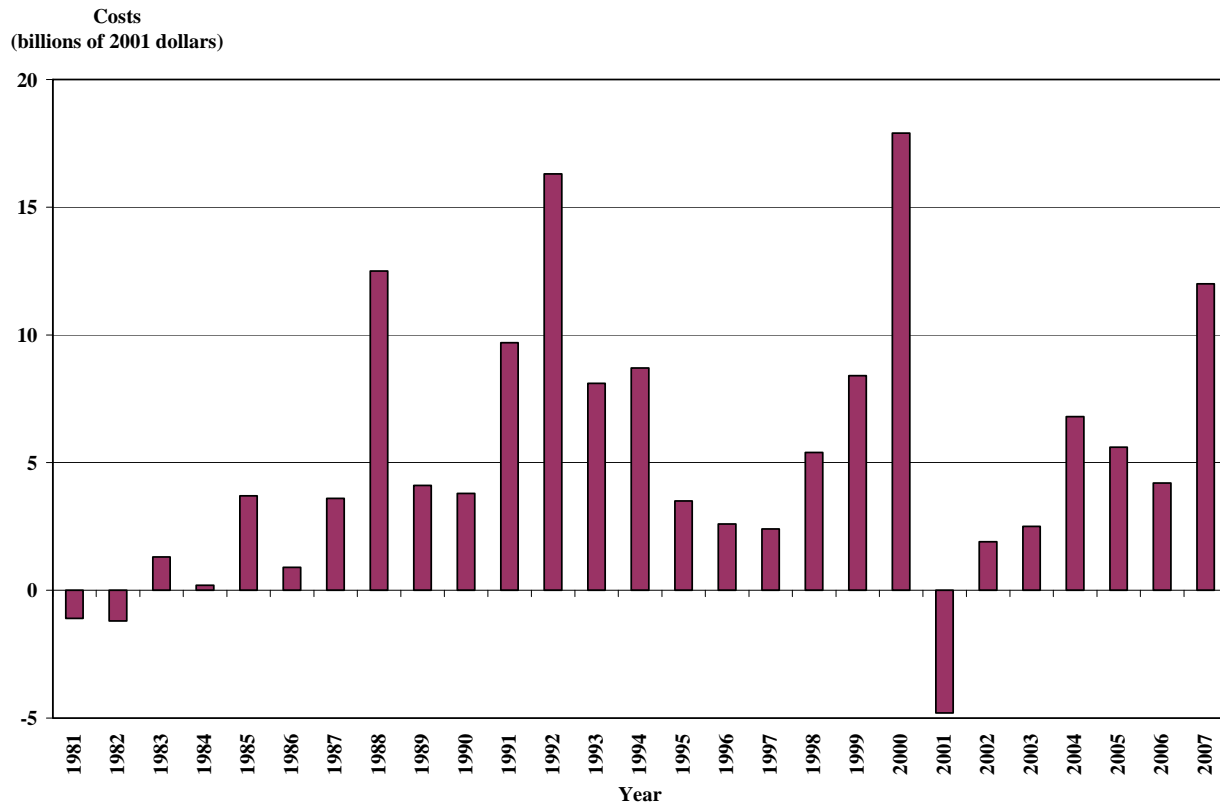
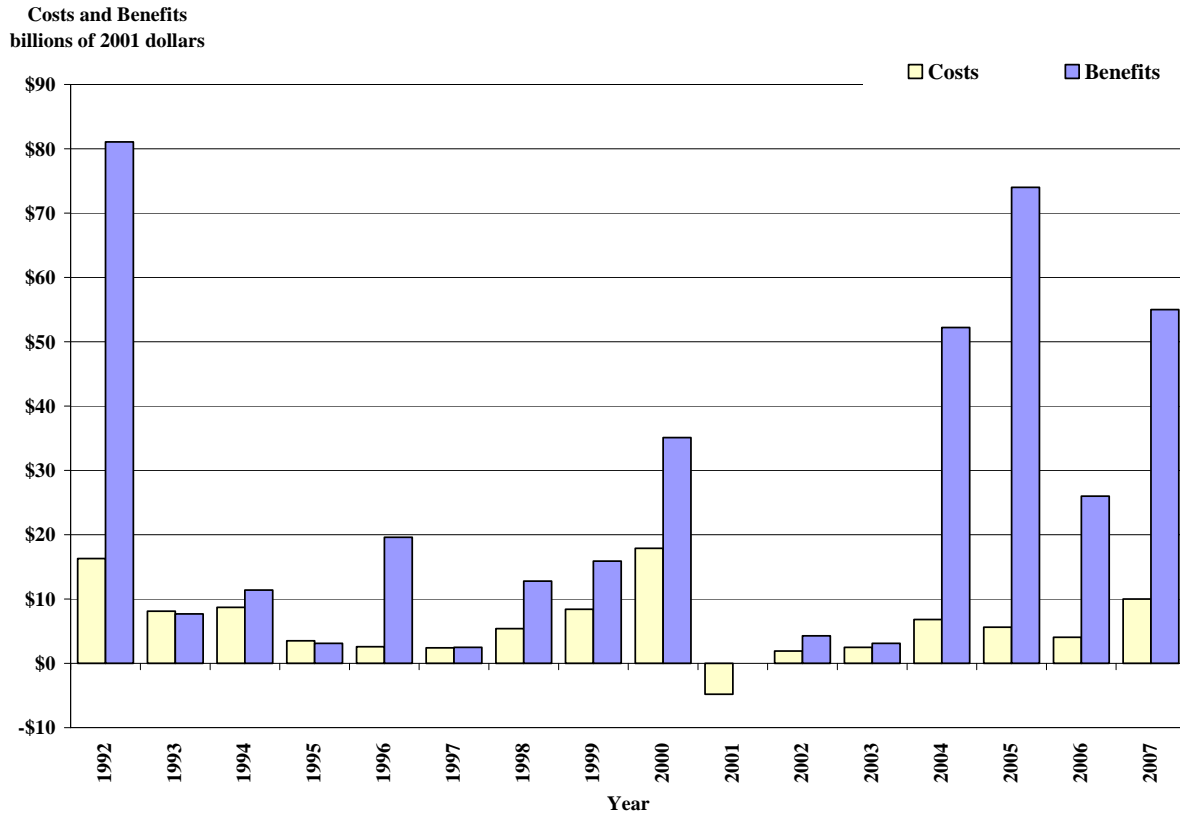


Figure 2-2 shows the benefits and costs of major rules issued from October 1, 1992, to September 30, 2007. Benefit estimates for the rules (with three noted exceptions)⁵⁴ that comprise the overall estimates are presented in various tables in the 11 annual Reports that OMB has completed (including this Report). Note that the four highest years for benefits (1992, 2004, 2005, and 2007) are mostly explained by four 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.⁵⁵

⁵⁴The 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.

⁵⁵ This chart does include the impacts of EPA’s 2005 Clean Air Interstate Rule. On July 11, 2008, the DC Circuit Court vacated rule; however, in response to EPA’s petition, the Court on December 23, 2008, remanded the rule without vacatur, which keeps it this rule in effect while EPA conducts further proceedings consistent with the Court’s July 11 opinion.

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. The figure does not show data beyond 1992 because of a lack of comparable data on benefits.

Readers should note that these are *ex ante* estimates. 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. The groundwork for the regulations issued by one administration is often begun in a previous administration.⁵⁶

⁵⁶For 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. 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 is charged with promulgating its own Information Quality Guidelines. OMB has 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 released their final guidelines, which became effective immediately. The OMB government-wide guidelines require agencies to 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.⁵⁷ 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.⁵⁸ 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 D 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.⁵⁹

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 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

⁵⁷See http://www.whitehouse.gov/omb/inforeg/info_quality_posting_083004.pdf.

⁵⁸See *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.

⁵⁹See *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, four additional appeals have been 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

The correction requests received in FY 2007 are 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. 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 and seven appeals (three relating to FY 2007 requests and four relating to FY 2006 requests). For details relating to the specific requests, including agency responses, we encourage readers to visit agency Information Quality websites (see Section A in the Appendix D for a link to agency web pages). As shown below, we categorize how agencies respond to requests in a more detailed manner in this Report. For instance, we include the category of “other corrections.” This category is used when the agency response does not provide the specific changes that are 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 was classified in the “other corrections” category. OMB continues to use the “other processes/mechanisms” category to describe responses that are 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.

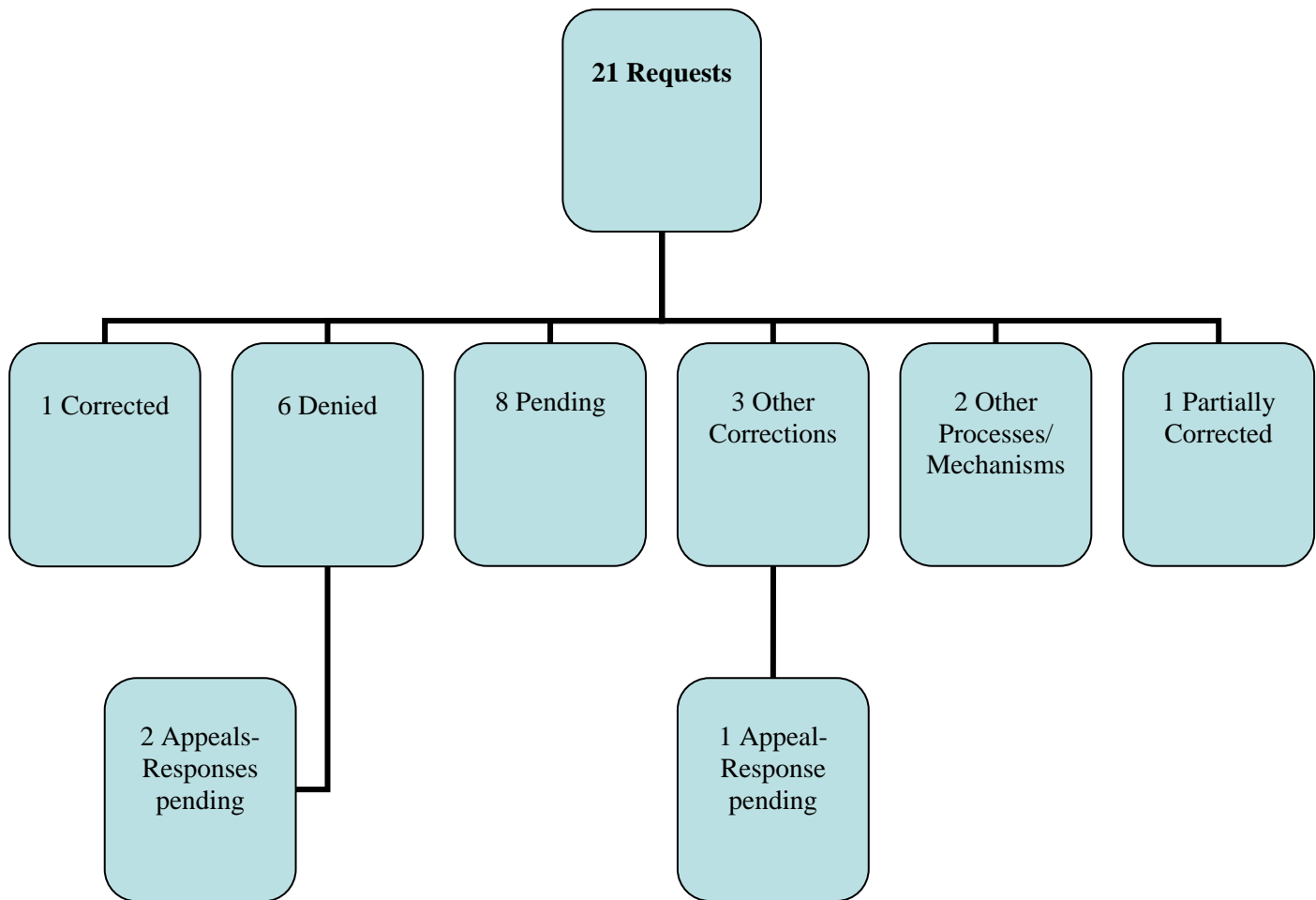


Figure 3-1: Status of IQ Correction Requests Received in FY 2007

As noted in the 2007 Report,⁶⁰ 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 remained pending from the agencies. The pending correction requests have been 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 responded to nine of

⁶⁰ 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.

these correction requests and continued to work on responses to the remaining four at the end of FY 2007.

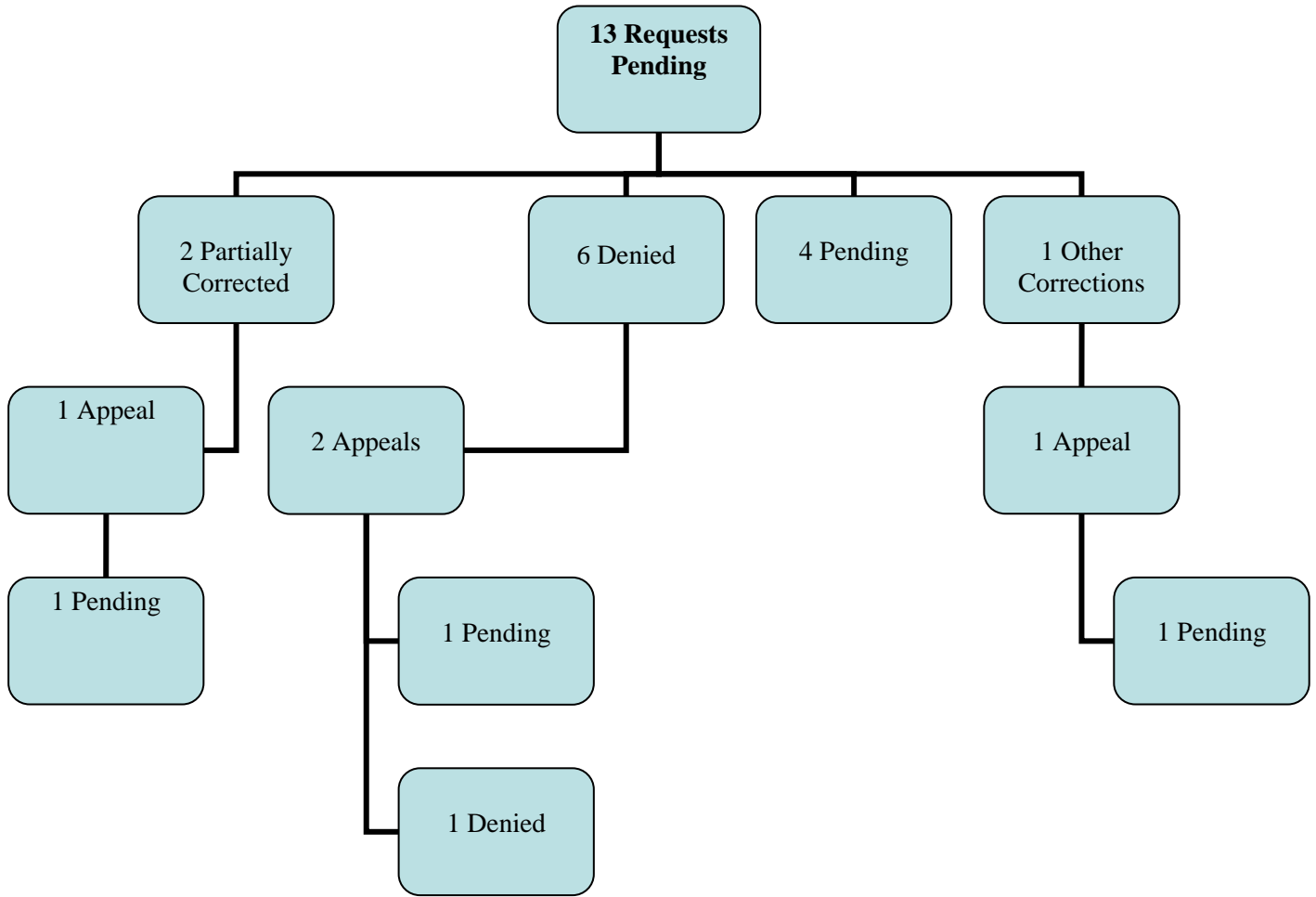


Figure 3-2: FY 2007 Status of Pending Correction Requests from FY 2004, FY 2005 and FY 2006

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.

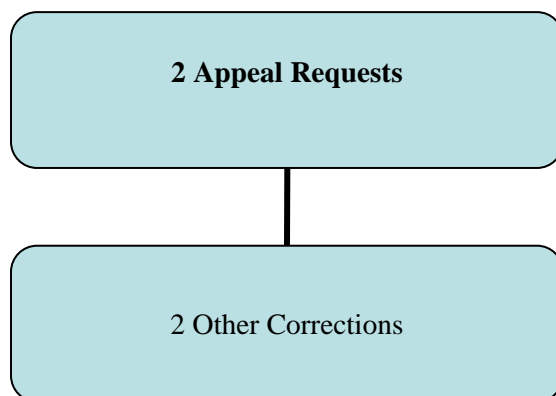


Figure 3-3: FY 2007 Status of Pending Appeal Requests from FY 2003 and FY 2006

Legal update

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).⁶¹ The Peer Review Bulletin requires executive agencies to ensure that all “influential scientific information” they disseminate after June 16, 2005 is 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.”⁶² The term “influential” is to be interpreted

⁶¹ See <http://www.whitehouse.gov/omb/memoranda/fy2005/m05-03.pdf>

⁶² 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

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.⁶³

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. It directs agencies 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 should 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 have 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.

⁶³ 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, enhances 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 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. 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.

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).

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. Section B in the Appendix D 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 Agriculture,⁶⁴ Commerce,⁶⁵ Health and Human Services,⁶⁶ Interior,⁶⁷ Labor, and Transportation, Housing and Urban Development, Justice, 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.

From time to time, other agencies produce or sponsor influential scientific information, but do not 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 Section C in the Appendix D.

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.⁶⁸ 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,⁶⁹ while other departments have chosen to have individual agencies host their own agendas.⁷⁰ Furthermore, some agencies have chosen to provide a single agenda for both influential scientific information and highly influential scientific assessments,⁷¹ while

⁶⁴ 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.

⁶⁵ 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.

⁶⁶ The Food and Drug Administration, the Center for Disease Control and Prevention, and the National Toxicology Program are compliant with the Bulletin.

⁶⁷ The Fish and Wildlife Service has an exemplary peer review process. The US 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.

⁶⁸ For instance, the Environmental Protection Agency's incorporation with its science inventory project

⁶⁹ For instance, the agenda for the Department of Transportation

⁷⁰ For instance, the agendas for the Department of Health and Human Services and the Department of the Interior

⁷¹ For instance, the agenda for the Department of Commerce

others provide two separate agendas.⁷² 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,⁷³ 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.⁷⁴ OMB is currently working with 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 constitutes the second full year of implementation for the Peer Review Bulletin. Tables 3-3 A and B below summarize the results of the annual data call for the first two years of implementation 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 was 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 are 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. Furthermore, discussions with agencies suggest that the Bulletin has encouraged additional rigor,

⁷² For instance, the agenda for the Department of Transportation

⁷³ 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.)

⁷⁴ 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>)

even strengthening the underlying peer review process for those reviews that would have happened in the absence of the Peer Review Bulletin.

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.⁷⁵ The assessments underlying these decisions are subject to review and input from technical experts, but the Service has determined that due to the extremely limited time between when data are collected and analyzed and because 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.⁷⁶ 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 provided 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.

⁷⁵ <http://www.fws.gov/migratorybirds/MBPeerReviewWaiver.pdf>

⁷⁶ <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 ⁷⁷	
	2006	2007	2006	2007	2006	2007	2006	2007	2006	2007	2006	2007
Department of Agriculture ⁷⁸	19	71	8	9	0	0	0	0	0	1	3	0
Department of Commerce ⁷⁹	19	24	3	2	0	0	0	0	6 80	14	0	17
Department of Defense ⁸¹	2		2		0		0		1		N/A	
Department of Energy ⁸²	1	2	1	2	0	0	0	0	1	1	0	2
Department of Health and Human Services ⁸³	31	32	6	7	0	0	0	0	3	24	1	0
Department of the Interior ⁸⁴	51	68	1	1	1	1	4	0	1	0	1	0
Department of Justice ⁸⁵	0	3	0	0	0	0	0	0	0	0	0	0
Department of Labor ⁸⁶	2	0	1	0	0	0	0	0	0	0	0	0
Department of Transportation ⁸⁷	12	14	5	10	0	0	0	0	0	1	1	3

⁷⁷ 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*.

⁷⁸ 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.

⁷⁹ The Department of Commerce agency reporting peer reviews in FY 2006 was the National Oceanic and Atmospheric Administration.

⁸⁰ Incomplete count (minimum number).

⁸¹ The only Department of Defense agency reporting peer reviews in FY 2006 was the Army Corps of Engineers.

⁸² The only Department of Energy peer reviews reported in FY 2006 and FY 2007 were associated with climate change science program.

⁸³ 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.

⁸⁴ The Department of the Interior agency reporting peer reviews in FY 2006 was the Fish and Wildlife Service, the Minerals Management Service, and the US Geological Survey.

⁸⁵ The Department of Justice agency reporting in FY2007 was the Executive Office for US Trustees.

⁸⁶ The Department of Labor agency reporting peer reviews in FY 2006 was Employee Benefits Security Administration.

⁸⁷ 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 ⁷⁷	
	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 ⁸⁸	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

⁸⁸ 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, FY2006 - 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 13422,⁸⁹ which amends Executive Order 12866 and clarifies OMB's authority to coordinate interagency review of agencies' significant guidance documents.⁹⁰ 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).⁹¹ These documents are 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 rationale underlying 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.⁹²

To accomplish its goal, the Good Guidance Practices Bulletin establishes 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 review and approve the agency's issuance of significant guidance documents.
- Agencies maintain on their websites current lists of their significant guidance documents that are in effect, so that the regulated community can know what guidance applies to it.
- Agencies provide the public with access to and the opportunity to provide feedback on the significant guidance documents. Agencies advertise on their websites a means for the public to submit comments electronically on these guidance documents.
- For those guidance documents that are economically significant, agencies publish notices in the *Federal Register* announcing that the draft documents are available (on

⁸⁹ Executive Order 13422 (January 23, 2007), available at http://www.whitehouse.gov/omb/inforeg/eo12866/fr_notice_eo12866_012307.pdf.

⁹⁰ Section 9 of Executive Order 12866, as amended.

⁹¹ OMB, Final Bulletin for Agency Good Guidance Practices (January 18, 2007), available at <http://www.whitehouse.gov/omb/memoranda/fy2007/m07-07.pdf>.

⁹² See public comments on the draft Good Guidance Practices Bulletin, available at http://www.whitehouse.gov/omb/inforeg/good_guid/c-index.html.

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.⁹³ This memorandum is designed to respond to frequently-asked questions and guide the agencies to substantial compliance. As of July 2008, the agencies had worked 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.⁹⁴ 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 seeks to correct these problems is through its requirement that agencies provide the public with access to, and the opportunity to provide feedback on the agency's significant guidance documents.⁹⁵ 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.⁹⁶ 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.⁹⁷

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, categorized both by issuing office and environmental topic. The Department of Labor has also done a noteworthy job of making its guidance documents available to the public.

⁹³ 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>.

⁹⁴ Preamble to the Good Guidance Practices Bulletin.

⁹⁵ Section III of the Good Guidance Practices Bulletin.

⁹⁶ Section III(1)(a) of the Good Guidance Practices Bulletin.

⁹⁷ Section III(2) of the Good Guidance Practices Bulletin.

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 designate one of the agency’s Presidential Appointees⁹⁸ to be its Regulatory Policy Officer (RPO), to advise OMB of the designation, and to update OMB annually on the status of this designation.⁹⁹ 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].”¹⁰⁰

The current list of agency Regulatory Policy Officers is as follows:¹⁰¹

⁹⁸ 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.

⁹⁹ Section 6(a)(2) of Executive Order 12866, as amended.

¹⁰⁰ Section 6(a), Executive Order 12866.

¹⁰¹ The current list of agency Regulatory Policy Officers is on OMB’s website, *available at*: http://www.whitehouse.gov/omb/infoereg/regpol/agency_reg_policy_officers.pdf.

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

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).¹⁰² 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.¹⁰³ This Memorandum also benefited from feedback received on OMB's Proposed Risk Assessment Bulletin issued in 2006 (Proposed Risk Assessment Bulletin).¹⁰⁴

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 committed to working with the Federal agencies to ensure consistency with the updated principles.

Agency Risk Analysis Guidance Documents

As part of OMB's 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 asked agencies to provide suggestions for risk analysis topic areas where further interagency coordination and dialogue would be useful.¹⁰⁵ As a result of this request to agencies, OMB and OSTP learned that while some agencies have many publicly available guidance documents regarding their risk

¹⁰² US 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.

¹⁰³ OMB and OSTP, *Updated Principles for Risk Analysis* (2007), available at <http://www.whitehouse.gov/omb/memoranda/fy2007/m07-24.pdf>.

¹⁰⁴ 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.

¹⁰⁵ 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.

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 fewer 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 reports that NHTSA has no written guidance on risk assessment, but comments 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 suggests, 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 continues 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 initiate 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 approaches with 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. The 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, EU Scientific Committees and Panels, and 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, regulatory realities, and organization of risk assessment within the EU, US, and Canada. 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 revealed many similarities, leading the group to 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, which took place on November 13 - 14, 2008 in Brussels. This global risk assessment dialogue, hosted by the European Commission's DG-SANCO, included members of the public as well as governmental representatives, and built upon the July 2008 discussions. The Global Risk Assessment Dialogue was intended to be the first regular, international bi-annual conference. It builds upon the Transatlantic Risk Assessment Dialogue of the European Commission with the US and Canada. The US, EU, Canadian, Japanese, Chinese, Australian, and Russian governments attended the conference. The topics ranged from specific to broad and included communicating uncertainty, weight of evidence and causality criteria, science and policy analysis, approaches to the assessment of non-threshold (mutagenic) carcinogens, key aspects of exposure assessment, and emerging issues such as computational toxicology. The participants agreed that this global dialogue conference should continue (i.e., every two years). An outcome of this meeting was a discussion of specific topic areas where further collaboration and joint products would be useful. Working groups identified specific topics relating to uncertainty and terminology, non-threshold carcinogens, exposure assessment, and emerging issues. Each working group is planning to produce outputs by 2010. The conference website can be viewed at: http://ec.europa.eu/health/ph_risk/ev_20081113_en.htm.

In addition to the efforts above, the July workshop participants expressed a widespread interest in further discussions regarding how risk assessors, risk managers, and economists can work together more efficiently and more effectively, among other topics. Participants also expressed interest in discussing the acceptability of risk, and risk communication challenges. Both these topics will be considered for future transatlantic risk dialogue activities.

CHAPTER IV: 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 have recently finalized a report on how our respective Regulatory Impact Analysis guidelines take into account 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.¹⁰⁶ Knowing how regulation affects trade may help to ensure that regulatory policy does not become a tool for establishing unnecessary barriers to trade, whether deliberately or not.

Recent studies demonstrate the correlation between better business regulations and economic growth.¹⁰⁷ This research suggests that a regulatory regime that offers transparent rules based on clear regulatory principles 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, find that incompatible services market regulations often raise barriers to market entry and affect trade flows. Ultimately, more regulated local services sectors' export performance suffers due to a lack of competition, and consumers are 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.

Section B provides 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, and was modified slightly in response to comments to the Draft version of this Report.

¹⁰⁶ The final report, titled "Review of the Application of EU and US Regulatory Impact Assessment Guidelines on the Analysis of Impacts on International Trade and Investment," draft report, and public comments are available at <http://www.whitehouse.gov/omb/inforeg/regpol.html#opp>

¹⁰⁷ Please see Chapter 1, Section F of this Report for a discussion of this research.

B. Incorporating Trade Impacts into Regulatory Impact 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, understanding the benefits and costs of regulatory actions is important for decision makers and the public.

Further, Executive Order 12866 states that 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.

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.

The Cost of Regulation: 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 that 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? OMB 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 US citizens is the following. A

regulation is introduced, which leads the United States to stop or restrict the import of a particular product. US citizens who 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 may 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 OMB 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.

C. Response to Public Comments on the Analyzing International Effects of Regulation

Commenters (A) are supportive of the guidance, stating that it provides “an excellent articulation of the impact regulation can have on trade and investment.” They suggest that such a discussion be either (i) incorporated into OMB Circular A-4 or (ii) issued as a separate Memorandum. OMB has carefully evaluated the methods to disseminate this clarification of agency responsibilities, and believes this guidance would be useful to incorporate into OMB Circular A-4. Due to the pending change in Administration, however, OMB does not feel it would be appropriate to do so at this time. In the meantime, OMB believes the discussion in this Chapter provides agencies with a useful framework for satisfying their obligations to consider the international impacts of proposed and final regulations.

Similarly, Commenter (B) suggests that OMB issue guidance on analyzing the effects of regulations on international trade and investment. This Commenter further suggests that the Unlawful Internet Gambling Enforcement Act rule be the “initial test case” for this guidance.

Commenters (A) suggest providing a discussion of “the role voluntary international standards play in minimizing any adverse impact regulation might have on trade and investment,” (p. 2) that draws from OMB Circular A-119 and the National Technology Transfer and Advancement Act. OMB agrees with this suggestion. The original OMB-Secretariat General of the EC Joint report includes a similar recommendation, and the EU-US High Level

Regulatory Cooperation Forum has undertaken a joint project to enhance mutual understanding of US and EU approaches to the use of standards in regulation.

OMB Circular A-4 states that analyses should include “a manageable number of alternatives to be evaluated according to the formal principles of the Executive Order.” In cases where a regulation may have a significant effect on international trade and investment, existing international standards or regulatory approaches, if applicable, should be analyzed as an explicit regulatory alternative under the requirements of OMB Circular A-4. This is also consistent with the requirements established by OMB Circular A-119 and the National Technology Transfer and Investment Act, which require US agencies to evaluate and consider private sector standards, including international standards, as one alternative when developing regulations, and to justify cases when they have not adopted a private sector standard. OMB Circular A-4 recognizes, however, that “[t]he number and choice of alternatives selected for detailed analysis is a matter of judgment. There must be some balance between thoroughness and the practical limits on analytical capacity.” Agencies are encouraged to work with OMB on a case-by-case basis to ensure regulatory analyses are consistent with their existing obligations to consider alternative approaches, including the use of private sector standards.

**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 2006 through September 2007; the rules published before October 2006 are described in last year's report.

In recent years, this report has been included along with our final Report to Congress on the Benefits and Costs 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, OMB is 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.

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 G contains discussions of 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 V: REVIEW OF SIGNIFICANT REGULATORY MANDATES

In FY 2007, Federal agencies issued 11 final rules that were subject to Sections 202 and 205 of the Unfunded Mandate Reform Act of 1995 (UMRA), as they require expenditures 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). The Department of Homeland Security (DHS) issued four of these rules, the Department of Transportation (DOT) issued two rules, and the Departments of Labor (DOL), Health and Human Services (HHS), Energy (DOE), Agriculture (USDA), and the Environmental Protection Agency (EPA) each issued one rule.

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 airport 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 US airports-of-entry.

DHS's primary estimate of the cost of this rule is \$206 million 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 \$126.8 million 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, 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 \$1.75 billion 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.

Chemical Facility Anti-Terrorism Standards (72 FR 65396). This final rule establishes risk-based performance standards, and requires vulnerability assessments and the development and implementation of site security plans for major chemical facilities. Specifically, it requires facilities to undergo a “top screen” to determine whether or not they need to be further regulated. As a result of the top screen, a smaller number of the most risky facilities would be identified for classification in one of the four risk tiers, triggering additional security planning and analysis requirements.

DHS estimates that this rule will cost \$835 million - \$1,535 million annually. 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 significantly greater than \$100 million (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, but the vehicle manufacturers and their suppliers are expected to incur in the aggregate, of more than \$122 million annually. Therefore, this rulemaking constitutes a private sector mandate under UMRA.

Side Impact Protection Upgrade—Federal Motor Vehicle Safety Standard (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--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. This final rule also 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 \$140 million. 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. Department of Energy

Energy Efficiency Standards for Electric Distribution Transformers (72 FR 58190). Under the authority of the The Energy Policy and Conservation Act (EPCA), this final rule establishes energy efficiency standards for liquid-immersed and medium-voltage, dry-type distribution transformers manufactured for sale in the United States, or imported to the United States, on or after January 1, 2010.

DOE estimates this rule will have an annual cost of \$381-428 million. This final rule would not impose any cost on small governments or significantly or uniquely affect small governments. However, DOE 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.

F. Department of Agriculture

Prohibition of the Use of Specified Risk Materials for Human Food and Requirements for the Disposition of Non-Ambulatory Disabled Cattle (72 FR 38700). This final rule amends the Federal meat inspection regulations to designate the brain, skull, eyes, trigeminal ganglia, spinal cord, vertebral column, and dorsal root ganglia (DRG) of cattle 30 months of age and older, and the tonsils and distal ileum of the small intestine of all cattle, as "specified risk materials" (SRMs), which are inedible and prohibited for use for human food. The USDA took this action in order to minimize human exposure to the agent that causes bovine spongiform encephalopathy (BSE).

USDA estimates this rule will have an annual cost of \$171 million. This final rule would not impose any cost on small governments or significantly or uniquely affect small governments. However, USDA 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.

G. 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 \$400 million. 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 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, 2007. 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 are adjusted to 2001 dollars using the latest Gross Domestic Product (GDP) deflator, available from the Bureau of Economic Analysis at the Department of Commerce.¹⁰⁸ 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 affect 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.

¹⁰⁸National 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, 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.

To address this issue in part, 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 these recommended best practices, the benefits and costs presented 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 continue to 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 18 major rules reviewed by OMB from October 1, 2006 through September 30, 2007, 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 12 rules finalized in 2006-2007 that were added to the Chapter I accounting statement totals.

**Table A-1: Summary of Agency Estimates for Final Rules
October 1, 2006 - 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 US. 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 US 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, US 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: 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: http://www.regulations.gov/fdmspublic/component/main?main=DocketDetail&d=EPA-HQ-OAR-2005-0036</p>
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>

Rule [FR Cite]	Agency	Benefits	Costs	Other Information
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>
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 US, and to prevent such passengers and crew from departing on vessels leaving the US. 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 unescorted 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 Report to Congress. It consists of the annualized and 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.

While we limit the Chapter 1 accounting statement to regulations issued over the previous ten years, we have included in this Appendix the benefits and cost estimates provided for the economically significant rulemakings that have been covered in previous Reports in order to provide transparency.

**Table B-1: Estimates of Annual Benefits and Costs of Twelve Major Federal Rules
October 1, 1996 - 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 - 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 Costs¹⁰⁹
Promulgated by Independent Agencies
October 1, 1997 - 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

¹⁰⁹ 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 10 statutorily mandated fee assessment rules from 1997 through 2007.

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

http://www.ocio.usda.gov/qi_guide

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

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

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

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/IOCR.htm>

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

Department of the Interior:
<http://www.doi.gov/ocio/iq>
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 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_O
VERVIEW](http://www.gsa.gov/Portal/gsa/ep/contentView.do?contentId=12667&contentType=GSA_O
VERVIEW)

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&appli
cation=ACROBAT](http://www.mspb.gov/netsearch/viewdocs.aspx?docnumber=251846&version=252119&appli
cation=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/>

US 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/oce/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>

US 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. This is again provided for 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.¹¹⁰ In this Report, we determine 76 of the 189 nominations to be priorities, and also identify as 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 69 of the 76 reform items are now complete as of January 2009.

¹¹⁰This 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
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)
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 US, Canada, and Mexico & cannot be changed unilaterally by the US. 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 US, Canada, and Mexico.

Table E-1: 2004 Manufacturing Regulatory Reform Nomination Status

#	Reform Name	Nominator	Agency	Promised Action	Date	Status
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.
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 November 19, 2008 (73 FR 69567)

Table E-1: 2004 Manufacturing Regulatory Reform Nomination Status

#	Reform Name	Nominator	Agency	Promised Action	Date	Status
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.
26	EEO-1	US 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.

Table E-1: 2004 Manufacturing Regulatory Reform Nomination Status

#	Reform Name	Nominator	Agency	Promised Action	Date	Status
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.
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.

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	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	Complete: Final Rule published on December 19, 2008 (73 FR 77953).

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); US 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 published on October 30, 2008 (73 FR 64668)

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); US 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); US Chamber of Commerce (19)	EPA	Final Rule or Guidance	Mar-07	Complete: Final rule published on December 22, 2008 (73 FR 78199).
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	Complete: Final rule published on June 4, 2008 (73 FR 31756)

Table E-1: 2004 Manufacturing Regulatory Reform Nomination Status

#	Reform Name	Nominator	Agency	Promised Action	Date	Status
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 developing a proposed rule.
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	Complete: Published final rule on December 5, 2008 (73 FR 74235).
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	Complete: See item #46 above.
83	Leak-Detection and Repair Regulatory Programs	National Association of Manufacturers (9)	EPA	Final Rule	Mar-07	Complete: 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.

Table E-1: 2004 Manufacturing Regulatory Reform Nomination Status

#	Reform Name	Nominator	Agency	Promised Action	Date	Status
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 .
88	Potential to Emit (PTE) Test	Deere & Company (1); Motor and Equipment Manufacturers Association (41)	EPA	Proposed Rule	Jan-06	Overdue.
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). Final rule published on October 5, 2007 (72 FR 56903).

Table E-1: 2004 Manufacturing Regulatory Reform Nomination Status

#	Reform Name	Nominator	Agency	Promised Action	Date	Status
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)
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.

Table E-1: 2004 Manufacturing Regulatory Reform Nomination Status

#	Reform Name	Nominator	Agency	Promised Action	Date	Status
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)
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).

Table E-1: 2004 Manufacturing Regulatory Reform Nomination Status

#	Reform Name	Nominator	Agency	Promised Action	Date	Status
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.
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.

Table E-1: 2004 Manufacturing Regulatory Reform Nomination Status

#	Reform Name	Nominator	Agency	Promised Action	Date	Status
121	Do Not Fax Rule	National Federal of Independent Business (8); National Association of Manufacturers (9); US 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); US 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: Final rule published on November 17, 2008 (73 FR 67933)
145	Permanent Labor Certification	US 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 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.
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	US 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/ibox/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-2 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@eeoc.gov
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.Wheelless@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: PEER REVIEW AND PUBLIC COMMENTS

We wish to express our sincere appreciation for the thoughtful comments we have received on the draft 2008 Report. In particular, we would like to thank our invited Peer Reviewers Robert W. Hahn (Reg-Markets Center, AEI Center for Regulatory and Market Studies), Winston Harrington (Resources for the Future), and Richard Morgenstern (Resources for the Future). Below is a listing of all written comments submitted to OMB, and the numbers of letters assigned to their comments. The public and peer review comments are available for review at http://www.whitehouse.gov/omb/info/reg/repol-reports_congress.html and <http://www.Regulations.gov>.

Peer Reviewers

1. Robert W. Hahn, Reg-Markets Center, AEI Center for Regulatory and Market Studies
2. Winston Harrington, Resources for the Future
3. Richard Morgenstern, Resources for the Future

Public Comments

- A. Adrian Van Den Hoven, BUSINESSEUROPE, and Sean Heath, US Chamber of Commerce
- B. Jim Tozzi, Center for Regulatory Effectiveness
- C. Richard B. Belzer, Regulatory Checkbook

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. This appendix summarizes selected consultation activities by agencies whose actions affect State, local and tribal governments.¹¹¹

Five agencies (the Departments of Energy, Education, Commerce, Housing and Urban Development, and the Environmental Protection Agency) have provided examples of consultation activities that involved State, local and tribal governments not only in their regulatory processes, but also in their program planning and implementation phases. These agencies have worked to enhance the regulatory environment by improving the way in which the Federal Government relates to its intergovernmental partners. In general, many of the departments and agencies not listed here (including the Departments of Justice, State, Treasury, and Veterans Affairs, the Small Business Administration, and the General Services Administration) do not often impose mandates upon States, localities or tribes, and thus have fewer occasions to consult with these governments.

As the following descriptions indicate, Federal agencies conduct a wide range of consultations. Agency consultations sometimes involve multiple levels of government, depending on the agency's understanding of the scope and impact of the rule. OMB continues to work with agencies to ensure that consultation occurs with the appropriate level of government.

A. Department of Energy

Support for National Governors Association's Securing a Clean Energy Future Initiative: Department of Energy (DOE) support for the National Governors Association's Securing a Clean Energy Future Initiative.

The purpose of this initiative is to enact energy policies at the State level that will help develop and deploy cleaner sources of energy to power America's vehicles, homes, and workplaces more efficiently. DOE officials, including those in the Department's Office of Energy Efficiency and Renewable Energy, consulted with State governors and State government representatives to determine the Federal role in this initiative. The entities and persons who would be affected by this initiative include large and small businesses, units of State and local governments, homeowners, and other residents of States.

¹¹¹ The consultation activities described in this appendix are illustrative of intergovernmental consultations conducted by Federal agencies and are not limited to consultations on regulations meeting the UMRA threshold for an unfunded mandate. Similarly, this should not be considered an exhaustive list of Federal consultation activities.

The National Governors Association and DOE each hosted meetings leading to development and launching of the Securing a Clean Energy Future Initiative on September 12, 2007. The issues and concerns related to the types of activities would be included in the initiative and the funding of those activities.

With financial assistance from DOE, the initiative will promote State clean energy policies that result in greater efficiency in the use of existing energy resources, promote non-petroleum based fuels, take steps to reduce greenhouse gas emissions, and accelerate the research and development of advanced clean energy technologies. As a result of consultation with States during the reporting period, DOE has agreed to provide funding in 2008 that will be used to: (1) provide technical support for development of State energy policies; (2) suggest ways States can leverage their research and development investments in advanced energy technologies; (3) advise States on how to use public assets and procurement policies to foster the use of advanced energy technologies and practices in the private sector; (4) increase States' resiliency to energy supply disruptions; and (5) promote future State energy policy dialogues and educational sessions.

Support for National Governors Association's Securing a Clean Energy Future Initiative: Framework to Provide Guidance for Implementation of the US Department of Energy's American Indian and Alaska Native Tribal Government Policy.

The Framework supports improving consultation and communication with Indian Nations, and enhances participation in the actions undertaken by certain DOE offices early in their decision-making processes. Participation by the tribes may relate to cultural resources protection, long-range planning, and other decisions that may affect the interests of Indian Nations. The Framework covers all facilities, programs, and sites of the following DOE organizations: the National Nuclear Security Administration, the Office of Nuclear Energy, the Office of Science, and the Office of Environmental Management. The initiative impacted tribal governments, agencies, and staff of the tribal lands in proximity to the Idaho National Laboratory, the Hanford site, and Los Alamos National Laboratory.

DOE started its consultation with tribes on this issue in 2005. Ongoing discussions continued while drafts of the Framework were circulated within DOE. The final Framework was signed for distribution by the Under Secretary for Nuclear Security, the Under Secretary of Energy, and the Under Secretary for Science on November 27, 2007.

Tribes raised several issues of concern:

1. The need for increased education for DOE employees about tribal governments;
2. The need to include contractors for the Framework guidelines; and
3. The concern that all of DOE was not subject to the Framework.

The tribes, through the Office of Environmental Management's State and Tribal Government Working Group, provided substantial drafting language to the draft Framework.

This document was ultimately approved by Secretary Bodman and distributed on November 27, 2007.

B. Department of Education

Two Percent Proposed Regulations

On April 9, 2007, the Department published final regulations (72 FR 17748) amending regulations under Title I of the Elementary and Secondary Education Act of 1965 (Title I) to provide States with additional flexibility regarding State, Local Educational Agency (LEA), and school accountability for the achievement of a group of students with disabilities who can make significant progress, but may not reach grade-level achievement standards within the same time frame as other students. The document also included amendments to the final regulations under Part B of the Individuals with Disabilities Education Act (IDEA) to incorporate changes made to State assessment requirements under the IDEA by the Individuals with Disabilities Education Improvement Act of 2004, and to incorporate the assessment option proposed in the Title I regulations. The Department published a notice of proposed rulemaking (NPRM) on these topics on December 15, 2005 (70 FR 74624).

The regulations affect State Educational Agencies (SEAs), LEAs, public elementary and secondary schools, teachers, students with disabilities and their parents.

In response to the NPRM, more than 300 parties submitted comments, including representatives of SEAs, LEAs, school boards, and parents. The need for the NPRM was raised to the Department by State and LEA assessment professionals who were concerned that the assessment alternatives contemplated in the pre-existing Title I regulations (regular assessments to grade-level achievement standards and alternate assessments for students with the most significant cognitive disabilities), and reflected in the IDEA, did not recognize that there was a group of students with disabilities who were not the most significantly cognitively disabled, but who could not achieve to grade-level academic achievement standards. Based on the concerns raised, the Department convened several meetings with State and LEA officials, parents of students with disabilities, and researchers to learn more about the issues involved in assessing students with disabilities, the concerns of parents and advocates for ensuring that all students with disabilities be held to high academic achievement standards, and about how some States were designing assessments for students with disabilities.

The comments were generally favorable to the basic concept in the NPRM of allowing States to assess a specific percentage of their students with disabilities using assessments based on modified academic achievement standards. However, the comments raised many issues, including: how to identify this group of students; how to ensure that the modified academic achievement standards would be challenging for this population, and how they could differ from grade-level academic achievement standards; how to include the scores of assessments based on modified academic achievement standards in calculations of annual yearly progress; and how to

ensure that students with disabilities received the appropriate accommodations that they needed to participate in the assessments.

As a result of the comments on the NPRM, the Department made a number of changes to the final regulations under Title I and IDEA. The final regulations provide more detailed information about what is meant by modified academic achievement standards, which students with disabilities may be assessed based on modified academic achievement standards and have their proficient and advanced scores included in calculations of annual yearly progress, and what constitutes an assessment based on modified academic achievement standards. The regulations on modified academic achievement standards also include a number of safeguards to ensure that a student with disabilities who is assessed based on modified academic achievement standards has access to grade-level content so that the student has the opportunity, over time, to reach grade-level academic achievement standards.

Academic Competitiveness Grants Proposed Regulations

On August 7, 2007 (72 FR 44050), the Department published an NPRM for the Academic Competitiveness Grant (ACG) and National Science and Mathematics Access to Retain Talent Grant (National SMART Grant) programs, which were added to the Higher Education Act of 1965, as amended (HEA) by the Higher Education Reconciliation Act of 2005 (Pub. L. 109-171), enacted on February 8, 2006, 20 U.S.C. 1070a-1 (HERA). The NPRM was published as a result of negotiated rulemaking that was conducted between February and April 2007.

ACG regulations affect college students and their parents, institutions of higher education, SEAs, and public and private secondary schools.

Prior to publishing the NPRM, the Department held four public hearings to discuss what issues would be discussed during negotiated rulemaking. These meetings, hosted by senior officials at the Department, solicited input from groups interested in high school issues and the linkage to college. Negotiated rulemaking was conducted over the course of three sessions and included a representative of a State department of education and the National Governors Association.

Interested parties expressed concern that the requirements for the ACG program in the first several years of implementation not be so narrow as to preclude large numbers of students from qualifying for the program, given that they had little notice to take a “rigorous secondary school program of study.” Others expressed a desire for the Department to set a high bar on the definition of “rigorous secondary school programs of study” to encourage students to take high-level courses in high school. The participants at the negotiated rulemaking discussed amending the regulations to permit SEAs to request that rigorous secondary school programs of study be recognized by the Secretary for the current school year, as well as school years in the future. The participants also discussed the requirement that, to be eligible for a first-year ACG, a student

must not have been previously enrolled in a program of undergraduate education, and the impact that the enrollment of high school students as regular students, as defined in 34 C.F.R. §600.2, would have on the title IV funding of State institutions.

In response to the comments, the Department proposed to change the regulations to allow SEAs to propose rigorous programs of study for recognition for both the current and future school years, and to provide for continued recognition of advanced and honors programs as rigorous for school years subsequent to the 2005-2006 school years. In addition, the Department proposed to change the regulations on prior enrollment to ensure that a student would not be disqualified for a first-year ACG award if that student enrolled in an ACG eligible program while in high school, so long as the student was above the age of compulsory school attendance at the time and never received Federal student aid funds while in high school.

C. Department of Housing and Urban Development

Indian Housing Block Grant Program Formula

The Native American Housing Assistance and Self-Determination Act of 1996 (NAHASDA) (25 U.S.C. 4101 *et seq.*) established a comprehensive program of housing assistance to Indian tribes and their tribally designated housing entities (TDHEs). NAHASDA eliminated several separate assistance programs for Indian tribes and replaced them with a single block grant program – the IHBG program. The regulations for the IHBG program are codified at 24 CFR part 1000.

Under the IHBG program, HUD makes assistance available to eligible Indian tribes for affordable housing activities. The amount of assistance made available to each Indian tribe is determined in accordance with the allocation formula that was developed using negotiated rulemaking procedures (IHBG Formula). A regulatory description of the IHBG Formula is located in subpart D of 24 CFR part 1000 (§§ 1000.301-1000.340). The April 20, 2007 final rule made several revisions to the regulations for the IHBG Formula. The final rule followed publication of a February 25, 2005 proposed rule, and took into consideration the 49 public comments received on the proposed rule.

The regulation impacts Indian tribal governments and their tribally designated housing entities (TDHES) eligible to receive funding under the IHBG program.

Section 1000.306 of the IHBG program regulations provides that the IHBG Formula shall be reviewed within 5 years after issuance. HUD established the IHBG Formula Negotiated Rulemaking Committee (Committee) for the purposes of reviewing the regulations at 24 CFR part 1000, subpart D, and negotiating recommendations for a possible proposed rule modifying the IHBG Formula. The Committee membership consisted of 24 elected officers of tribal governments (or authorized designees of those tribal governments). The Committee membership reflected a balanced representation of Indian tribes, both geographically and based on size. In

addition to the tribal members, there were two HUD representatives on the Committee. The first meeting of the Committee took place in April 2003, and the Committee continued to meet thereafter on approximately a monthly basis. The Committee met a total of seven times to negotiate the proposed rule, with the final meeting being held in January 2004. All of the Committee sessions were announced in the *Federal Register* and were open to the public, and interested members of the public actively participated in the workgroup sessions.

The February 25, 2005 proposed rule reflected the consensus decisions reached by the Committee during the negotiated rulemaking process on the best way to address certain areas of the IHBG Formula that the Committee determined required change. The public comment period on the proposed rule closed on April 26, 2005. HUD received 49 public comments from Indian tribes on the proposed rule. The Committee met on January 31 through February 1, 2006 to review and consider responses to the public comments. A drafting workgroup was charged with developing the preamble to this final rule. The membership of the workgroup consisted of HUD and tribal representatives. The two-day meeting, which was open to the public, was announced in the *Federal Register* through a notice published on January 13, 2006.

The Committee undertook a comprehensive review of the IHBG Formula and identified certain areas that required clarification, were outdated, or were not operating as intended by the original negotiated rulemaking committee. As noted above, the regulatory changes made by the final rule reflect the consensus decisions reached by the Committee during the negotiated rulemaking process on the best way to address these issues. These amendments are summarized below.

The Committee also considered a variety of proposals for suggested changes during the course of the negotiations for which consensus was not achieved. These issues included: (1) revising the definition of “median formula income” as used in the formula; (2) the definition of “substantial noncompliance” with program requirements that would trigger the possibility of HUD-imposed sanctions; (3) replacement of the “allowable expense level” used in the formula to adjust for geographic and other differences in the monthly operating costs incurred by Indian tribes; (4) the use of alternative data sources other than US Decennial Census data; and (5) the inclusion of multi-racial Census population data.

The final rule made several changes and updates to the IHBG Formula. These revisions included: (1) updating the definition of the term “formula area” used to determine the geographic area served by recipients; (2) the establishment of new procedures for dividing funding when formula areas overlap; (3) clarification of the procedures to be used when reporting changes to formula data; (4) revised minimum funding provisions for small Indian tribes; and (5) the establishment of new procedures for challenging data and the appeal of HUD formula determinations.

Self Insurance Plans Under the Indian Housing Block Grant (IHBG) Program

NAHASDA requires recipients of IHBG program assistance to maintain adequate insurance coverage for housing units that are owned and operated or assisted with grant amounts, in compliance with such requirements as may be established by the Secretary of HUD. Historically, commercial insurers have been unwilling to provide insurance for Indian housing at an affordable rate, so HUD encouraged the National American Indian Housing Council (NAIHC) to form a risk pool composed solely of Indian housing authorities to provide the legally required insurance coverage. While generally addressing the required insurance, the part 1000 regulations did not set specific standards under which IHBG-assisted housing units may be insured by nonprofit Indian housing risk pools. The proposed rule was intended to ensure that the statutory requirement of NAHASDA regarding the maintenance of adequate insurance is met in a cost-effective manner by regulating the provision of insurance for IHBG-assisted properties.

The May 29, 2007 final rule established standards for recipients under the IHBG program to purchase insurance through nonprofit insurance entities owned and controlled by Indian tribes and TDHEs. The standards established by the final rule include, for example, qualifications of key staff and financial reserves. In many cases, tribes cannot obtain commercial insurance for their assisted housing at an affordable cost, and so this rule provides an important option. The final rule followed the publication of a March 7, 2006 proposed rule, and took into account the six public comments received on the proposed rule.

State governments and Indian tribes are affected by this rule. States are potentially affected because the rule preempts State law in respect to tribal insurance entities organized under this rule and approved by HUD. Indian tribes are affected because the rule sets standards and requirements for tribes seeking to establish self-insurance entities. Attorneys general of each of the 50 states and each Indian tribe were consulted. In addition, these entities participated in the general public comment process for the rule.

HUD conducted its consultations in writing. HUD, by letter dated December 16, 2004, notified the attorneys general of each of the 50 states of its intention to promulgate regulations that would govern the insurance of tribal housing under the IHBG program and the potentially preemptive effect of the rule. On April 12, 2005, HUD sent letters to all eligible tribal funding recipients under the IHBG program and their TDHEs informing them of the nature of the forthcoming rule and soliciting comments.

The consultation with the states did not give rise to any concerns, but only requests for clarification. HUD did receive 5 comments from Indian tribes on the rule, involving potential improvements or technical concerns, and HUD addressed each of these comments in the final rule.

HUD made clarifying and technical changes in response to input received during the consultation process. Language was added clarifying that the rule applies to liability insurance as well as property insurance for the covered properties. The perceived lack of coverage of

liability insurance was the most frequently asserted comment by Indian tribes as a result of the consultation process and public comment process. In addition, terminology used to describe the areas to which the rule applies was modified in response to comments.

D. Department of Commerce

Establishment of Marine Reserves and a Marine Conservation Area Within the Channel Islands National Marine Sanctuary

This final rule, issued by the National Oceanic and Atmospheric Administration's (NOAA) National Marine Sanctuary Program in May 2007, established a network of marine zones within the Channel Islands National Marine Sanctuary (CINMS). Two types of zones were established, marine reserves and marine conservation areas. All extractive activities and injury to Sanctuary resources are prohibited in marine reserves. Commercial and recreational lobster fishing and recreational fishing for pelagic species are allowed within the marine conservation area, while all other extraction and injury are prohibited.

The rule has a small impact on existing consumptive users, such as commercial fishermen. It provides benefits to non-consumptive recreational users, such as an increase in diversity and abundance of wildlife for viewing and photography. NOAA consulted with local, State, and Federal agencies, as well as the Pacific Fishery Management Council (PFMC). In particular, NOAA worked closely with the California Department of Fish and Game (CDFG).

Development of the marine zones occurred in three distinct phases: (1) a community-based phase; (2) a State of California regulatory phase; and (3) a Federal regulatory phase. The CINMS Advisory Council, an advisory board of representatives from the community and Federal, State, and local government agency representatives, created a multi-stakeholder "Marine Reserves Working Group" or "MRWG." The MRWG met monthly from July 1999 – May 2001. It provided NOAA and the CDFG with two potential designs for the reserve system. Based on this comprehensive stakeholder process, options were developed by NOAA and the CDFG, and published in local papers and on the CINMS website. NOAA and CDFG held several meetings with constituent groups regarding these options, and then prepared a recommendation for a network of marine reserves. With support from NOAA, the State of California prepared the necessary regulatory documents and regulations to establish marine zones in state waters. The State adopted the regulations and the marine zones became effective in April 2003.

Following the publication of California's regulations, NOAA hosted scoping meetings with the public, CINMS Advisory Council, and PFMC. In 2005, NOAA specifically consulted with local, State, and Federal agencies and the PFMC. NOAA published a proposed rulemaking in late 2006, and then held two hearings on the proposal. The State of California submitted comments on the proposal during this time.

NOAA's original proposal would have established marine zones in both Federal and State waters in the CINMS. In October 2006, the State indicated an overlay of Federal regulations was "unnecessary and duplicative," and thus it could only support Federal regulations and implementation of marine reserves in Federal waters, rather than overlapping Federal regulation in State waters.

The alternative supported by the State did not overlay State waters with Federal regulations. This left several "gaps" in the network where there was no State or Federal regulation. The State did, however, declare its intent to close these gaps under State authorities, and NOAA deferred action on overlaying the state waters portion of the network to give the State an opportunity to close those gaps. The State took the necessary action in October 2007, and NOAA determined that Federal regulations in the state waters portion of the network was therefore unnecessary at that time.

E. Environmental Protection Agency

Consultation Mechanisms, General Outreach Activities and Communication Aids

EPA has several mechanisms to help State, local, and tribal officials learn about the agency's regulatory plans, and to let them know how they can engage in the rule-development process. For example, EPA distributes reprints of the semi-annual Regulatory Agenda to more than 300 State, local, and tribal government organizations and leaders. It also participates in a Federal Government-wide, State and local governments web site. In addition, EPA supports hotlines in both EPA Headquarters and the Regions where callers can get information on several topics, including regulatory and compliance information (further discussion of these communication aids below).

In 1993, EPA chartered a cross-media advisory body under Federal Advisory Committee Act (FACA), the Local Government Advisory Committee (LGAC). Supported by resources from the Office of Congressional and Intergovernmental Relations, the LGAC is composed primarily of elected and appointed local government officials from communities across the nation. Committee members provide advice and recommendations that assist the EPA in developing a stronger partnership with local governments – a partnership that ultimately yields improved State and local government capacity to provide environmental programs and services. Likewise, the Small Community Advisory Subcommittee (SCAS), a subcommittee of the LGAC, routinely addresses issues and concerns facing smaller US communities, and develops recommendations for the LGAC on regulations, policies, and guidance affecting the environmental services they depend on.

The LGAC meets approximately three times per year, and provides the Agency with recommendations and advice on:

- Changes needed to allow flexibility and innovation to accommodate local needs without

compromising environmental performance, accountability or fairness;

- Ways to improve performance measurement and speed dissemination of new environmental protection techniques and technologies among local governments;
- Improvements to program management and regulatory planning and development processes by involving local governments more effectively as partners in environmental management; and
- Projects to help local governments deal with the challenge of financing environmental protection infrastructure.

The Tribal Operations Committee similarly addresses tribal interests. The program offices regularly work with groups of State, local, and tribal officials to address specific environmental and programmatic issues. Examples include media-specific FACA committees, regulatory negotiation advisory committees, and policy groups.

EPA and States share responsibility for implementing national environmental programs and success in meeting the nation's environmental goals depends on effective EPA-State partnerships. Since 1995, EPA has been working with States to build the National Environmental Performance Partnership System (NEPPS), a collaborative, results-oriented system for environmental management that has become the predominant way in which EPA and States work together to deliver environmental programs. Under NEPPS, EPA and States set priorities and design and implement strategies for achieving environmental and public health goals together. The joint Partnership and Performance Work Group, comprised of EPA leaders and high-level State officials drawn from the membership of the Environmental Council of the States (ECOS), leads the effort to build performance partnerships and provides an ongoing forum for raising and resolving policy and implementation issues and improve joint planning. EPA also consults with ECOS, the only national organization representing the State environmental commissioners, on the full range of program and policy matters affecting States.

The Agency continues to work with States under the National Environmental Performance Partnership System (NEPPS), principally through the Environmental Council of the States (ECOS) whose objective is to increase States' participation in agency activities, particularly those affecting State-implemented programs. Committees consisting of both State and EPA members perform most of this work through forums that are open to other stakeholders. EPA and the ECOS have an active joint workgroup to address continuing implementation issues and to identify and remove remaining barriers to effective implementation of NEPPS. ECOS has also launched several other consultation projects with EPA, including work on children's health issues, a partnership to build locally and nationally accessible environmental systems, and development of core performance measures.

Office of Prevention, Pesticides and Toxic Substances (OPPTS) Continues its General Outreach Activities

OPPTS did not publish any final rules in 2007 with "Federal mandates" that may result in expenditures to State, local, and tribal governments, in the aggregate, or to the private sector, of \$100 million or more in any one year. OPPTS has, however, several continuing outreach mechanisms related to its mission that allow OPPTS to routinely secure State and tribal insights and advice on issues related to the implementation of OPPTS' role in protecting public health and the environment from potential risk from toxic chemicals. These institutionalized processes are therefore, to some extent, independent of specific rulemaking activities. Nevertheless, they provide an open forum for State, local, and tribal governments to raise concerns about existing or pending OPPTS regulatory activities, which often leads to a meaningful dialogue on new Federal policies or changes to existing Federal policies. A few of these OPPTS outreach mechanisms are discussed below.

The Office of Pesticide Programs (OPP) in OPPTS uses the State Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) Issues Research and Evaluation Group (SFIREG), originally established in 1974 by cooperative agreement between EPA and the American Association of Pesticide Control Officials (AAPCO), the association that represents State-level pesticide regulatory officials. SFIREG identifies, analyzes, and provides State comment on pesticide regulatory issues, and provides a mechanism for ongoing exchange of information about EPA and State pesticide programs. With a full committee and two subcommittees, there are eight regularly-scheduled meetings each year that offer State officials the opportunity to meet with EPA to discuss pesticide issues, including regulations in progress. One example of results from consulting with SFIREG is the development of implementation guidance for the Container/Containment Rule promulgated under section 19(f) of FIFRA. The container/-containment rule establishes standards for pesticide containers and bulk containment structures.

Over the past several years, OPP consulted and received significant input from the Pesticide Program Dialogue Committee (PPDC). The PPDC provides a forum for a diverse group of stakeholders to provide feedback to the pesticide program on various pesticide regulatory, policy, and program implementation issues. Membership to the PPDC includes environmental and public interest groups, pesticide manufacturers and trade associations, user and commodity groups, public health and academic institutions, Federal and State agencies, and the general public. Topics of discussion at past meetings have included the following: inerts disclosure, registration review, spray drift, non-animal testing, antimicrobial pesticides, endangered species, reduced risk pesticides, labeling, minor uses, ecological standards, fees for service, experimental use permits, environmental marketing claims, outreach to the public, and several implementation issues emanating from the Food Quality Protection Act of 1996. This PPDC has provided a forum for meaningful dialogue and collaboration on addressing new Federal policies or changes to existing Federal policies. For example, the Spray Drift Workgroup (SDWG) was established under the auspices of the PPDC to seek stakeholder input on how to mitigate risks to water from pesticide spray drift. The SDWG met multiple times to discuss this topic and develop recommendations for EPA. In October 2007, EPA discussed its

plan for addressing these recommendations with the PPDC and is in the process of implementing the resulting changes, which will be discussed in a future report when completed.

OPPTS' Office of Pollution Prevention and Toxics (OPPT) created the Forum on State Tribal Toxics Action (FOSTTA) in the early 1990s as a vehicle to encourage State and tribal involvement in OPPT decision making. OPPT has procured the services of ECOS and NTEC to ensure appropriate and adequate State and tribal representation at the FOSTTA meetings. OPPT has also established a tribal program to better communicate EPA's programs and activities with Native American Indian Tribes, to build more effective partnerships with tribes to safeguard and protect the environment from toxic hazards, and to promote pollution prevention in Indian country. Some major activities of the tribal program include grants funding, internal training on tribal issues, follow-up activities from EPA Tribal Operations Committee meetings, interagency coordination efforts, and stakeholder outreach. OPPT is committed to working in partnership with tribal governments via appropriate and effective consultation.

OPP's Tribal Pesticide Program Council (TPPC) is a tribal technical resource, and program and policy dialogue and development group, focused on pesticide issues and concerns. The Council meets twice a year and provides a vehicle through which tribes can voice opinions on national pesticide policies and raise tribal pesticide issues to Federal attention. The TPPC is a strong partner with the EPA to ensure that tribes will continue to provide a major impetus for the long-term strategic direction taken by the OPPTS Tribal Program as it strives to build tribal capacity and produce an agency pesticide strategy that is responsive to tribal needs and concerns. In addition, the TPPC serves as a technical resource pool for tribes in Indian country. The TPPC is composed of authorized representatives from Federally-recognized tribes, Indian nations, and intertribal organizations. Authorization must be in writing by a letter from either the Tribal Chairperson or a letter or resolution from the Tribal Council or similar governing body. At this time there are 42 authorized representatives, including some authorized alternates. Thirty-two tribes or Indian nations have authorized representatives.

Office of Policy, Economics and Innovation (OPEI) Outreach Activities

EPA's National Center for Environmental Innovation (NCEI) and the Office of Cross-Media Programs (OCMP) in OPEI routinely provide support to States to promote regulatory efficiency and improved environmental results. Through grants, direct staff assistance, partnership and leadership programs, and other forms of support, a number of NCEI and OCMP programs engage States in creating a more performance-based environmental regulatory system.

The national Performance Track program recognizes and rewards facilities that demonstrate strong environmental performance which exceed current requirements. Currently, the program has over 500 members. Over 20 States have active performance-based environmental programs similar to Performance Track. The Performance Track program works closely with State counterparts. In FY 2007, NCEI continued to consult with States to address regulatory issues that can hinder smart growth at the local level, and continued work through industry-specific partnerships to improve environmental performance in specific industry sectors.

The Sector Strategies Program works on policies and projects to help major economic sectors improve their environmental performance and energy efficiency. Participating sectors in the program include major US industries such as steel manufacturing, construction, and oil & gas production. The 12 sectors in the program have 875,000 facilities throughout the United States and contribute \$3.2 trillion to the gross domestic product. The program works with individual State agencies and multi-state organizations on important issues that affect sector performance at the state-level. Examples include policies that affect attainment of regional air quality standards, resources that prompt the beneficial reuse of industrial byproducts, and partnerships to promote voluntary stewardship actions at seaports and shipyards.

During FY 2007, NCEI provided grant resources to State regulatory agencies to implement innovative strategies and approaches. NCEI continued to expand its State Innovation Grants Program, selecting seven projects for funding from the 2007 competition. These projects reflected NCEI's strategic investment in assisting States to implement innovation in environmental programs, specifically:

- the expansion (3 new projects/sectors) of the Environmental Results Program model (a compliance-assistance, performance self-certification and statistically-based auditing approach) for small business sectors;
- the implementation of the National Performance Track Program and parallel performance-based programs by States (3 states/projects); and
- further testing of Environmental Management Systems (EMS) in permitting (one state/project) to help businesses adopt continuous process improvement strategies for environmental performance.

NCEI selected these projects in a competition that was designed to respond to continued strong state interest in the program. NCEI also continued its collaborative work with States on a number of projects under the *Joint EPA/State Agreement to Pursue Regulatory Innovation*.

Likewise, NCEI provided information and assistance to States interested in the Environmental Results Program (ERP). ERP is an alternative regulatory approach to improve environmental performance and facility management in specific industry sectors, particularly those made up of small businesses. ERP integrates compliance assistance, self-certification, compliance assurance and enforcement, statistically-based inspections, and measurement to assess the environmental performance of facilities and overall sectors. In FY 2007, eighteen States pursued ERP in eleven sectors, overall. NCEI worked with interested States to adopt ERP or its components in the following ways: as a mandatory program requiring self-certification of all facilities in a sector; voluntarily, by encouraging facilities to participate in order to obtain the benefits of compliance assistance and the certainty of knowing their compliance status; or, in some cases, using ERP as an alternative to formal permitting for large numbers of small facilities. NCEI also assisted in forming a consortium of States implementing ERP programs, allowing the States to provide greater leadership and direction.

Reaching out to Local and Small Governments

EPA has developed a variety of materials intended to help small governments more easily understand the Agency's regulations. These materials include the Profile of Local Government Operations, the Local Government Environmental Assistance Network, the Small Government Agency Plan, a Newsletter/Internet site for Small Governments, a Guide to Federal Environmental Requirements for Small Governments, and a Regional Guide to Federal Environmental Requirements for Small Governments. Included below is a description of each tool:

- The Profile of Local Government Operations details all the environmental requirements with which a local government must comply, and organizes the information based on operations, i.e., motor vehicle servicing, property management, etc. This makes it easier for the representative of a local government responsible for an operation to find out about all the environmental requirements that might impact his or her operation, and where to find more detailed compliance information.
- EPA helps support the Local Government Environmental Assistance Network (LGEAN). This Internet-based information service (that has parallel toll-free voice and fax-back options) provides a first-stop for local government officials with questions about environmental compliance. The site contains information from EPA and eight participating nongovernmental organizations. Users can ask questions of experts, consult with their peers, review and comment on developing regulations, and find the full text or summaries of State and Federal environmental statutes. LGEAN alerts users to hot topics and new developments in environmental compliance, tells them where to find technical and financial support, and provides them with a grant writing tutorial.
- The Agency's interim Small Government Agency Plan supplements the intergovernmental consultations described above. The plan outlines the analysis rule writers complete to determine whether the regulatory requirements of a rule might uniquely affect small governments. Under the plan, EPA encourages attention to such factors as whether small governments will experience higher per-capita costs because of economies of scale. The plan also considers whether they would need to hire professional staff or consultants for implementation, or be required to purchase and operate expensive or sophisticated equipment. EPA publishes the findings under the Small Government Agency Plan in the *Federal Register* with proposed and final rules. When there are unique or significant impacts on small governments, EPA takes action to inform and assist them.
- Under a cooperative agreement funded by EPA, the International City/County Management Association (ICMA) publishes a newsletter designed for small governments covering regulatory and other environmental programs of interest to them. ICMA's *Environmental SCAN* is also published electronically on the Internet. Access is free to anyone interested in local government issues. The ICMA site links electronically to EPA's *Federal Register* site so readers interested in a regulation covered in the newsletter

can immediately gain access to the actual text. As part of the project, ICMA has also conducted several workshops for small government officials on regulatory and other environmental management topics.

- EPA publishes and distributes the *Guide to Federal Environmental Requirements for Small Governments*, a reference handbook to help local officials become familiar with Federal environmental requirements that may apply to their jurisdictions. The guide explains Federal regulations in a simple, straightforward manner. Mandated programs described in the guide include those for which small communities have major responsibilities, such as landfills, public power plants, and sewage and water systems.
- EPA Region VIII publishes and distributes a *Regional Guide to Federal Environmental Requirements for Small Governments*, a small community reference handbook to help local officials in Colorado, Montana, North and South Dakota, Utah and Wyoming become familiar with Federal environmental requirements that may apply to their jurisdictions. The guide includes up-to-date contact lists for State environmental programs.

Consultations that Changed EPA Policies

During the time period covered by this report, EPA did not publish any rules having a \$100 million or more annual impact on State, local, or tribal governments. However, it is the Agency's policy to conduct outreach and seek accommodations, proportionate to the anticipated burden, to minimize adverse impacts on States, tribes or local governments, in any rulemaking to which they are directly subject. The following are examples of when consultations resulted in substantive changes to rules:

Office of Solid Waste and Emergency Response (OSWER)

1. Rule-Related Consultations

a. Revisions to the Definition of Solid Waste

On March 26, 2007, EPA proposed revisions to the definition of solid waste under the Resource Conservation and Recovery Act (RCRA) hazardous waste regulations. The proposed revisions would streamline regulation of hazardous secondary materials to encourage the beneficial reclamation of these materials, as well as help conserve resources. By removing unnecessary controls, recycling of these materials will not only be safe, but less-costly and more efficient. The proposed rule would exclude the following materials from the Federal hazardous waste management requirements:

- Materials that are generated and reclaimed under the control of the generator (i.e., generated and reclaimed on-site, by the same company, or under “tolling” agreements);

- Materials that are generated and transferred to another company for reclamation provided certain conditions are met; and
- Materials that EPA determines to be non-wastes through a case-by-case petition process.

The proposal would also define legitimate recycling activities. Defining legitimate recycling ensures that only authentic recycling, and not treatment or disposal under the guise of recycling, receives the benefits of streamlined regulations.

These exclusions are not available for hazardous secondary materials that are: (1) considered inherently waste-like; (2) used in a manner constituting disposal or used to produce products that are applied to the land; or (3) burned for energy recovery or used to produce products that are burned as a fuel. Any hazardous secondary materials managed in these ways must still comply with the applicable Federal hazardous waste regulations.

After evaluating all public comments on the proposal, the Agency has prepared a draft final rule which is currently undergoing review by the Office of Management and Budget (OMB).

The proposed changes to the definition of solid waste would affect approximately 5,600 facilities handling about 1.5 million tons of hazardous secondary materials annually. The activities most affected are metals and solvent recycling. The Agency has estimated that this action would result in cost savings of about \$95 million from increased recycling activities over all affected industry sectors.

The proposal has been shaped by the States' involvement through public comments on the proposal, submitted by individual states and by the Association of State and Territorial Solid Waste Management Officials (ASTSWMO). In addition, Office of Solid Waste (OSW) staff and management have met with State representatives at ASTSWMO's national meetings and in other settings, and have also consulted with ASTSWMO's Hazardous Waste Recycling Task Force. States have also provided occasional input through weekly conference calls regarding definition of solid waste issues.

The issues raised by individual States and by ASTSWMO include:

- Exclusion for hazardous secondary materials reclaimed under the control of the generator: States generally supported this proposed exclusion, although some States wanted additional conditions regarding notification, recordkeeping and reporting, and storage. Some States were opposed to allowing an exclusion for land-based storage units.
- Exclusion for hazardous secondary materials that are transferred for the purpose of reclamation: some States wanted additional conditions regarding notification, recordkeeping and reporting, and management standards.
- Many States supported codifying the legitimacy criteria, however, some States supported making all the criteria mandatory.

- Some States were concerned about the non-waste petition process and the resource implications of reviewing these petitions.

EPA's interaction with the States and ASTSWMO has provided EPA a much more complete understanding of the issues that States will face in implementing this new rule and have thus allowed EPA to better address these issues in the draft final rule. It is critical that the issues that the States have raised be appropriately addressed because, in order for this rule to have its intended effect of encouraging legitimate and environmentally sound recycling, States authorized to implement the RCRA hazardous waste program must adopt the rule and make it effective in their jurisdictions. EPA believes that by understanding and addressing these implementation issues, EPA will be making it more likely that States will adopt the rule in a timely fashion.

b. 40 CFR Part 35 (subpart O), "Cooperative Agreements and Superfund State Contracts for Superfund Response Actions: Final Rule"

This final rule amends the regulation for Superfund Cooperative Agreements and Superfund State Contracts. The revisions to the regulation are as follows: (i) incorporate EPA policy changes since 1990 that impact this regulation; (ii) reduce the burden placed by this regulation on Cooperative Agreement recipients and parties to Superfund State Contracts; (iii) increase reliance on the federal Government's uniform administrative requirements for grants and Cooperative Agreements to State and local governments; (iv) authorize procedures that required deviations under the existing regulation; (v) expressly authorize previous program initiatives that were proven successful on a pilot basis; (vi) provide additional regulatory flexibility without negatively impacting cost recovery actions; (vii) update cross-references to other regulations that have changed or been removed; and (viii) eliminate references to obsolete forms. These revisions will improve the administration and effectiveness of Superfund Cooperative Agreements and Superfund State Contracts.

The revisions primarily affect States, Indian tribes, and intertribal consortia.

EPA consulted with representatives of State governments in developing this rule. Specifically, State representatives have been participating members of the workgroup in revising this rule throughout the entire process, and were given the opportunity to review and comment on drafts of this rule. Representatives from two States (Kansas and Illinois) who had expertise in this area participated in the workgroup meetings and the development of the rule. Also, the draft rule was provided to the Association of State and Territorial Solid Waste Management Officials.

EPA consulted with tribal officials early in the process of developing this regulation to permit them to have meaningful and timely input into its development. During the early deliberations on the revisions to this rule, a tribal representative was actively involved in the regulatory workgroup, and helped identify issues of likely concern to tribal governments. EPA, in turn, discussed those issues with tribal representatives participating in a concurrent initiative to enhance the State and tribal roles in Superfund. The rule also was informed to a large extent by the experiences of tribes and EPA during 16 years of experience working under the old

regulation. Ultimately, the EPA regulatory workgroup used the knowledge gained from consultation and experience to identify and incorporate beneficial changes for tribes into the regulation. The key concerns were as follows:

- Reduce burden placed upon cooperative agreement recipients;
- Expand scope of Core cooperative agreement funding; and
- Increase ability of Indian tribes to access cooperative agreement.

To address the above concerns, EPA revised the rule as follows:

- Permitted the combining of certain activities into one cooperative agreement, instead of having multiple cooperative agreements for each state;
- Eliminated the cost share requirement for support agency agreements;
- Linked the force accounts, small purchases, and cost dollar amounts to the simplified acquisition threshold;
- Reduced current progress report requirements that mandated quarterly reports;
- Permitted Core program dollars to be used to maintain program elements;
- Eliminated the requirement for demonstrating jurisdiction for all Tribal Core program and most tribal support agency agreements; and
- Permitted intertribal consortium to enter in a cooperative agreement with EPA.

2. Non-Rule Related Consultation Activities

a. Office of Solid Waste ASTSWMO General Outreach Activities Assistance Project.

The Office of Solid Waste (OSW) works with Association of State and Territorial Solid Waste Management Officials (ASTSWMO) to reduce the generation of waste and sustain the use of all natural resources by continuing to work together as co-implementers and the public in support of Goal 3: Land Preservation and Restoration.

ASTSWMO is a non-profit organization whose primary function is to enhance the State/Federal partnership in waste management, and provide technical assistance and forums for information exchange to assist States in developing their program capabilities in order to manage solid waste in the most efficient and effective manner possible.

The purpose of the grant to ASTSWMO is to assist the promotion of information exchange among State hazardous and solid waste officials and EPA officials to jointly resolve implementation issues and identify emerging issues that both entities face. OSW works with ASTSWMO members to reduce the generation of waste and sustain the use of all natural resources by continuing to work together as co-implementers and the public in support of Goal 3: Land Preservation and Restoration.

OSW has an on-going dialogue with ASTSWMO, including the several major subcommittees targeted to specific materials and waste management issues:

ASTSWMO Subcommittees

Hazardous Waste Subcommittee

- Enforcement and Compliance Assurance Task Force (funded by OECA)
- Performance Systems Task Force
- Corrective Action and Permitting Task Force
- Hazardous Waste Recycling Task Force
- Hazardous Waste Training Task Force
- Program Information Management (PIM) Task Force
- Hazardous Waste Program Operation Task Force

Program & Information Exchange Subcommittee

Sustainability Subcommittee

- Product Stewardship Task Force
- Green Chemistry Task Force
- Greener Cleanups Task Force
- Walk the Talk – Greening State Government Task Force

Solid Waste Subcommittee

- Municipal D Task Force
- Training and Technology Transfer Task Force
- Special Waste Task Force
- Beneficial Use Task Force

b. Tribal Solid Waste Interagency Steering Committee (TSWISC).

The mission of the Tribal Solid Waste Interagency Steering Committee (TSWISC) is to advise and support all member Federal agencies on major policy and implementation issues affecting Federal Agency Partner programs and activities in order to enhance protection of the environment and human health in Indian country. The TSWISC is comprised of the following federal organizations: the Office of Solid Waste (OSW), Bureau of Indian Affairs (BIA), Housing and Urban Development (HUD), Rural Development (RD), Department of Defense (DOD), and Indian Health Service (IHS).

The role of the Steering Committee is to ensure early and effective involvement of the federal agencies' senior management in the resolution of agency-wide Indian program policy issues. One of the issues that the Steering Committee is addressing in Indian Country is the Open Dump problem.

One of the projects that the TSWISC is overseeing is the Interagency Tribal Waste Management Assistance Project (Assistance Project). The TSWISC provides direction to the associated staff level Tribal Solid Waste Interagency Workgroup, which implements the Assistance Project. The Assistance Project is a multi-agency effort to help tribes throughout Indian Country close and prevent open dumps, clean up solid waste on tribal land, and develop safe solid waste management practices. In 1994, the US Congress found that most tribal governments and Alaskan Native entities lacked the financial and technical resources necessary to close these dumps and to develop comprehensive solid waste management plans. To address these needs, EPA signed a Memorandum of Understanding (MOU) in 2000 with several

Agencies, including IHS, BIA, DOD, HUD, and the Rural Utilities Service (RUS) to develop a coordinated open dump cleanup program.

Since 1999, over 163 projects have been awarded a total of 22 million dollars in funding and assistance to clean up and prevent open dumps. The Assistance Project funds activities that will result in cleaning up, upgrading, or closing open dumps, developing integrated solid waste management plans, designing regulations to enforce sound solid waste practices, and conducting training for community members to assist them in preventing illegal dumping. EPA's Office of Solid Waste and Emergency Response, Office of Solid Waste (OSW), Permits and State Programs Division (PSPD) coordinates the Interagency Workgroup's efforts on behalf of EPA, in collaboration with its EPA Regional Partners and other Federal agencies. The Interagency Workgroup is one of several venues in which open dumps are addressed; each of the Interagency Workgroup's member agencies provides funds to tribes under separate authorizing legislation.

c. ECOS Quicksilver Caucus.

The Office of Solid Waste (OSW) has been collaborating with the Quicksilver Caucus (QSC) on use of mercury in lamps, thermostats, switches and relays, dental amalgam, and thermometers.

The QSC was formed in May 2001 by a coalition of State environmental association leaders to collaboratively develop holistic approaches for reducing mercury in the environment. Caucus members, who share mercury-related technical and policy information, include the Environmental Council of the States (ECOS), the Association of State and Territorial Solid Waste Management Officials (ASTSWMO), the National Association of Clean Air Agencies (NACAA), the Association of State and Interstate Water Pollution Control Administrators (ASIWPCA), the Association of State Drinking Water Administrators (ASDWA), and the National Pollution Prevention Roundtable (NPPR).

OSW has coordinated with QSC over the past year through quarterly calls and follow-up calls/meetings regarding specific agency efforts. The purpose of these calls and meetings is to ensure that the QSC is up-to-date on OSW efforts related to mercury use and release.

As part of the overall working relationship with the ECOS Quicksilver Caucus, EPA and some of the New England states formed an informal working group to address issues that were being raised in the press regarding the risks of the mercury contained in compact fluorescent lamps. In particular, EPA worked with the Maine Department of Environmental Protection in the design and review of their lamp breakage study. The study was in response to recent press regarding the potential hazards of mercury from broken lamps. EPA provided input into development of the Maine lamp breakage study design and provided comments on the initial draft of the Maine results. Because the Maine study raised important technical issues, EPA has been in consultation with the New England states in developing details of a follow-up study commissioned by EPA to corroborate and expand on the Maine study.

With respect to work relating to lamps, OSW has been working with lamp manufacturers and major US retailers to develop, implement or expand recycling options. These efforts have been in coordination with State-level efforts, as many State and local agencies have developed collection/exchange programs for mercury-containing devices, such as thermometers, manometers, and thermostats, and recycling programs for fluorescent lamps. Some counties and cities also have household hazardous waste collection programs. In addition, OSW coordinated with the States and QSC in development of a study of drum top crushers, and the States and QSC have been consulted as OSW develops best management practices for their use as a means to enhance the recycling rate of spent fluorescent tubes.

Collaborative work on mercury-containing thermostats has included the development of a draft joint EPA/QSC letter to Honeywell, requesting continued participation in State- and National-level efforts to expand thermostat recycling. Work in this area is pending passage of legislation in several States to restrict land placement of old mercury-containing thermostats.

Finally, EPA conducted a year-long stakeholder process to better understand the international flow of elemental mercury. EPA was (and continues to be) in consultation with the QSC on issues related to long-term storage/retirement of surplus elemental mercury.

d. National Vehicle Mercury Switch Recovery Program (NVMSRP).

Mercury is one of the 31 priority chemicals that the Office of Solid Waste (OSW) is working to reduce in the environment. The National Vehicle Mercury Switch Recovery Program (NVMSRP) provides automotive dismantlers with information, materials, support, and incentives to remove mercury-containing switches from end-of-life vehicles before they are dismantled, crushed, shredded, and sent to furnaces that recycle the steel.

EPA has partnered with the States and collaborated with automobile manufactures, steel makers, scrap recyclers, automotive recyclers, and environmental groups to form the NVMSRP.

The Environmental Council of the States (ECOS) has been instrumental in the success of the NVMSRP. Early on in the development of the program, they passed a resolution in support of the program. In the very early days of program implementation, ECOS and State representatives worked with other partners to draft a model letter that States used to send to their dismantlers encouraging initial program participation. ECOS also fostered effective State participation in stakeholder roll-out meetings that occurred in each State.

Currently ECOS and the States are engaging in outreach in certain States to increase switch recovery and in data analyses to determine the commonalities of successful State programs that could be incorporated into the NVMSRP. The program partners are all increasing outreach to automobile and scrap recyclers in order to expand the program's reach and increase the number of switches that are captured.

The NVMSRP has enlisted nearly 6600 auto dismantlers and collected about 1.3 million switches, which add up to about 2800 lbs of mercury.

In FY 2007, EPA issued grant guidelines and reports as required by the underground storage tank (UST) provisions in the Energy Policy Act of 2005. These included:

- Secondary containment (11/06)
- Financial responsibility (1/07)
- Public record (1/07)
- Inspections (1/07)
- State compliance report for government-owned tanks (4/07)
- Operator training (8/07)
- Indian country report to Congress on underground storage tanks (8/07)

EPA developed the grant guidelines to help States reduce underground storage tank releases to the environment and implement the underground storage tank provisions in the Energy Policy Act. EPA developed the Indian country report to Congress, as directed in the Energy Policy Act.

EPA consulted with many affected UST stakeholders, such as States, tribes, environmental organizations, industry, and owner/operator organizations. EPA also set up workgroups comprised of State and tribal governments, and EPA headquarters and regional representatives. Workgroup members provided input to develop the guidelines and report, reviewed drafts, and submitted suggestions on ways to resolve issues. Workgroup sessions included a combination of in-person meetings (in those instances when many members were at a mutual location) and telephone conferences.

Public and intergovernmental partners raised the following issues:

- Limit the scope of the guidelines to what was required by statute;
- Provide States with flexibility to implement the guidelines; and
- Provide certainty to the regulated community.

EPA's consultation with stakeholders provided flexibility to States in how they could structure their underground storage tank regulatory programs, yet still meet the prevention requirements in the Energy Policy Act.