

**2007 Report to Congress
on the Benefits and Costs of
Federal Regulations
and Unfunded Mandates on
State, Local, and Tribal Entities**



2007

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

**2007 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 tenth 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, 1996 to September 30, 2006 range from \$99 billion to \$484 billion, while the estimated annual costs range from \$40 billion to \$46 billion. These totals are somewhat higher than those reported last year. The difference is largely due to the addition this year of the Environmental Protection Agency’s (EPA) Review of the National Ambient Air Quality Standards (NAAQS) for Particulate Matter (PM).
- During the past year, seven “major” final rules were adopted that had quantified and monetized benefits and costs. These rules added \$6.3 billion to \$44.8 billion in annual benefits compared to \$3.7 billion to \$4.3 billion in annual costs. One rule, EPA’s NAAQS for PM, accounts for 60 to 89 percent of these estimated benefits and for 62 to 64 percent of the corresponding costs.
- There were an additional three major final rules that were adopted last year that did not have quantified and monetized estimates of both benefits and costs. One of these three rules implemented an air cargo security program where the benefits of improved security are very difficult to quantify and monetize. The other two implemented migratory bird hunting regulations and estimated only the net benefits of bird hunting activities.

In addition, we report the latest results of our ongoing historical examination of the trends in Federal regulatory activity by noting the estimated benefits and costs of earlier rules and other analyses as appropriate back to 1992 and additional cost data for major rules dating back to 1981. As explained in Chapter II of this Report, the data reveal that:

- The average yearly cost of the major regulations issued between 2001 and 2006 is about 47 percent less than over the previous 20 years.
- Over the last 26 years, the major regulations reviewed by OMB have added at least \$126.9 billion to the overall yearly costs of regulations on the public.
- The benefits of major regulations issued from 1992 to 2006 exceed the costs by more than three fold.

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

Chapter III provides an update on agency implementation of the Information Quality Act (IQA) (Section 515 of the Treasury and General Government Appropriations Act, 2001 (Pub. L. No. 106-554, 31 U.S.C. § 3516 note)). The chapter summarizes the current status of correction requests that were received by agencies in FY 2006, and includes an update on the status of requests received in FY 2003, FY 2004, and FY 2005. The chapter also summarizes agency annual reports for the Information Quality Bulletin for Peer Review. This is the first year for which reports on the implementation of the Bulletin were required.

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

PART I: 2007 REPORT TO CONGRESS
ON THE BENEFITS AND COSTS OF FEDERAL REGULATIONS

INTRODUCTION

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

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

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

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

(C) recommendations for reform.

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

- Rules designated as “major” under 5 U.S.C. § 804(2);¹
- Rules designated as meeting the analysis threshold under 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 2006 and summarizes the benefits and costs of major regulations issued between September 1996 and 2006. 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 IQA, and Chapter IV summarizes agency compliance with UMRA.

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

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

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

CHAPTER I: THE BENEFITS AND COSTS OF FEDERAL REGULATIONS

This chapter consists of two parts: the accounting statement, and a brief report on regulatory impacts on State, local, and tribal governments, small business, wages, and economic growth. Part A revises the benefit-cost estimates in last year's Report by updating the estimates to the end of fiscal year 2006 (September 30, 2006). Like the 2006 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, 1996 to September 30, 2006.⁴ This means that 12 rules reviewed from October 1, 1995 to September 30, 1996 (fiscal year 1996) were included in the totals for the 2006 Report but are not included in the 2007 Report. A list of these FY 1996 rules can be found in Appendix B (see Table B-1). The dropping of the FY 1996 rules from the ten-year window is accompanied by the adding of seven FY 2006 rules.

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

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 91 regulations reviewed by OMB over the ten-year period from October 1, 1996 to September 30, 2006 that met two conditions:⁷ (1) each rule generated costs or benefits of at least \$100 million in any one year, and (2) a substantial portion of its benefits and costs were quantified and monetized by the agency or, in some cases, monetized by OMB. The estimates are therefore not a complete accounting of all the benefits and costs of all regulations issued by the Federal Government

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

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

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

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

during this period.⁸ As discussed in previous Reports, OMB has chosen a ten-year period for aggregation because pre-regulation estimates prepared for rules adopted more than ten years ago are of questionable relevance today. The estimates of the benefits and costs of Federal regulations over the period October 1, 1996 to September 30, 2006 are based on agency analyses subject 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 2006 Report. The increase in benefits is due primarily to the addition of an Environmental Protection Agency (EPA) rulemaking: the Review of the National Ambient Air Quality Standards (NAAQS) for Particulate Matter (PM). This rule will yield estimated average yearly benefits of \$4 billion to \$40 billion. The increase in costs is also due primarily to this PM rule, with estimated costs of about \$2.5 - \$2.8 billion per year. 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 benefits and costs generated by Federal regulation.

Table 1-1: Estimates of the Total Annual Benefits and Costs of Major Federal Rules, October 1, 1996 to September 30, 2006 (millions of 2001 dollars)

| Agency | Number of Rules | Benefits | Costs |
|---|-----------------|-----------------------|----------------------|
| Department of Agriculture | 6 | 3,454-3,692 | 2,106-2,215 |
| Department of Education | 1 | 633-786 | 349-589 |
| Department of Energy | 6 | 5,194-5,260 | 2,958 |
| Department of Health and Human Services | 17 | 20,746-32,946 | 3,781-4,071 |
| Department of Housing and Urban Development | 1 | 190 | 150 |
| Department of Justice | 1 | 275 | 108-118 |
| Department of Labor | 5 | 1,173-4,302 | 611-620 |
| Department of Transportation | 15 | 3,913-6,147 | 3,879-7,377 |
| Environmental Protection Agency | 39 | 62,917-430,004 | 25,235-28,055 |
| Total | 91 | 98,492-483,603 | 39,176-46,152 |

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

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

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, 1996-September 30, 2006 (millions of 2001 dollars)

| Agency | Number of Rules | Benefits | Costs |
|--|------------------------|-----------------|---------------|
| Department of Energy | | | |
| Energy Efficiency and Renewable Energy | 6 | 5,194-5,260 | 2,958 |
| Department of Health and Human Services | | | |
| Food and Drug Administration | 10 | 2,671-13,966 | 860-959 |
| Center for Medicare and Medicaid Services | 5 | 16,831-17,300 | 2,626-2,818 |
| Department of Labor | | | |
| Occupational Safety and Health Administration | 5 | 1,173-4,302 | 611-620 |
| Department of Transportation | | | |
| National Highway Traffic Safety Administration | 9 | 2,916-5,139 | 2,789-6,287 |
| Environmental Protection Agency | | | |
| Office of Air | 27 | 58,970-410,763 | 19,244-21,696 |
| Office of Water | 10 | 2,022-11,539 | 3,277-3,644 |

Based on the information contained in this and the previous nine Reports, the total benefits and costs of all Federal rules now in effect (major and non-major, including those adopted more than ten years ago) may be significantly larger than the sum of the benefits and costs reported in Table 1-1. More research is necessary to provide a stronger analytic foundation for comprehensive estimates of total benefits and costs by agency and program.

In order for comparisons or aggregation to be meaningful, benefit and cost estimates should correctly account for all substantial effects of regulatory actions, not all of which may be reflected in the available data. Any comparison or aggregation across rules should also consider a number of factors that our presentation does not address. To the extent that agencies have adopted different methodologies—for example, different monetized values for effects, different baselines in terms of the regulations and controls already in place, different rates of time preference, different treatments of uncertainty—these differences remain embedded in Tables 1-1 and 1-2. While we have relied in many instances on agency practices in monetizing benefits and costs, our citation of, or reliance on, agency data in this Report should not be taken as an OMB endorsement of all the varied methodologies used to derive benefit and cost estimates.

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

in this Report in Table A-1 of Appendix A. Table A-1 also provides links to agency analyses that are available electronically.

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

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

- Inhalation of fine particles is causally associated with a risk of premature death at concentrations near those experienced by most Americans on a daily basis. While no definitive studies have yet established any of several potential biological mechanisms for such effects, the weight of the available epidemiological evidence supports an assumption of causality.
- All fine particles, regardless of their chemical composition, are equally potent in causing premature mortality. This is an important assumption, because fine particles formed from power plant SO₂ and NO_x emissions are chemically different from fine particles emitted directly from both mobile sources and other industrial facilities, but no clear scientific grounds exist for supporting differential effects by particle type.
- The concentration-response function for fine particles is approximately linear within the range of outdoor concentrations under policy consideration. Thus, the estimates include health benefits from reducing fine particles in both attainment and non-attainment regions.
- The forecasts for future emissions and associated air quality modeling are valid.
- The valuation of the estimated reduction in mortality risk is largely taken from studies of the tradeoff associated with the willingness to accept risk in the labor market.

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

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

In this section, we examine in more detail the benefits and costs of the 28 major final rules for which OMB concluded review during the 12-month period beginning October 1, 2005, and ending September 30, 2006. These major rules represent approximately 9 percent of the 325 final rules reviewed by OMB during this period, and approximately seven-tenths of one percent of the 3,765 final rules published in the *Federal Register* during this period. OMB believes, however, that the benefits and costs of major rules capture the vast majority of the total benefits and costs of all rules subject to OMB review.¹⁰

Of the 28 rules, ten were “social regulations,” which may require substantial additional private expenditures as well as provide new social benefits.¹¹ Of the ten social regulations, we are able to present estimates of both monetized benefits and costs for seven rules. The estimates are aggregated by agency in Table 1-3, and each rule is summarized in Table 1-4. One of the rules for which we were not able to present estimates of both benefits and costs implemented a program to improve air cargo security. The benefits of improved security are very difficult to quantify and monetize; however, the agency did estimate the cost of this rule, which is summarized in Table 1-5.¹² The other two final rules, both migratory bird hunting rules, are “enabling” rules that permit hunting of migratory birds for which the agency did not estimate costs. Thus we did not include those migratory bird hunting rules in the totals in Tables 1-1 through 1-3. It is difficult to estimate the costs of these two rules since costs are typically associated with requirements or restrictions on activities imposed by rules. Instead, the agency estimated the value the rule provides to hunters. We attempt to summarize the available information on the non-monetized impacts, and/or provide links to such information where available, for all ten of these rules in the “other information” column of Table A-1.

The remaining 18 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.¹³ Their effects on

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

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

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

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

¹³Economists recognize, however, 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

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 28 economically significant rules reviewed by OMB, ten regulations require substantial private expenditures or provide new social benefits. We are able to present monetized benefits and costs for 70 percent (seven of ten) of the rules, and for about 80 percent (seven of nine) 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 benefits and costs by agency of these major rules reviewed by OMB over the past year, and Table 1-4 provides a summary of each regulation. These tables are the basis for the totals in the accounting statement in Section A of this chapter.

In assembling these tables of estimates of benefits and costs, OMB has applied a uniform format for the presentation of benefit and cost estimates in order to make agency estimates more closely comparable with each other (for example, annualizing benefit and cost estimates), and OMB has monetized quantitative estimates where the agency has not done so. For example, we have converted agency projections of quantified benefits, such as estimated injuries avoided per year or tons of pollutant reductions per year, to dollars using the valuation estimates discussed in Appendix A of this Report and in Appendix B of our 2006 Report, which can be found at http://www.whitehouse.gov/omb/inforeg/2006_cb/2006_cb_final_report.pdf. Table A-1 in Appendix A also reports the available impact information, as reported by the agencies, on the ten social regulations reviewed by OMB in the time period covered by this Report.

Table 1-3: Estimates of the Total Annual Benefits and Costs of Major Federal Rules, October 1, 2005 to September 30, 2006 (millions of 2001 dollars)

| Agency | Number of Rules | Benefits | Costs |
|---|------------------------|---------------------|--------------------|
| Department of Health and Human Services | 1 | 196-660 | 82-274 |
| Department of Labor | 1 | 35-862 | 263-271 |
| Department of Transportation | 2 | 999-1,199 | 666-755 |
| Environmental Protection Agency | 3 | 5,113-42,109 | 2,720-2,965 |
| Total | 7 | 6,344-44,830 | 3,731-4,265 |

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). *Economic Report of the President* (2008). Council of Economic Advisers.

**Table 1-4: Estimates of the Total Annual Benefits and Costs of Major Rules Reviewed
Between October 1, 2005 and September 30, 2006 (millions of 2001 dollars)**

| Rule | Agency | Benefits | Costs | Explanation of OMB Calculations |
|--|---------------|---------------------|--------------------|---|
| Electronic Prescribing Standards | HHS-CMS | 196-660 | 82-274 | We converted agency annual impact estimates to 2001 dollars. |
| Occupational Exposure to Hexavalent Chromium | DOL-OSHA | 35-862 | 263-271 | We converted agency annual impact estimates to 2001 dollars. |
| Congestion and Delay Reduction at Chicago O'Hare International Airport | DOT/FAA | 153-164 | .3 | We converted agency annual impact estimates to 2001 dollars. |
| Light Truck Average Fuel Economy Standards, Model Years 2008-2011 | DOT/NHTSA | 847-1,035 | 666-754 | We converted agency annual impact estimates to 2001 dollars and annualized the reported present value impacts over 10 years at 3 percent and 7 percent discount rates. |
| Standards of Performance for Stationary Compression Ignition Internal Combustion Engines | EPA/Air | 679-757 | 56 | EPA reported estimated impacts in the year 2015. We linearly interpolated the impact for the transition period and annualized at 7 percent and 3 percent from 2007 to 2015. We also monetized the tons of emissions reduced using the method describe in Appendix B of our 2006 Report. |
| Review of the National Ambient Air Quality Standards (NAAQS) for Particulate Matter | EPA/Air | 3,837-39,879 | 2,590-2,833 | EPA reported estimated impacts in the year 2020. We linearly interpolated the impact for the transition period and annualized at 7 percent and 3 percent from 2007 to 2020. |
| National Primary Drinking Water Regulations: Stage 2 Disinfection Byproducts Rule | EPA/Water | 598-1,473 | 74-76 | The uncertainty range on benefits is based on the highest and lowest mean impact across different scenarios EPA reported. It varied the discount rate and the monetization approach across these scenarios. We also converted agency annual impact estimates to 2001 dollars. |
| Total | | 6,344-44,830 | 3,731-4,265 | |

Homeland Security Regulation

Table 1-5 presents the available impact information on the one major homeland security regulation adopted in the past year by the Transportation Security Administration (TSA) of the Department of Homeland Security (DHS). Because the benefits of homeland security regulation are a function of the likelihood and severity of a hypothetical future terrorist attack, they are very difficult to forecast, quantify, and monetize. For the purposes of Table 1-5, we have annualized and converted the cost estimates to 2001 dollars in a manner similar to Table 1-4. We have also summarized the available information on how the agency forecasts that the rule will improve security or otherwise prevent or mitigate the consequences of a terrorist attack.

Table 1-5: Estimates of the Total Annual Benefits and Costs of Major Federal Rules: Major Homeland Security Regulation, October 1, 2005-September 30, 2006 (millions of 2001 dollars)

| Rule | Agency | Benefits | Costs | Other Information |
|---------------------------------|---------------|---|--------------|---|
| Air Cargo Security Requirements | DHS-TSA | The goal of this regulation is to protect our society from acts of terrorism involving the use of aircraft. This regulation contains provisions that would prevent unauthorized persons, explosives, incendiaries, and other destructive substances or items from being introduced into the air cargo supply chain. | 185-187 | OMB converted DHS cost estimates to 2001 dollars. No other adjustment to agency estimate. |

OMB has also compiled the total impact of all major, economically significant homeland security rules that have been finalized since the creation of the DHS and that contain monetized costs. Since DHS was created, agencies have finalized ten major homeland security regulations that impose a total cost on the economy of between \$2.2 billion to \$4.1 billion a year.¹⁴

C. Regulations Implementing or Adjusting Federal Budgetary Programs

Of the 28 economically significant rules reviewed by OMB, 18 implement or adjust Federal budgetary programs. Of these, four rules were issued by the Departments of Agriculture (USDA), two by the Department of Education (ED), nine by the Health and Human Services (HHS), one by Homeland Security (DHS), one by Veterans Affairs (VA), and one by the Social Security Administration (SSA). The budget outlays associated with these rules are “transfers” from taxpayers to program beneficiaries, on behalf of program beneficiaries, or fees collected from program beneficiaries; therefore in past Reports OMB has referred to these rules as “transfer” rules. These rules are summarized below in Table 1-6.

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

Table 1-6: Agency Rules Implementing or Adjusting Federal Budgetary Programs, October 1, 2005 to September 30, 2006¹⁵

| Rule [FR Cite] | Agency | Beneficiary | Description |
|--|---------------|--|--|
| Emergency Forestry Conservation Reserve Program [71 FR 31915] | USDA | Landowners that experienced a loss of 35 percent or more of merchantable timber due to hurricanes. | \$404.1 million was authorized in 2006 for this program, which may be paid out over a ten-year period as a lump sum or in annual payments; hence annualized estimates may vary substantially. The agency estimates 10-year discounted transfers of between \$353 million and \$378 million (using a 7 percent and 3 percent discount rate). |
| 2005 Hurricane Disaster Assistance Programs [71 FR 27188] | USDA | Producers affected by hurricanes who suffered eligible losses | USDA is providing \$250 million for crop disaster, livestock, tree, and aquaculture assistance from Section 32 funds. These funds will be distributed by five new programs: Hurricane Indemnity Program (HIP); Tree Indemnity Program (TIP); Feed Indemnity Program (FIP); Livestock Indemnity Program (LIP); and Aquaculture Grants. |
| Percentages for Direct and Counter-Cyclical Program Advance Payments [71 FR 17982] | USDA | Federal Government | About \$90 million of 2007-crop direct payments is expected to shift from calendar year 2006 into calendar year 2007 because of the direct payment percentage change. While no net impact in nominal dollars on income is expected, the postponement of some advance payments does have some time value. OMB has identified the Federal Government as the beneficiary, because the rulemaking leads to an estimated reduction in the real value of payments of approximately \$3 million for the 2006 crop and \$15 million for the 2007 crop. |
| Extension of the Milk Income Loss Contract (MILC) Program [71 FR 19621] | USDA | Dairy Producers | The MILC Program supports the dairy industry by providing direct counter-cyclical payments to milk producers when the Boston Milk Marketing Order Class I price for fluid milk falls below the benchmark of \$16.94 per hundredweight. Transfers during the extended period, FY 2006 and FY 2007, are expected to be between \$700 and \$900 million based on estimated milk prices during the period. |
| Administrative Review Process for Adjudicating Initial Disability Claims [71 FR 16424] | SSA | Disability Beneficiaries. | This rule amends the administrative review process for applications for benefits based on whether you are disabled under title II of the Social Security Act, or applications for Supplemental Security Income payments that are based on whether you are disabled or blind under title XVI of the Act. Annual transfers of the rule are estimated to be \$140.6 million. |
| Traumatic Injury Protection Rider to Servicemembers' Group Life Insurance (SGLI) [70 FR 75940] | VA | U.S. Military Service Members | This rule provides automatic insurance for any SGLI insured who sustains a serious traumatic injury as prescribed by the Secretary of Veterans Affairs in collaboration with the Secretary of Defense. Annual transfers of the rule are estimated to be \$485 million, \$400 million of which is for retroactive payments. |

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

| Rule [FR Cite] | Agency | Beneficiary | Description |
|--|---------------|-------------------------------------|--|
| Special Community Disaster Loans Program [70 FR 60443] | DHS | Local Governments | This rule allows the Federal Emergency Management Agency (FEMA) to provide loans greater than \$5 million to local governments impacted by Hurricanes Katrina and Rita. As a result, FEMA disbursed over \$1 billion in loans during Fiscal Year 2006. Additional disbursements under the program are not anticipated. |
| Student Assistance General Provisions [71 FR 64401] | ED | Postsecondary Students | These rules for the Academic Competitiveness Grants and National SMART Grant programs specify the eligibility requirements for a student to apply for and receive an award under these programs. Annual transfers of the rule are estimated to be \$694 million. |
| Federal Student Aid Programs [71 FR 64377] | ED | Postsecondary Students | These rules reflect the provisions of the Higher Education Reconciliation Act of 2006 that affect students, borrowers and program participants in the Federal student aid programs authorized under Title IV of the Higher Education Act. Annual transfers of the rule are estimated to be \$976 million. |
| Conditions for Coverage for Organ Procurement Organizations (OPOs) [71 FR 30982] | HHS | Medicare and Medicaid Beneficiaries | This rule establishes new conditions for coverage for OPOs. The estimated benefits are more than \$1 billion each year, based on the number of lives HHS expects would be saved and the decrease in associated dialysis costs by increasing organ donation and transplantation due to increased OPO performance. The estimated impact of this rule on the Medicare program is \$37 million in the first year and \$136 million over 5 years. |
| Conditions for Payment of Power Mobility Devices (PMDs), Including Power Wheelchairs and Power-Operated Vehicles [71 FR 17021] | HHS | Medicare Providers | This rule sets forth revised conditions for Medicare payment of PMDs and defines who may prescribe PMDs. No transfer estimates for this rule are available. |
| Home Health Prospective Payment System Rate Update for Calendar Year 2006 [70 FR 68132] | HHS | Medicare Providers | This rule updates the 60-day national episode rates and the national per-visit amounts under the Medicare prospective payment system for home health agencies. This rule is estimated to increase expenditures by \$370 million in CY 2006. |
| Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates [70 FR 68516] | HHS | Medicare Providers | This rule revises the Medicare hospital outpatient prospective payment system to implement applicable statutory requirements and to implement certain related provisions of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003. This rule is estimated to increase expenditures by \$1,400 million in Calendar Year (CY) 2006. ¹⁶ |
| Medicare Program; Application of Inherent Reasonableness Payment Policy to Medicare Part B Services (Other Than Physician Services) [70 FR 73623] | HHS | Federal Government | This rule has no immediate economic effect on current Medicare payments. However, it establishes a process that could be used in the future to set reasonable and equitable payment amounts. HHS believes that the future application of the inherent reasonableness authority has the potential to have significant impact on Medicare payment amounts. |

¹⁶ Estimated impacts of this rule were revised by the agency (see www.cms.hhs.gov/apps/media/press/release.asp?Counter=1711).

| Rule [FR Cite] | Agency | Beneficiary | Description |
|---|---------------|--------------------|---|
| Inpatient Psychiatric Facilities Prospective Payment System Payment Update [71 FR 27040] | HHS | Medicare Providers | This rule updates the prospective payment rates for Medicare inpatient hospital services provided by inpatient psychiatric facilities (IPFs). This rule is estimated to increase expenditures by \$170 million in Rate Year (RY) 2007. |
| Revisions to Payment Policies Under the Physician Fee Schedule for CY 2006 and Certain Provisions Related to the Competitive Acquisition Program of Outpatient Drugs and Biologicals - Part B [70 FR 70116] | HHS | Federal Government | This rule addresses Medicare Part B payment policy, including the physician fee schedule that are applicable for calendar year (CY) 2006; and finalizes certain provisions of the interim final rule to implement the Competitive Acquisition Program (CAP) for Part B Drugs. This rule is expected to reduce Medicare expenditures by \$2,668 million in 2006. |
| Prospective Payment System (PPS) for Long-Term Care Hospitals RY 2007 [71 FR 27798] | HHS | Federal Government | This rule updates the annual payment rates for the Medicare PPS for inpatient hospital services provided by long-term care hospitals. This rule is expected to reduce expenditures by \$156 million in RY 2007. |
| Changes to the Hospital Inpatient Prospective Payment Systems (IPPS) and Fiscal Year 2007 Rates [71 FR 47869] | HHS | Medicare Providers | This rule updates the Medicare hospital IPPS for operating and capital-related costs, implements changes arising from continuing experience with these systems, and implements changes made by the Deficit Reduction Act of 2005 (Pub. L. 109-171). This rule is expected to increase expenditures by \$3,889 million in FY 2007. |

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. 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, 2005 to September 30, 2006. GAO reported that three of these agencies issued a total of four major rules during this period.

As Table 1-7 indicates, one of the rules included a discussion of benefits and costs, and reported monetized costs. OMB does not know whether the rigor and extent of the analyses conducted by these agencies are similar to those of the analyses performed by agencies subject to Executive Order 12866, since OMB does not review rules from these agencies.

OMB has received a number of requests urging that we expand our role in evaluating benefit-cost analyses from so-called independent agencies¹⁷ by describing the benefits and costs of rules issued by independent agencies consistent with the reports provided for the agencies whose regulations are reviewed by OMB under Executive Order 12866. In response to these requests, we have added to 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 1997 through 2006, which we present in Table 1-8. Although most of these rulemakings were summarized in previous annual OMB Reports, the reader should note that OMB's 1997 Report did not tabulate major rules from independent agencies, and OMB did not finalize a Report in 1999. OMB reconstructed the estimates for these two time periods 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. OMB is reporting all of the rules from 1997 through 2006 on a fiscal year basis (see Table 1-8). The number of rules presented in earlier Reports therefore, may not match the number of rules presented here. We also present information on the extent to which the independent agencies reported benefit and cost information for these rules in Tables 1-9 through 1-11.

¹⁷ See, for example, Hahn, Robert W., and Litan, Robert E 2006. An Analysis of the Ninth Government Report on the Costs and Benefits of Federal Regulations. AEI-Brookings Joint Center for Regulatory Studies, Regulatory Analysis 06-05; Belzer, Richard, 2006, Comment on the 2006 Draft Report to Congress on the Costs and Benefits of Federal Regulations; Mannix, Brian, 2005. Comment on the 2005 Draft Report to Congress on the Costs and Benefits of Federal Regulations; Hahn, Robert W., Litan, Robert E., and Malik, Rohit 2005. An Analysis of the Eighth Government Report on the Costs and Benefits of Federal Regulations. AEI-Brookings Joint Center for Regulatory Studies, Regulatory Analysis 05-02; Gattuso, James, 2004. Comment on the 2004 Draft Report to Congress on the Costs and Benefits of Federal Regulations; Hahn, Robert W., and Litan, Robert E 2004. An Analysis of the Seventh Government Report on the Costs and Benefits of Federal Regulations. AEI-Brookings Joint Center for Regulatory Studies, Regulatory Analysis 04-03; Langer, Andrew, 2004, Comment on the 2004 Draft Report to Congress on the Costs and Benefits of Federal Regulation. All comments on the draft Reports cited here are available at http://www.whitehouse.gov/omb/info/reg/regpol-reports_congress.html.

**Table 1-7: Major Rules Issued by Independent Regulatory Agencies,
October 1, 2005 to September 30, 2006**

| Agency | Rule | Information on Benefits or Costs | Monetized Benefits | Monetized Costs |
|------------------------------------|---|---|----------------------------------|----------------------------|
| Federal Communications Commission | Air-Ground Telecommunications Services [70 FR 76414] | No ¹⁸ | No | No |
| Federal Communications Commission | Implementation of the Commercial Spectrum Enhancement Act and Modernization of the Commission's Competitive Bidding Rules and Procedures [71 FR 6214] | No ¹⁸ | No | No |
| Consumer Product Safety Commission | Standard for the Flammability (Open Flame) of Mattress Sets [71 FR 13472] | Yes The Final Regulatory Analysis is available online at: http://www.cpsc.gov/LIBRARY/FOIA/FOIA06/brief/mattabc.pdf | \$955-1,166 million/yr. (\$2005) | \$343 million/yr. (\$2005) |
| Nuclear Regulatory Commission | Revision of Fee Schedules; Fee Recovery for FY 2006 [71 FR 30722] | No ¹⁸ | No | No |

As we have stated in earlier Reports, there are several challenges associated with assembling and evaluating the available information on regulatory analysis for rules issued by independent agencies. First, in developing our Reports, we have relied on the information assembled by GAO. In many cases, however, the independent agencies provided GAO only limited or no information on their regulatory analysis. In addition, in many cases it is difficult to obtain additional information on their regulatory analyses. For example, the FCC does not provide this information with the publication of their rules in the *Federal Register* or post the associated regulatory analysis on its website.

Second, the type of analysis appropriate for rules issued by the independent regulatory agencies may differ from the analysis needed for most of the rules issued by the regulatory agencies subject to OMB review under Executive Order 12866. Many of the regulations promulgated by the independent agencies are economic regulations, rather than social regulations. While the objective of the analysis is the same for both cases (that is, identifying the social welfare effects due to the regulation), the analysis for economic rules will likely focus primarily on the regulation's impact on the operation of the regulated markets (such as the effects on competition, entry, and the quality of the products offered). In addition, a number of rules issued by the independent agencies are "fee" rules to raise revenues to support agency regulatory activity. For example, ten of twelve major rules issued by the Nuclear Regulatory Commission over the past ten years were fee rules where the agency reported to GAO information on the estimated fees.

¹⁸The GAO reported that a Regulatory Flexibility Analysis was conducted to estimate the effect on small businesses, although no Benefit-Cost Analysis was conducted.

In some cases, the independent agencies have conducted extensive regulatory analysis. For example, the Consumer Product Safety Commission's Standard for the Flammability (Open Flame) of Mattress Sets monetized and reported the estimated annual benefits and costs for the rule. We believe, however, that the current efforts by the independent agencies to quantify and monetize benefits and costs are often limited. In many instances, agencies may simply quantify and monetize incidental paperwork burden associated with rules, but not the other effects on the affected entities or sectors of the economy. Since OMB does not review these rules, we do not know the rigor and extent of the analyses conducted when benefits and costs are analyzed.

**Table 1-8: Total Number of Rules Promulgated by Independent Agencies
October 1, 1996 to September 30, 2006**

| Agency | 1997 | 1998 | 1999 | 2000 | 2001 | 2002 | 2003 | 2004 | 2005 | 2006 |
|---|-----------|-----------|-----------|-----------|----------|----------|----------|----------|-----------|----------|
| Consumer Product Safety Commission (CPSC) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 |
| Federal Communications Commission (FCC) | 8 | 19 | 7 | 8 | 2 | 4 | 0 | 1 | 4 | 2 |
| Federal Energy Regulatory Commission (FERC) | 0 | 0 | 0 | 2 | 0 | 0 | 0 | 0 | 0 | 0 |
| Federal Reserve System | 1 | 0 | 0 | 1 | 0 | 0 | 1 | 1 | 0 | 0 |
| Federal Trade Commission (FTC) | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 1 | 0 |
| National Credit Union Administration (NCUA) | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Nuclear Regulatory Commission (NRC) | 1 | 2 | 1 | 2 | 1 | 1 | 1 | 1 | 1 | 1 |
| Pension Benefit Guaranty Corporation (PBGC) | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Securities and Exchange Commission (SEC) | 7 | 5 | 4 | 6 | 3 | 3 | 5 | 1 | 5 | 0 |
| Total | 17 | 26 | 14 | 20 | 6 | 8 | 7 | 4 | 11 | 4 |

In Table 1-9, OMB presents the total number of major rules for which the independent agencies reported some information on benefits or costs to the GAO. In Tables 1-10 and 1-11, OMB presents the percentage of major rules for which the benefits and costs are monetized.

**Table 1-9: Total Number of Rules with Some Information on Benefits or Costs¹⁹
October 1, 1996 to September 30, 2006**

| Agency | 1997 | 1998 | 1999 | 2000 | 2001 | 2002 | 2003 | 2004 | 2005 | 2006 |
|---|-----------|----------|----------|-----------|----------|----------|----------|----------|----------|----------|
| Consumer Product Safety Commission (CPSC) | -- | -- | -- | -- | -- | -- | -- | -- | -- | 1 |
| Federal Communications Commission (FCC) | 3 | 5 | 0 | 1 | 0 | 0 | 0 | 1 | 0 | 0 |
| Federal Energy Regulatory Commission (FERC) | -- | -- | -- | 2 | -- | -- | -- | -- | -- | -- |
| Federal Reserve System | 1 | -- | -- | 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) | 7 | 4 | 4 | 6 | 3 | 3 | 5 | 1 | 5 | -- |
| Total | 11 | 9 | 5 | 11 | 3 | 3 | 5 | 3 | 5 | 1 |

¹⁹ Tables 1-9 through 1-11 exclude all fee assessment rules promulgated by independent agencies. FCC promulgated six fee assessment rules from 1997 through 2002. NRC promulgated statutorily mandated ten fee assessment rules from 1997 through 2006.

**Table 1-10: Percent of Rules with Monetized Benefits,
October 1, 1996 to September 30, 2006**

| Agency | 1997 | 1998 | 1999 | 2000 | 2001 | 2002 | 2003 | 2004 | 2005 | 2006 |
|---|------|------|------|------|------|------|------|------|------|------|
| 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 | 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) | 28 | 0 | 0 | 0 | 66 | 33 | 20 | 100 | 40 | -- |

**Table 1-11: Percent of Rules with Monetized Costs,
October 1, 1996 to September 30, 2006**

| Agency | 1997 | 1998 | 1999 | 2000 | 2001 | 2002 | 2003 | 2004 | 2005 | 2006 |
|---|------|------|------|------|------|------|------|------|------|------|
| Consumer Product Safety Commission (CPSC) | -- | -- | -- | -- | -- | -- | -- | -- | -- | 100 |
| Federal Communications Commission (FCC) | 0 | 6 | 0 | 0 | 0 | 0 | -- | 100 | 0 | 0 |
| Federal Energy Regulatory Commission (FERC) | -- | -- | -- | 0 | -- | -- | -- | -- | -- | -- |
| Federal Reserve System | 0 | -- | -- | 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) | 14 | 40 | 25 | 33 | 100 | 100 | 80 | 100 | 100 | -- |

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

This chapter of the Report benefited from input OMB received from peer reviewers and commenters who responded to OMB’s request for comments on the draft Report published earlier. Peer reviewer (1) stated that the accounting statement is steadily generating useful information. Peer reviewers (2 and 3) noted the expanded discussion on independent agencies and applauded OMB’s efforts. Peer reviewer (2) stated the Report still has significant room for improvement, and commenters (C and D) criticized the overall approach of aggregating benefits and costs.

Independent agencies

In the draft Report, OMB specifically solicited comments on the following: (1) the completeness of the list of rules for independent agencies; (2) additional information on independent agency rulemaking analyses; and (3) the quality of independent agency regulatory impact analysis and conformity of these analyses with the principles of OMB's Circular A-4. OMB did not receive any peer review or public comment on these issues. However, peer reviewer (2) suggested that OMB include a discussion of the benefits and costs of anti-trust activities in the Report. OMB believes that while a discussion of the benefits and costs of anti-trust activities may have merit in another context, it is beyond the scope of this Report.

Scope of the report

Peer reviewer (1) and commenter (D) criticized our treatment of rules that implemented Federal budgetary programs, including our practice of excluding rules of this type from aggregate estimates of the benefits and costs of agency rulemaking. These comments point out that rules designed to implement budget expenditures also generate benefits and costs not accounted for in budgetary figures. Benefits and costs are associated with the behavioral changes caused by the spending programs, and in addition, there are the opportunity costs of the tax revenue required to fund the program.

OMB agrees that rules that implement Federal budgetary programs often have benefits and opportunity costs in addition to the budgetary dollars spent.²⁰ We continue to believe, however, that our approach of separately identifying budgetary rules has merit.²¹ OMB believes this Report is properly focused on regulations that impose costs primarily through private sector mandates rather than those regulations that facilitate Federal budget programs. OMB does see merit in providing more information about these rules, and we encourage agencies to use their professional judgment and to develop and provide this information to the extent that it is available and practicable to do so.

Comments on the Overall Quality of Analysis

All three peer reviewers suggested that OMB present agencies' best estimates of expected benefits and costs in addition to the range of benefits and costs. OMB will consider providing agency best estimates as part of future reports to the extent practicable.

Commenter (A) stated that OMB should provide incremental benefits and costs in addition to the total benefits and costs. OMB encourages agencies to report both total and incremental benefits and costs associated with regulation in OMB's Circular A-4 (p. 16). However, OMB believes that this Report is not an appropriate venue to present this information. The purpose of this report to Congress is to assess the total benefits and costs associated with regulation, and aggregating incremental benefits and costs with different baselines and different increments is analytically not tractable. Instead OMB provides links to individual RIAs so that

²⁰ See Footnote 13 for more discussion.

²¹ Note that this Report provides for the first time, estimates of the on-budget effects of these rules.

interested readers can review the incremental benefits and costs associated with the options evaluated by the individual RIAs.

Peer reviewer (3) and commenter (A) suggested that the Report present outcome measures, fatalities reduced and life years saved along with the monetized benefit estimates. OMB agrees that agencies should present non-monetized expected outcomes using the most appropriate unit of measurement for the purpose at hand in their regulatory analysis. Circular A-4 provides some guidance in this regard, particularly as pertains to public safety and health rulemakings. Moreover, it states that “OMB encourages agencies to report results with multiple measures of effectiveness that offer different insights and perspectives” (p. 13). OMB provides links to individual RIAs for the interested reader.

Peer reviewer (3) and commenter (A) urged OMB to report disaggregated benefits and costs, including by household, business size, type of regulation, growth in burden, effect on State and local entities, household income categories, and type of programs (e.g., food safety, clean air). OMB Circular A-4 states that regulatory analyses should provide a description of distributional effects, and outlines directions for such descriptions. OMB strongly encourages agencies to adhere to this guidance. This report provides links to RIAs, and interested readers are encouraged to examine these analyses.

Peer-reviewer (3) and commenter (A) criticized the limitation of our accounting statement to final rules put in place over the previous ten years. As we stated in the final 2004 Report in response to similar comments, we continue to believe that the 10-year window is the appropriate time period for this accounting statement, since OMB does not believe that the pre-regulation estimates of the benefits and costs of rules issued over ten years ago are very reliable or useful for informing current policy decisions. In Chapter I, OMB discussed the many reasons why ex-ante estimates of regulations may not be accurate, and notes that this inaccuracy almost certainly increases with time. OMB will continue, however, to report the estimated benefits and costs of earlier rules and other analyses as appropriate back to 1992 and additional cost data for major rules dating back to 1981 (as seen in Figure 2-1).

Peer reviewer (3) suggested that OMB report the extent to which RIAs have received some peer review. OMB believes agencies should report any outside consultation and peer review in their regulatory analyses; but, also notes that the OMB and interagency review process serves as an alternative form of review.

Commenter (A) suggested that the Report describe key limitations, uncertainties, and potential inaccuracies in benefit-cost analysis for each rule. OMB encourages agencies to be as transparent as possible in describing assumptions, key limitations, and uncertainties associated with regulatory analyses. This Report provides links to the agency regulatory impact analyses for interested readers.

Commenter (D) stated that the Bush Administration should not take credit for the benefits and costs of Clean Air Act rules. This Report does not take credit; it merely reports estimates of benefits and costs of regulations that were promulgated in the relevant time periods.

Commenter (C) suggested deleting the following text from the Report: “The best measure of the overall value of regulation is net benefits; that is, benefits to society minus costs to society.” The commenter appears to be criticizing the concepts of quantification and monetization. The best measure of expected value of regulations is net benefits; but the quantification and monetization of both benefits and costs may be incomplete in many rulemaking processes. However, incomplete quantification and monetization does not invalidate these concepts.

Commenter (A) stated that OMB should discuss the Federal drinking water regulations more in the Report. The links to the Federal drinking water regulations are provided in this Report.

Other Issues

Peer reviewer (3) stated that OMB should provide a discussion on how many regulations cite market failure, government failure, or other compelling public need as basis for intervention. OMB agrees, consistent with Executive Order 12866 as amended, that agencies should describe the specific need for regulation where possible. Circular A-4 offers guidance toward that end: “Before recommending Federal regulatory action, an agency must demonstrate that the proposed action is necessary” (p. 3) by including a discussion of market failure, government failure, or other compelling public need in the regulatory impact analyses. However, OMB recognizes that some regulatory analyses discuss multiple reasons for Federal intervention, and it is therefore often difficult to pinpoint a single type of failure as the basis for intervention. The links for individual regulatory analyses are provided in this Report.

Peer reviewers (2 and 3) urged OMB to report on the range of alternatives examined by agencies in promulgating a regulation, including alternatives that are not legally permissible. Peer reviewer (2) also suggested a discussion on the extent to which agencies maximized net benefits in selecting regulatory options. OMB recognizes the importance of examining alternatives. OMB Circular A-4 states that a 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. This report provides links to individual RIAs so that interested readers can review the range of options evaluated in the regulatory analysis.

Peer reviewer (3), and commenter (A) recommended that OMB provide its independent benefit and cost estimates of Federal regulation. OMB carefully reviews all major proposed regulations. It is OMB’s view that the interagency review process under Executive Order 12866 operates to moderate any alleged agency bias in estimating benefits and costs. OMB also notes that it does adjust agency benefit and cost estimates to help ensure consistency of estimates across agency regulatory analyses. First, OMB adjusted all estimates to 2001 dollars; OMB also monetized quantified but non-monetized estimates where possible; and finally, OMB annualized estimates of net present values to provide yearly streams of benefits and costs. These adjustments are discussed in Appendix B-1.

Peer reviewer (3) stated that OMB should report on ex ante and ex post research on benefits and costs of regulation and report on whether such literature is reflected in the agency analysis. Commenter (A) recommended that OMB and EPA conduct a retrospective study on drinking water regulation. OMB included a discussion on this topic in the 2005 Report, *Validating Regulatory Analysis* and included a review of retrospective analyses that have found both ex-ante benefit and cost estimates to be both under- and over-estimated. OMB agrees that it is useful to compare actual with predicted estimates and encourages such efforts. OMB will consider conducting additional literature reviews in future Reports.

Peer reviewer (2) made the suggestion that OMB facilitate the use of information markets to increase overall economic efficiency and to inform regulatory decision making. In particular, the reviewer noted several regulatory hurdles to establishing information markets including (1) current prohibition on internet gambling and (2) the need to shift the regulatory oversight of information markets from States to the Federal Government. OMB agrees that information markets are an interesting new area of research, and we encourage the commenter to keep us apprised of relevant new findings.

All three peer reviewers suggested that OMB develop a scorecard that reports agency compliance with Circular A-4. OMB will consider including a discussion of agency compliance with OMB Circular A-4 in future reports.

OMB received a number of comments on the issue of future guidance. Peer reviewer (1) recommends that OMB provide default monetized values to improve consistency across agencies. OMB Circular A-4 offers substantial guidance on monetization. Because agencies must address questions of monetization that are unique to their respective areas of rulemaking, OMB allows agencies some discretion to develop internally consistent standards for monetization, within the framework prescribed by Circular A-4. OMB believes that the guidelines promulgated by Circular A-4 are sufficiently detailed to lead to consistent monetization across agencies.

Peer reviewer (1) recommends that OMB provide future directions of the risk assessment guidance in the annual report to Congress. On September 19, 2007 OMB and OSTP released a memorandum on Updated Principles for Risk Analysis. This memorandum updates previous principles from 1995 with reference to more recent guidance from the scientific community, the Congress, and the Executive Branch. The memorandum is available at: <http://www.whitehouse.gov/omb/memoranda/fy2007/m07-24.pdf>.

Peer reviewers (1 and 2) suggested 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 we have mentioned in previous reports, most prominently in our 2003 Report where we dedicated a chapter to homeland security regulations, 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 answer the question of 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 the costs. We encourage DHS and other agencies regulating homeland security to continue to develop this methodology in order to adopt, as much as possible, alternative analytical frameworks as a basis for evaluating their regulatory actions. We also invite comment in future reports on methods and tools to help facilitate this analysis.

Peer reviewers (1 and 3) suggested a discussion of whether this Report has helped develop better regulatory analysis and consequently better regulation, monitor activities at individual agencies, linking ex ante regulatory analysis with ex post PART, GPRA or other performance measures, and informing supplemental accounts to the National Income and Product Accounts. Linking this Report to various ex post performance measures, future regulation and agency activities, and the National Income and Product Accounts is beyond the scope of this Report.

Commenter (B) suggested that OMB provide an update on the current status of the 76 priority reforms from the 2004 round of reform nominations relating to the manufacturing sector. OMB will provide an update on status in the 2008 draft report.

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, six 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

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.

to 9,300 avoided bladder cancer cases annually, with an estimated monetized value of \$0 to \$4 billion per year. Possible reductions in rectal and colon cancer and adverse reproductive and developmental effects were not quantified.

- *EPA's National Primary Drinking Water Regulations: Interim Enhanced Surface Water Treatment* (1998): This rule establishes new treatment and monitoring requirements (primarily related to filtration) for drinking water systems that use surface water as their source and serve more than 10,000 people. The purpose of the rule is to enhance health protection against potentially harmful microbial contaminants. EPA estimated that the rule will impose total annual costs of \$300 million per year. The rule is expected to require treatment changes at about half of the 1,400 large surface water systems, at an annual cost of \$190 million. Monitoring requirements add \$96 million per year in additional costs. All systems will also have to perform enhanced monitoring of filter performance. The estimated benefits include average reductions of 110,000 to 338,000 cases of cryptosporidiosis annually, with an estimated monetized value of \$0.5 to \$1.5 billion, and possible reductions in the incidence of other waterborne diseases.
- *EPA's National Pollutant Discharge Elimination: System B Regulations for Revision of the Water Pollution Control Program Addressing Storm Water Discharges* (1999): This rule expands the existing National Pollutant Discharge Elimination System program for storm water control. It covers smaller municipal storm sewer systems and construction sites that disturb one to five acres. The rule allows for the exclusion of certain sources from the program based on a demonstration of the lack of impact on water quality. EPA estimates that the total cost of the rule on Federal and State levels of government, and on the private sector, is \$803.1 million annually. EPA considered alternatives to the rule, including the option of not regulating, but found that the rule was the option that was “most cost effective or least burdensome, but also protective of the water quality.”
- *EPA's National Primary Drinking Water Regulations; Arsenic and Clarifications to Compliance and New Source Contaminants Monitoring* (2001): This rule reduces the amount of arsenic that is allowed to be in drinking water from 50 ppb to 10 ppb. It also revises current monitoring requirements and requires non-transient, non-community water systems to come into compliance with the standard. This rule may affect either State, local or tribal governments or the private sector at an approximate annualized cost of \$206 million. The monetized benefits of the rule range from \$140 to \$198 million per year. The EPA selected a standard of 10 ppb because it determined that this was the level that best maximizes health risk reduction benefits at a cost that is justified by the benefits, as required by the Safe Drinking Water Act.
- *EPA's National Primary Drinking Water Regulations: Long Term 2 Enhanced Surface Water Treatment* (2005): The rule protects against illness due to cryptosporidium and other microbial pathogens in drinking water and addresses risk-risk trade-offs with the control of disinfection byproducts. It requires the use of treatment techniques, along with monitoring, reporting, and public notification requirements, for all public water systems that use surface water sources. EPA estimates the total cost of the rule on Federal and State levels of government, and on the private sector, is between \$60 and \$170 million

per year.

- *EPA's National Primary Drinking Water Regulations: Stage 2 Disinfection Byproducts Rule* (2006): The rule protects against illness due to drinking water disinfectants and disinfection byproducts (DBPs).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 of \$100 million or more for the State, local, and tribal governments, in the aggregate in the private sector in any one year. While the annualized costs fall below the \$100 million threshold, the costs in some future years may be above the \$100 million mark as public drinking water systems make capital investments and finance these through bonds, loans, and other means. EPA's year-by-year cost tables do not reflect that investments through bonds, loans, and other means spread out these costs over many years. The cost analysis in general does not consider that some systems may be eligible for financial assistance such as low-interest loans and grants through such programs as the Drinking Water State Revolving Fund.

Although these seven EPA 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, 13 percent, 9 percent, and 6 percent of rules listed in the Fall 2007 Unified Regulatory Agenda cited some impact on State, local, or tribal governments, respectively.

Impact on Small Business

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

The Chief Counsel of Office of Advocacy of the Small Business Administration recently sponsored a study that estimated the burden of regulation on small businesses.²⁴ This is the third

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).

²⁴Crain, W.M. 2005. "The Impact of Regulatory Costs on Small Firms." Report prepared for the Office of Advocacy, U.S. Small Business Administration. Available at <http://www.sba.gov/advo/research/rs264tot.pdf>.

in a series of studies on small business regulation conducted on behalf of the Office of Advocacy.²⁵ This study found that regulatory costs per employee decline as firm size—as measured by the number of employees per firm—increases. Crain estimates that the total cost of Federal regulation (environmental, workplace, economic, and tax compliance regulation) was 45 percent greater per employee for firms with fewer than 20 employees compared to firms with over 500 employees.

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

The Office of Advocacy reports annually on the overall performance of agency compliance with the RFA and Executive Order 13272, and the Office of Advocacy efforts to improve the analysis of small business impacts and to persuade agencies to afford relief to small businesses. The comprehensive report for FY 2005 was published in April 2006 and can be found at <http://www.sba.gov/advo/laws/flex/05regflx.pdf>. It contains four main sections. Section one provides an overview of the 25-year history of the RFA. Section two provides a summary of agency compliance with Executive Order 13272 and with the RFA in FY 2005. Section three provides the Office of Advocacy's agency-by-agency review of RFA compliance in FY 2005. Section four of this report discusses the Office of Advocacy's regulatory flexibility model legislative initiative and three related success stories. 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.

Impact on Wages

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

²⁵The other two reports are Hopkins, T., 1995, “Profiles of Regulatory Costs;” and Crain, W.M. and T. Hopkins 1999, “The Impact of Regulatory Costs on Small Firms.” These reports are also available on the Office of Advocacy’s website.

1. 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 a cost in inefficiency from reduced competition, a cost which consumers must bear. Workers’ wages do not go as far when, as consumers, they face higher prices for goods that are inefficiently produced. Moreover, growth in real wages, which are limited generally by productivity increases, will not grow as fast without the stimulation of outside competition.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 known are the significant differences in growth rates and indicators of well being, perhaps for the same reasons, seen among economies with smaller differences in the degree of government control and the quality of regulation.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 161 countries.³¹ The index is composed of independent variables divided into ten broad factors that attempt to measure different aspects of economic freedom: trade policy, fiscal burden, government intervention, property rights, banking and finance, wages and prices, regulation, informal market activity, and for the first time in the 2007 report, labor freedom. They find a very strong relationship between the index and per capita Gross Domestic Product (GDP). According to the refined index presented in the 2007 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 does not prove that economic freedom causes economic growth. Economic growth could cause economic freedom or both could be correlated with an unknown third factor. More suggestive is the data on changes in these indicators. The 2004 version of this report looks at this issue in depth by examining the relationship between the change in the index since 1995 and the average GDP growth rate over seven years. After grouping the 142 countries (for which they had complete data) into quintiles, they find a very strong association between improvement in the index and growth rates. The first quintile of countries grew at a rate of 4.9 percent per year, almost twice the 2.5 percent growth rate of the fifth quintile.

Since 1997, the Fraser Institute of Vancouver, B.C. has published the Economic Freedom of the World index, which now includes data for 130 countries.³² The rank of the top ten economies is Hong Kong (1), Singapore (2), New Zealand, Switzerland, and the United States (3), Ireland and the United Kingdom (6), Canada (8), and Iceland and Luxembourg (9). The index, which is based on 38 data points, many of them from surveys published by other

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 Tim Kane, Kim R. Holmes, and Mary Anastasia O'Grady, *2007 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: 2006 Annual Report*. Fraser Institute, Vancouver, BC.

institutions, measures five major concepts: size of government, legal structure and security of property rights, access to sound money, freedom of exchange with foreigners, and regulation of credit, labor, and business. The latest report finds that the index is highly correlated not just with per capita income and economic growth, but with other measures of well being, including life expectancy, the income level of the poorest 10 percent, adult literacy, corruption-free governance, civil liberties, the United Nations' Human Development Index, infant survival rates, 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 recently began a multi-year project to catalogue international differences in the scope and manner of regulations based on objective measures of regulatory burden – such as the number of procedures required to register a new business and the time and costs of registering a new business, enforce a contract, or go through bankruptcy. The first volume (*Doing Business in 2004, Understanding Regulation*) of the annual series examines for 130 countries five fundamental aspects of a firm's life cycle: starting a business, hiring and firing workers, enforcing contracts, obtaining credit, and closing a business.³³ The second volume (*Doing Business in 2005, Removing Obstacles to Growth*) updates these measures and adds data about registering property and protecting investors.³⁴ The third volume (*Doing Business in 2006, Creating Jobs*) updates the previous measures, expands the number of countries to 155, and adds three more sets of indicators: dealing with licenses, paying taxes, and trading across borders.³⁵ The first volume contained three major conclusions:

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

The second volume added three more main findings:

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

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

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.

The World Bank found that rich countries regulate less in all respects covered in the report and that common law and Nordic countries regulated less than countries whose legal systems are based on socialist principles. The top ten countries ranked on the ease of doing business based on the ten indicators were in order: New Zealand, Singapore, the United States, Canada, Norway, Australia, Hong Kong (China), Denmark, the United Kingdom, and Japan.³⁶

Like the studies based on broader and more subjective indicators, the World Bank study found that both labor productivity and employment were positively correlated with less regulation. The study found that heavier regulation was associated with greater inefficiency of public institutions and more corruption. The resulting regulation often had a perverse effect on the people it was meant to protect. Overly stringent regulation of business created strong incentives for businesses to operate in the underground or informal economy. The study cited the example of Bolivia, one of the most heavily regulated economies in the world, where an estimated 82 percent of business activity occurs in the informal sector. The study also found most women's share of private sector employment was positively correlated with less rigid regulation of labor markets.

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

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

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

It is interesting to note that these principles correspond fairly closely to the principles of regulatory reform that the United States has attempted to follow over the last 25 years.³⁷

³⁶See *Doing Business in 2006*, p. 3. There is a high degree of association between this ranking, which is based on objective measures, and the ranking from the Gwartney and Lawson study, which was based on subjective assessments.

³⁷For a description of the United States' regulatory reform program, see Executive Order 12291, *Federal Regulation*, (February 17, 1981), and Executive Order 12866, *Regulatory Planning and Review*, (September 30, 1993). In addition, OMB has discussed regulatory review and reform in several of our annual Reports to Congress, which are available at http://www.whitehouse.gov/omb/inforeg/regpol-reports_congress.html. See, for example Chapter 1 of *Stimulating Smarter Regulation: 2002 Report to Congress on the Costs and Benefits of Regulations and Unfunded Mandates on State, Local, and Tribal Entities*. Office of Management and Budget; and OMB Circular A-4, *Regulatory Analysis*, reproduced as Appendix D in *Informing Regulatory Decisions: 2003 Report to Congress*

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

The empirical results suggest that regulatory reforms have positive effects not only in product markets, where they tend to increase investment, innovation and productivity, but also for employment rates.³⁸

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

The major efforts to determine the effect of regulatory policies on economic performance described all use quite different indicators of regulatory quality and include different types of regulation, yet reach very similar conclusions. Giuseppe Nicoletti and Frederic Pryor examined three different indices of regulation, one objectively estimated and two based on subjective surveys of businessmen: one index examined only product markets, a second index examined both product and labor markets, and the final index includes financial and environmental regulations. The paper found statistically significant correlations among the three indices, despite the differences in coverage and methodologies.⁴⁰ A second group of researchers, who have done work for the World Bank, also found a strong correlation between regulation of entry into markets and the regulation of labor. They attribute this to their finding that the legal origin of regulation explains regulatory style. As they put it ... "countries have regulatory styles that are pervasive across activities and shaped by the origin of their laws."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

on the Costs and Benefits of Regulations and Unfunded Mandates on State, Local, and Tribal Entities, Office of Management and Budget.

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.*

A more recent body of literature, which combines the data sets of regulatory indicators discussed above as well as others, provides additional support to the supposition that excess regulation tends to reduce growth. Several papers by Norman Loayza, Ana María Oviedo, and Luis Servén use instrumental variable techniques to isolate the exogenous variation in regulation and determine the causal impact of regulation on economic growth, thereby reducing the reverse causality problem discussed above.⁴³ These studies also find that when the quality of regulation as measured by indicators of better governance (such as democratic accountability and absence of corruption) increases, the regulatory burden effect is smaller. These studies also find that both the volatility of economic growth and the size of the informal sector increase with regulation.

This pattern of findings provides strong support for policies that pursue “Smarter” or “Better” regulation⁴⁴ -- whether the country is a high-income OECD country or a developing country. The results are also consistent with economic theory, which predicts that economic growth is enhanced by regulatory policies that promote competitive markets, secure property rights, and intervene to correct market failures rather than to increase State influence.⁴⁵

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.⁴⁶ Both types of regulation, if poorly designed, harm economic growth as well as the social benefits that follow from economic growth. Our regulatory analysis guidelines (OMB Circular A-4) have a presumption against price and entry controls in competitive markets and thus deregulation is often appropriate.⁴⁷ For social regulation, Circular A-4 requires identification of market failure or other compelling need, and an analysis of the benefits and costs of regulations and their alternatives. In this case, smarter regulation may result in rules that are more stringent, less stringent, or just better designed to be more cost-effective. Regulation that utilizes performance standards rather than design standards or uses market-oriented approaches rather than direct controls is often more cost-effective because it enlists competitive pressures for social purposes. Social regulation often clarifies or defines property rights so that market efficiency is enhanced.

⁴³Norman Loayza, Ana María Oviedo, Luis Servén, “Regulation and Macroeconomic Performance,” World Bank Policy Research Paper No. 3469 (2005) and Norman Loayza, Ana María Oviedo, Luis Servén. “The Impact of Regulation on Growth and Informality: Cross-Country Evidence” AEI-Brookings Joint Center (May 2005).

⁴⁴The US uses the term “Smarter Regulation” and the UK, Canada, Ireland and the EU all use the term “Better Regulation” to describe their reform programs.

⁴⁵See 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.

⁴⁶Note 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.

⁴⁷Although 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.

Regulation that is based on solid economic analysis and sound science is also more likely to provide greater benefits to society at less cost than regulation that is not.⁴⁸ Thus a smarter or better regulation program relies on sound analysis and utilizes competition to improve economic growth and individual well-being in similar ways for both economic and social regulation. It is not surprising that countries that do well with one type of regulation tend to do well with the other. Nevertheless, more research is needed to determine how different types of regulation (e.g., economic versus social rules or product market versus labor market regulations) influence economic growth and well being.

⁴⁸The benefits of such a regulatory program will not show up just as an increase in measured GDP but will also show up as improvements in health, safety, and the environment. First, the regulations are designed to provide such public goods in the most cost-effective way, and second, the higher economic growth provided by a well-run regulatory reform program will increase the demand for, and the ability of the economy to supply, such public goods.

CHAPTER II: TRENDS IN BENEFIT AND COST ESTIMATES

A. Trends in Benefit and Cost Estimates

Since OMB began to compile records in 1981 through the end of 2006, Federal agencies have published 122,140 final rules in the *Federal Register*. Of these final rules, 21,253 were reviewed by OMB under Executive Order 12866 procedures. Of these OMB-reviewed rules, 1,192 were considered “major” rules, primarily due to their anticipated impact on the economy (e.g., estimated benefits and/or costs were in excess of \$100 million annually). As discussed in Chapter I, many major rules implement budgetary programs and involve transfers from taxpayers to program beneficiaries. Since 1981, OMB has reviewed 259 major rules with estimated benefits and/or costs to the private sector or State and local governments of over \$100 million annually.

Last year’s Report presented estimates of the overall costs of major rules issued by Federal agencies from 1981 to 2005. 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 2006 Report pointed out some of the concerns we had with these estimates, including that, because they are prospective, they might not present an accurate picture of these regulations’ actual impacts. Chapter III of our 2005 Report surveys what we know about the validation of *ex ante* estimates of benefits and costs of Federal regulation by *ex post* studies.

The best measure of the overall value of regulation is net benefits; that is, benefits to society minus costs to society. Below we present benefits and cost measures for the years 1992 to 2006 for 134 rules, for which reasonably complete monetized estimates of both benefits and costs are available. In addition, we extend the cost estimates back to 1981, the beginning of the regulatory review program at OMB, and include regulations with cost but not benefit estimates.⁴⁹

In exploring the impact of rulemaking on the economy in the early 1980s, we found that several important deregulatory actions resulted in a net decrease in compliance costs. We include the net cost savings generated by these regulations as “negative costs” for those years. To be consistent, we have also modified our estimates for later years to include regulatory actions that reduced net costs. In 2004, the Department of Transportation (DOT) issued two regulations that resulted in net cost savings: one rule reduced minimum vertical separation for airspace and the second increased competition in the computer reservation system for airline travel. Similarly, Occupational Safety and Health Administration’s (OSHA) ergonomics rule issued November 14, 2000 but repealed by Senate Joint Resolution No. 6 passed by Congress and signed by the President in March 2001 (Pub. L. No. 107-5) is recorded as a \$4.8 billion cost

⁴⁹To 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.

addition in 2000 and a \$4.8 billion cost savings in 2001.⁵⁰ Another important change is the inclusion of DOT's 1993 air bag rule, which had been left out of our calculations in 1993 because Congress had mandated the rule.⁵¹ We made this change to be consistent with OMB Circular A-4, Regulatory Analysis, issued in September 2003. Circular A-4 states that in situations where a rule simply restates statutory requirements, incremental benefits and costs should be measured relative to the pre-statute baseline.

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

Figure 2-1 presents the cost estimates from January 20, 1981 through September 30, 2006. Over the last 26 years, \$126.9 billion of annual regulatory costs (2001 dollars) have been added by the major regulations issued by the Executive Branch agencies and reviewed by OMB. This means that, on average, almost \$5 billion in annual costs have been added each year over this period. Several patterns are present. Note, in particular, the tendency for regulatory costs to be highest in the last year before a President leaves office (1988, 1992, and 2000). The average annual costs of the regulations issued over the past six years have been 47 percent lower than the average annual costs of the regulations issued during the previous 20 years.⁵²

⁵⁰ We 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.

⁵¹ Our 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.

⁵² Note that this trend would have been 44 percent if the ergonomics rule were not included.

Figure 2-1: Costs of Major Rules (1981-2006)

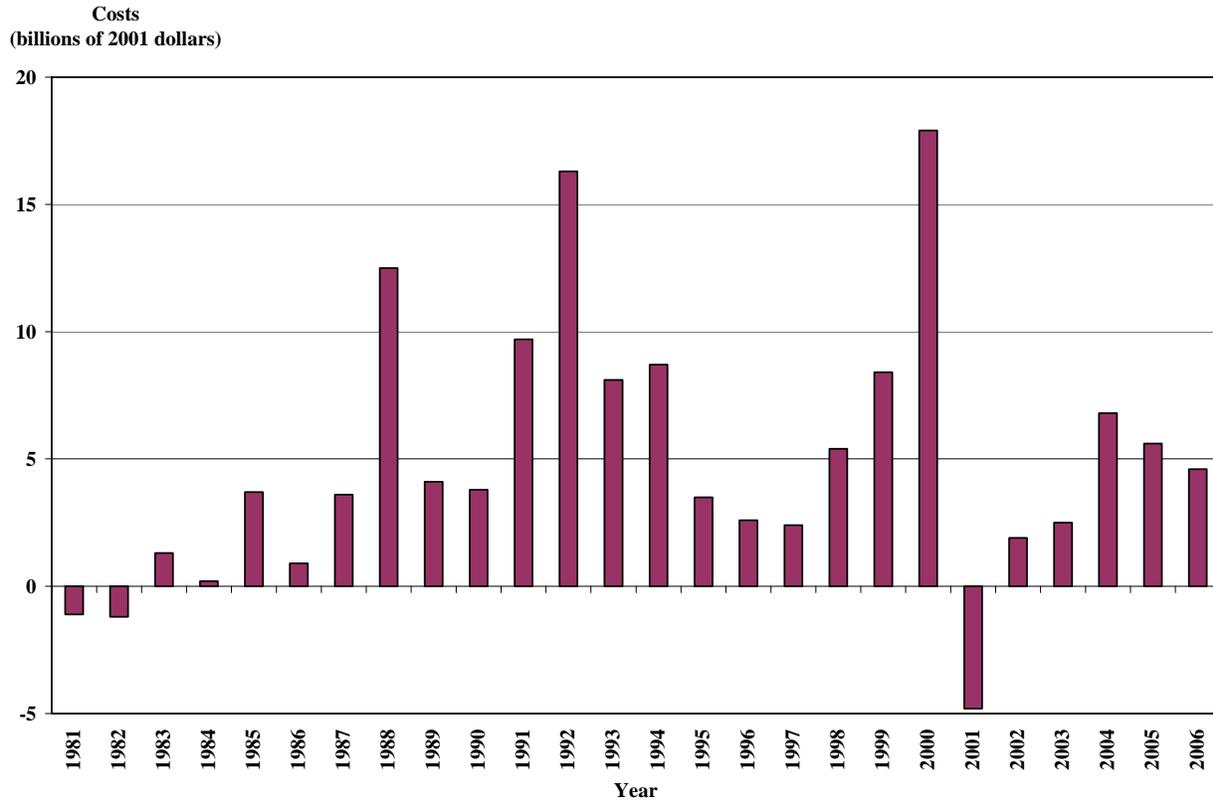
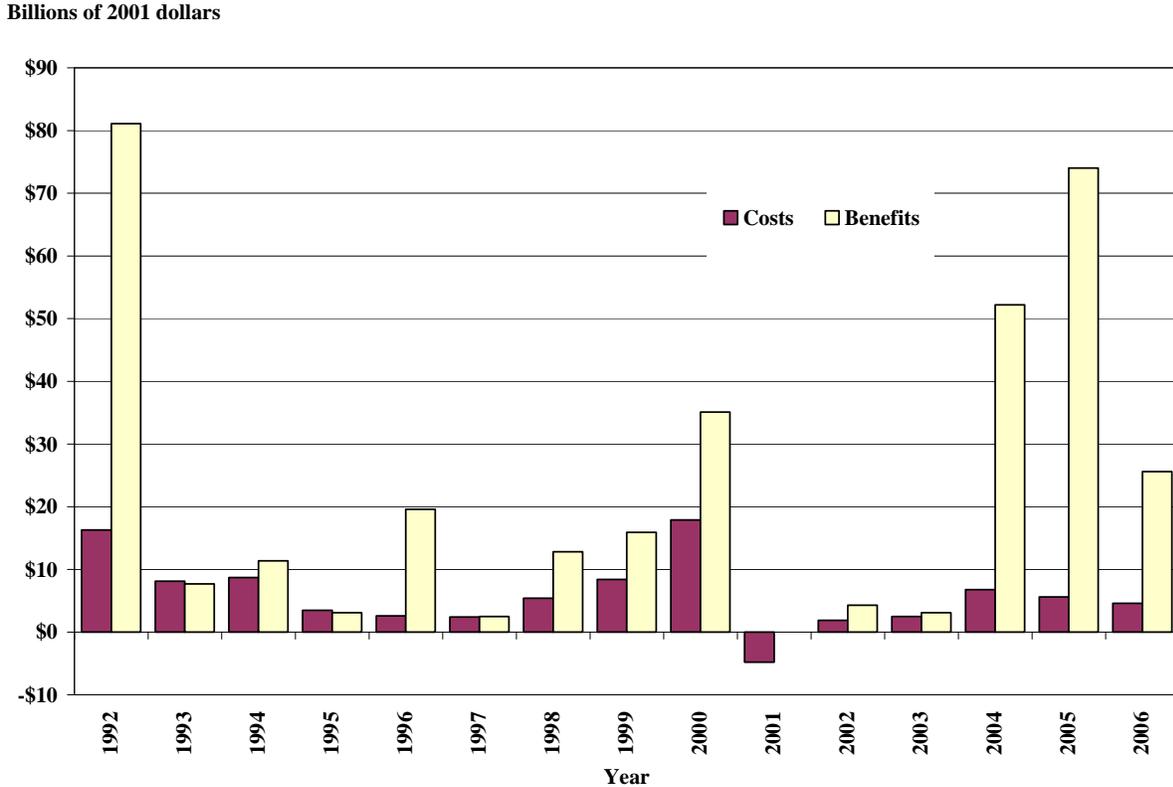


Figure 2-2 shows the benefits and costs of major rules issued from October 1, 1992, to September 30, 2006. Benefit estimates for the rules (with three noted exceptions)⁵³ that comprise the overall estimates are presented in various tables in the ten annual Reports (including this Report) that OMB has completed. Note that the three highest years for benefits, 1992, 2004, and 2005 are mostly explained by three EPA regulations: the 1992 acid rain permits regulation, the 2004 non-road diesel engine rule, and the 2005 interstate air quality rule. Since more major rules had cost estimates than benefit estimates, it is likely that benefit estimates are understated relative to the cost estimates included in Figure 2-2.

⁵³The exceptions, as discussed above, are DOT's 1993 airbag rule, OSHA's 2000 ergonomics rule, and DHS's 2005 air cargo security requirements rule. We did not include benefit estimates for the ergonomics rule because of the speculative nature of the estimates and the difficulty of determining the cause and/or mitigation of the great majority of ergonomic injuries. After the rule was overturned under provisions of the Congressional Review Act, the number of muscular skeletal disorders (MSDs) declined significantly more than OSHA's regulatory impact analysis (RIA) predicted would occur under the standard. The RIA estimated that MSDs would decline from 647,344 to 517,344 after 10 years of compliance. Instead, three years after the standard (which had never gone into effect) had been overturned, MSDs declined to 435,180 in 2003 (the last year for which data is available). The reason that voluntary actions to reduce MSDs are effective may be that employers and employees alike have strong incentives, due to worker's compensation costs and lost productivity, to reduce the incidence of MSDs.

Figure 2-2: Benefits and Costs of Major Rules (1992-2006)



The difference between benefit and cost shows the net benefits of major regulations from 1992 through September 2006. We were unable to go back beyond 1992 because of a lack of comparable data on benefits. Figure 2-2 also shows that in no year were costs significantly greater than benefits, even though benefits are likely understated relative to the costs since agencies estimate costs but not benefits for some of the rules reviewed by OMB over this time period.⁵⁴

We wish to emphasize that (1) these are *ex ante estimates*, (2) as discussed elsewhere in this Report (see Appendix A) as well as previous Reports, the aggregate estimates of benefits and costs derived from different agency’s estimates and over different time periods are subject to methodological inconsistencies and differing assumptions, and (3) the groundwork for the regulations issued by one administration are often begun in a previous administration.⁵⁵

⁵⁴In 1993 and 1995, costs exceeded benefits by about \$400 million in each year.

⁵⁵For 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.

B. Response to Peer Reviews and Public Comments on Trends in Benefit and Cost Estimates

Peer reviewer (1) suggested the Report should maintain objectivity by removing any “political” overtones in this chapter. Commenter (C) stated that linking macroeconomic performance to net benefits of rules is problematic. Lastly, Peer reviewer (3) suggested that OMB clarify whether the studies discussed in this chapter focus on high-income countries or all countries, and the strength of relationship between the level of regulation and macroeconomic variables. OMB has addressed the comment regarding politicization by removing specific calculations of trends focusing on different administrations. OMB has retained, though, a discussion regarding the general trends over the past 15 to 20 years versus recent trends over the past 6 years regarding costs of major rules and net benefits. OMB also clarified in the Report (1) high income countries vs. all countries issue, and (2) the relationship between regulation and macroeconomic variables in Chapter I.

Peer reviewer (3) recommended assessing whether the benefits justify the costs on U.S. competitiveness (domestically and internationally). OMB believes that the “Trends” report examines welfare implications, based on the benefit-cost analysis conducted by agencies in accordance with the Circular A-4.

Peer reviewer (1) suggested that OMB should consider additional econometric analysis of trends and conditioning factors. Econometric analysis of trends and conditioning factors is outside the scope of this report. OMB provides the basic trends.

CHAPTER III: UPDATE ON THE IMPLEMENTATION OF THE INFORMATION QUALITY ACT

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

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

In August 2004, the OIRA Administrator issued a memorandum to the President's Management Council requesting that agencies post all Information Quality correspondence on agency web pages to increase the transparency of the process.⁵⁶ In their FY 2004 Information Quality Reports to OMB, agencies provided OMB with the specific links to these web pages and OMB provided this information to the public in our 2005 update on Information Quality.⁵⁷ This increase in transparency allows the public to view all correction requests, appeal requests, and agency responses to these requests. The web pages also allow the public to track the status of correction requests that may be of interest. An updated list of agency web pages is provided in Appendix C-1 of this Report.

Whereas the correction request and appeals processes are designed to address the quality of information after dissemination, the Information Quality Guidelines also require pre-dissemination quality assurance measures. Peer review is one form of pre-dissemination review. Peer review is a highly regarded procedure used in the scientific community to promote independent review and critique by qualified experts and also is respected by the courts.⁵⁸ The Guidelines specifically provide a presumption of objectivity for information that has been peer reviewed.

After two rounds of public comment, a National Academy of Sciences workshop, and an interagency review process, OMB issued additional guidance on this aspect of information quality in the form of the Final Information Quality Bulletin for Peer Review⁵⁹ (the Bulletin). The Bulletin, which was issued on December 16, 2004, is designed to enhance the practice of peer review of government science documents. The implementation requirements for the

⁵⁶See http://www.whitehouse.gov/omb/inforeg/info_quality_posting_083004.pdf.

⁵⁷See *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.

⁵⁸ See *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993).

⁵⁹ See Issuance of OMB's “Final Information Quality Bulletin for Peer Review,” December 16, 2004, <http://www.whitehouse.gov/omb/memoranda/fy2005/m05-03.pdf>

Bulletin became fully effective on December 16, 2005. The Bulletin has a separate annual reporting requirement; FY 2006 was the first year for which agencies were required to report to OMB about the number and nature of the peer reviews conducted.

In previous Reports, OMB has presented a thorough discussion of the IQA and its implementation, including a discussion of perceptions and realities, legal developments, improving transparency, suggestions for improving correction requests, and the release of the OMB Information Quality Bulletin for Peer Review.⁶⁰

This chapter provides a summary of the current status of correction requests that were received in FY 2006, as well as an update on the status of requests received in FY 2003, FY 2004, and FY 2005. Our discussion of the individual correction requests and agency responses is minimal because all correspondence between the public and the agencies regarding these requests is publicly available on the agencies' Information Quality web pages. Finally, we discuss progress in implementing the Bulletin for Peer Review and summarize the annual peer review reports from the agencies.

A. Request for Correction Process

New Correction Requests and Appeal Requests Received by the Agencies in FY 2006

Table 3-1 below lists the departments and agencies that received requests for corrections FY 2006. As it shows, in FY 2006 a total of 22 requests for correction were sent to 8 different departments and agencies. All of the departments and agencies listed below have received correction requests in the past. Associated with these requests, only one appeal, sent to the Department of Transportation, was filed in FY 2006. However, as some of the agency responses were sent at the end of FY 2006 or were still pending at the end of FY 2006, there is a possibility that additional appeals may be filed.

⁶⁰See 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.

Table 3-1: Departments and Agencies that Received Information Quality Correction Requests in FY 2006

| Agency | Number of FY06 Correction Requests |
|---|---|
| Department of Commerce | 1 |
| Department of Defense | 3 |
| Department of Health and Human Services | 7 |
| Department of the Interior | 1 |
| Department of Labor | 1 |
| Department of Transportation | 3 |
| Consumer Product Safety Commission | 1 |
| Environmental Protection Agency | 5 |
| Total | 22 |

Further, as shown below in Table 3-2, there were an additional 6 appeals filed in FY 2006. These appeal requests were sent to the agencies following receipt of responses to correction requests that were initiated in FY 2004 or FY 2005.

Table 3-2: Departments and Agencies that Received Information Quality Appeals Requests in FY 2006, Following Responses to Requests Initiated in FY 2004 or FY 2005

| Agency | Number of FY06 Appeals |
|---|-------------------------------|
| Department of Health and Human Services | 2 |
| Department of Labor | 2 |
| Environmental Protection Agency | 2 |
| Total | 6 |

Details concerning the 22 requests and 6 appeals can be found at the agencies' Information Quality websites (see Appendix C-1 for a link to agency web pages). The correction requests received in FY 2006 were as diverse and interesting as those received in previous years. For instance, the Department of Defense received a request for correction from the Center for Regulatory Effectiveness regarding a report on predatory lending practices directed at members of the armed forces and their dependents; the Department of Health and Human Services received two requests from the National Legal and Policy Center regarding disseminations made by the Substance Abuse and Mental Health Services Administration (SAMHSA) concerning the

health effects of smokeless tobacco; the Fish and Wildlife Service (part of the Department of the Interior) received a correction request on behalf Coloradoans for Water Conservation and Development and the Colorado Farm Bureau regarding disseminations concerning the Preble’s meadow jumping mouse; and EPA received a request for correction from a private corporation regarding information disseminated in an enforcement and compliance database.

Figure 3-1 shows the status of the 22 FY 2006 correction requests. For details relating to the specific requests, including agency responses, readers are encouraged to visit agency Information Quality websites. As shown below, this year we are categorizing how agencies responded to requests in a more detailed manner. For instance, we are including the category of “other corrections.” This category is used when the agency response does not provide the specific changes that were requested, but instead makes other changes. For example, instead of modifying information on the webpage related to smokeless tobacco, SAMHSA chose to remove the information completely while the agency works on revisions. Because the requestor asked for revisions to the information rather than removal, this has been classified in the “other corrections” category. OMB continues to use the “other processes/mechanisms” category to describe responses that were handled by other pre-existing processes at the agencies. For example, a request to EPA regarding information in its underground injection rule that is being challenged in the courts was not substantively addressed through the Information Quality process. Instead, EPA stated that the litigation and settlement discussions will be addressing similar issues and that if these processes do not resolve the requestor’s information quality concerns, the requestor could then resubmit a new request for correction.

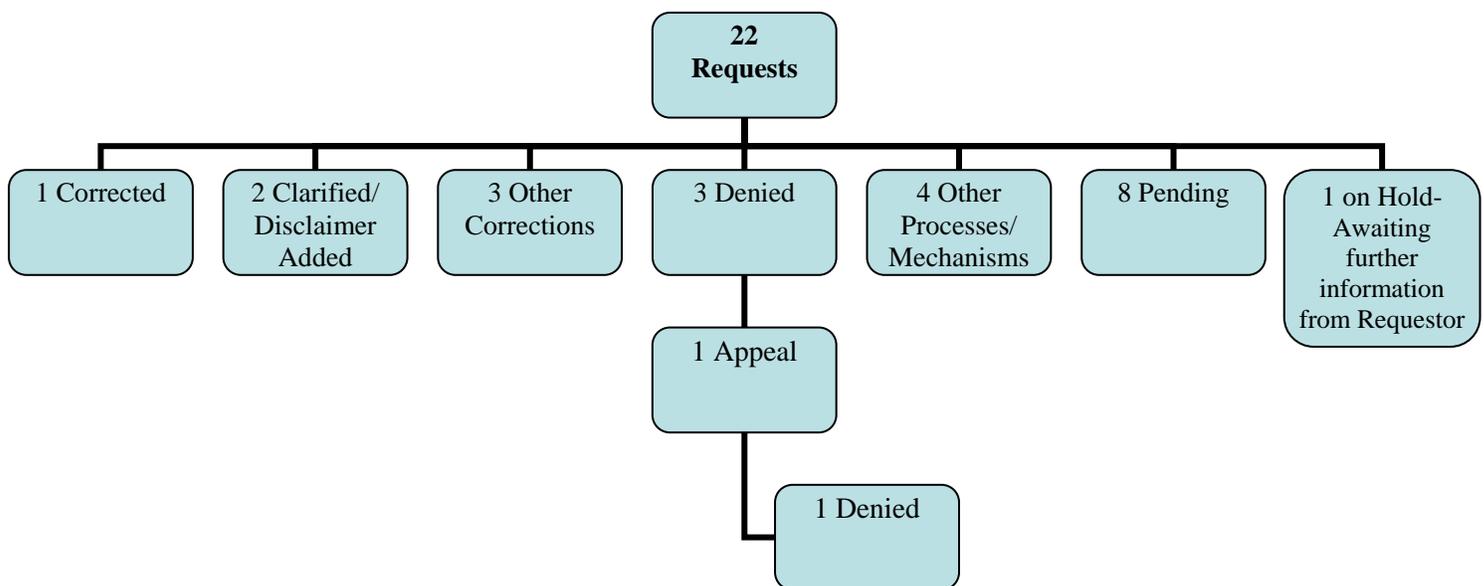


Figure 3-1: Status of IQ Correction Requests Received in FY2006

As noted in our 2006 final Report,⁶¹ 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, and in FY 2005 there were 24 correction requests.

Status of Outstanding Correction Requests Received by the Agencies in FY 2003-05

At the close of FY 2005, 13 Information Quality correction request responses and 6 appeal responses were pending from the agencies. Figure 3-2 shows the status of those outstanding correction request responses at the close of FY 2006. Agencies have responded to eight of these correction requests and were still working on responses to the remaining five.

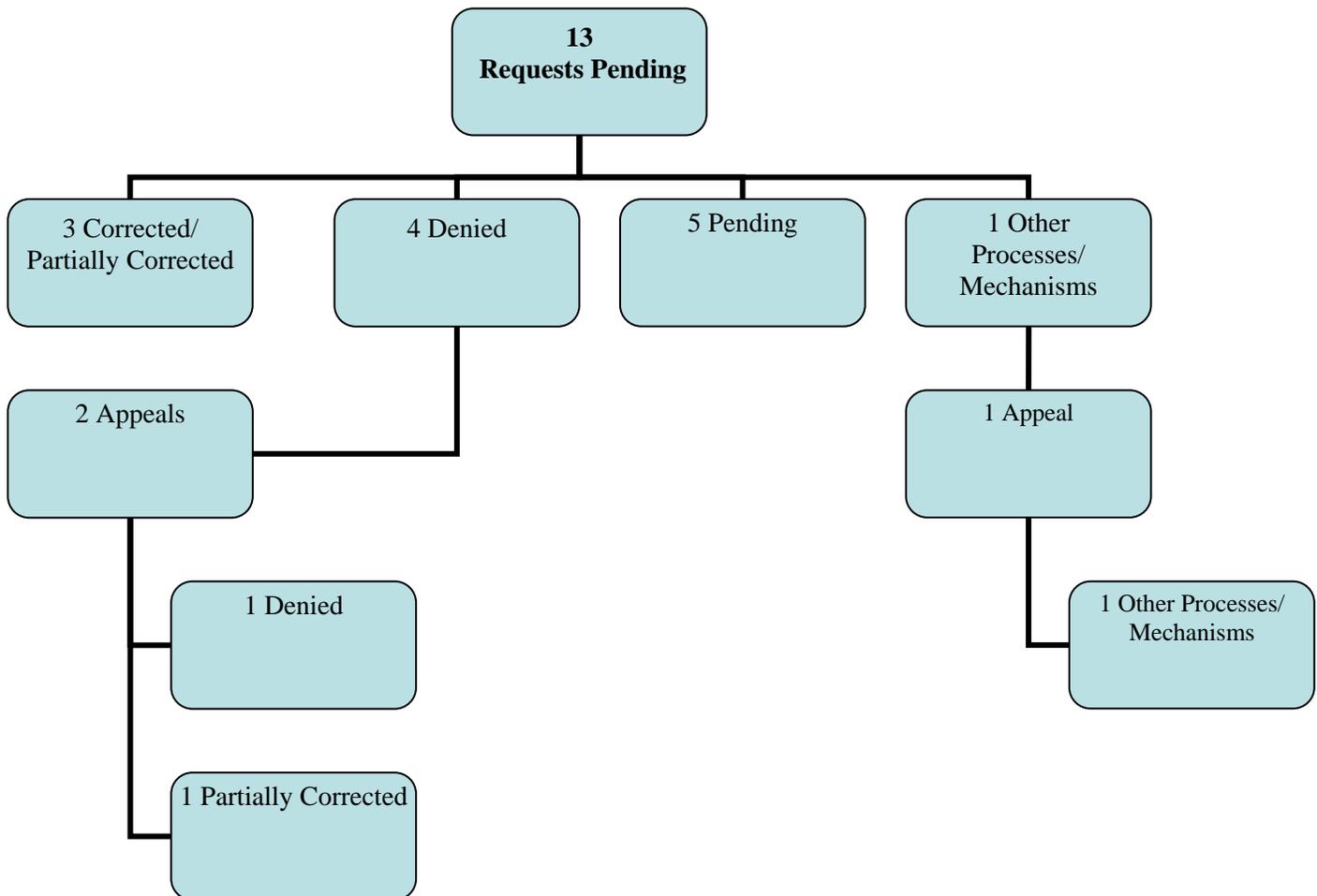


Figure 3-2: FY 2006 Status of Pending Correction Requests from FY 2004 and FY 2005

⁶¹ See 2006 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/2006_cb/2006_cb_final_report.pdf.

Figure 3-3 shows the status of the 6 appeal requests that were pending at the close of FY 2005. As this figure shows, two appeal responses are still pending. The Department of Transportation is continuing to work on its response to an appeal request it received in FY 2004 regarding the Federal Aviation Administration’s Age 60 rule, and the Environmental Protection Agency is continuing to work on its response to an appeal request it received in FY2005 regarding some of its environmental databases.

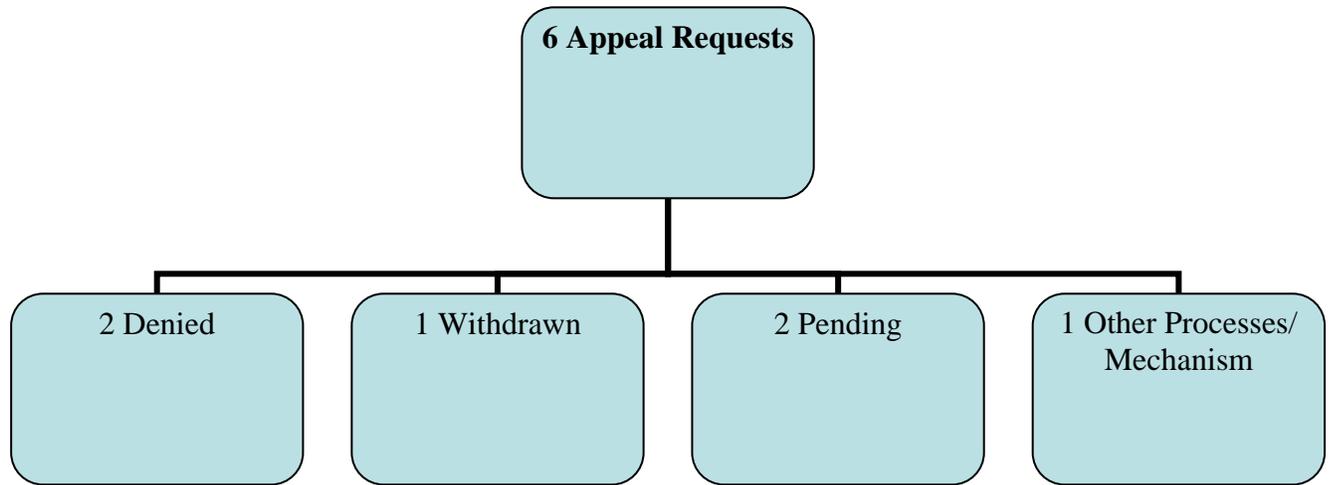


Figure 3-3: FY 2006 Status of Pending Appeal Requests from FY 2003, FY 2004, and FY 2005

B. Peer Review Process

The 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 Bulletin).⁶² The Bulletin requires executive agencies to ensure that all “influential scientific information” they disseminate after *June 16, 2005* has been peer reviewed.

“Influential scientific information” is defined as “scientific information the agency reasonably can determine will have or does have a clear and substantial impact on important public policies or private sector decisions.”⁶³ In the term “influential scientific information,” the

⁶² See <http://www.whitehouse.gov/omb/memoranda/fy2005/m05-03.pdf>

⁶³ 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 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.

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

One type of scientific information is a scientific assessment. For the purposes of the 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.⁶⁴

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

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

The 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. These mechanisms are discussed in detail in subsequent sections of this chapter.

⁶⁴ 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.

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

On June 16, 2005, the 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. FY 2006 was the first full year of implementation.

Peer Review Planning

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

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

The agenda is designed to encourage planning for peer review early in the information generation process; thus, the agenda should cover all information subject to the 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 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 disseminate (or peer review) in the next six months).

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

Readers are encouraged to visit the agendas for agencies of interest. We have asked 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, we requested that a hyperlink to each agency agenda be provided. Appendix C-2 provides the URLs for most agencies' peer review agendas.

Cabinet level departments with processes in place for proactively identifying documents subject to the Bulletin include the Departments of Agriculture, Commerce, Energy, Health and Human Services, Interior, Labor, and Transportation. Other agencies with processes in place for proactively identifying documents subject to the Bulletin include the Consumer Product Safety Commission, the Environmental Protection Agency, and the Federal Communications Commission.

There is another group of agencies that does, from time to time, produce or sponsor influential scientific information, but has not currently identified forthcoming information products subject to the Bulletin. We are 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, Housing and Urban Development, Justice, State 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. We are also working to improve peer review planning in a few agencies that are located within some of the larger departments that do have proactive policies in place (e.g., Agriculture and Energy). The Department of Homeland Security does not yet have a site; we are working with the department on this issue.

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

Although the Peer Review Planning Section of the Bulletin lays out the specific items that should be included in each peer review plan, OMB does not specify the format that agencies should use, thereby giving agencies the flexibility to incorporate their agendas into existing e-government and science planning initiatives.⁶⁵ 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,⁶⁶ while other departments have chosen to have individual agencies host their own agendas.⁶⁷ Furthermore, some agencies have chosen to provide a single agenda for both influential scientific information and highly influential scientific assessments,⁶⁸ while others provide two separate agendas.⁶⁹ The Bulletin specifically requires that agencies provide

⁶⁵ For instance, the Environmental Protection Agency's incorporation with its science inventory project

⁶⁶ For instance, the agenda for the Department of Transportation

⁶⁷ For instance, the agendas for the Department of Health and Human Services and the Department of the Interior

⁶⁸ For instance, the agenda for the Department of Commerce

⁶⁹ For instance, the agenda for the Department of Transportation

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,⁷⁰ 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.⁷¹ OMB is currently working with all of the agencies to ensure that the required information is posted and to ensure that the web sites are easy to locate and navigate. Among the agencies with active agendas, OMB finds the Department of Health and Human Services' Center for Disease Control's agenda particularly informative and easy to navigate.

FY 2006 Annual Report of Agency Peer Reviews

The Annual Reports Section (Section VI) of the 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 2006 constituted the first full year of implementation for the Bulletin. Agencies were requested to complete a template for reporting peer reviews that were completed pursuant to the Bulletin between October 1, 2005 and September 30, 2006 as well as the other information specified in Section VI. In general, the agencies have made important progress in implementing the Bulletin, summarized below in Table 3-3. We will continue to work with each of the agencies over the next year to ensure further progress.

For FY 2006, agencies reported to OMB that they conducted 159 peer reviews that fell within the scope of the Bulletin's provisions. This number includes all such peer reviews that were conducted, regardless of whether the final peer review report has been completed. Of the 159 reviews, 34 were reviews of highly influential scientific assessments.

We are aware that many of these reported peer reviews were part of preexisting processes, consistent with agency's or program's pre-Bulletin policy to conduct peer reviews of scientific information. Because we do not have baseline information as to how many peer reviews were conducted during FY 2005 and prior years, we are not in a position to say how many of the 159 peer reviews during FY 2006 were conducted specifically as a result of the Bulletin. However, we understand that additional peer reviews were indeed conducted in FY 2006. Even for those reviews that would have happened in the absence of the Bulletin, it is our understanding that the Bulletin has encouraged additional rigor, strengthening the underlying

⁷⁰ 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.)

⁷¹ 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>)

peer review process. As we and the agencies gather more experience, it will be easier in future years to identify and characterize trends.

Across all of the agencies, only one waiver, no deferrals, and no exemptions were invoked. The waiver was issued by the Fish and Wildlife Service (the Service) for the information underlying its annual regulations for hunting migratory game birds.⁷² The assessments underlying these decisions are subject to review and input from technical experts, but the Service determined that due to the extremely limited time between when data are collected and analyzed and decisions must be made regarding the hunting seasons, it was not possible to follow the requirements of the Bulletin for these reviews.

OMB acknowledges that peer review as described in the 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 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.⁷³

Sections II(3) and III(3) of the Bulletin lay out criteria for selection of peer reviewers, including expertise, balance, independence, and lack of conflict of interest. The 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 2006, agencies rarely found a 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. Specifically, only four peer reviews, all conducted by the Service, used reviewers pursuant to an exception in FY 2006.⁷⁴ We hope that the infrequent need for this exemption, as seen in this first year of implementation, alleviates concerns raised by some public commenters that agencies would not be able to identify sufficient external reviewers.

The preamble to the Bulletin discusses how public participation in peer review can be a potentially important aspect of obtaining a high quality product through a transparent process. As such, the Bulletin encourages public participation whenever feasible and appropriate. Examples of public participation processes include open peer review panels, public meetings, and requests for written comments. For peer reviews completed in FY 2006, 19 included public meetings. Public comments were solicited as a component of many of the review processes that had been underway before the introduction of the Bulletin; however, it is not clear whether such comments were (or are now) routinely shared with the peer reviewers.

⁷² <http://www.fws.gov/migratorybirds/MBPeerReviewWaiver.pdf>

⁷³ <http://www.cio.noaa.gov/itmanagement/prplans/ID22.html>

⁷⁴ These were reviews for the FY 2005 Investigational Report: Incidence of *Ceratomyxa Shasta* and *Parvicapsula mimibicornis* by histology and QPCR in juvenile Klamath River Chinook Salmon; the Willowy monardella Proposed Critical Habitat; the Idaho Springsnail 12-month finding; and the Three Willamette Valley Species (Fender’s Blue Butterfly, Kincaid’s Lupine, and Willamette Daisy) Final Critical Habitat Determination.

Section V (3) of the Bulletin requires agencies to establish a mechanism for allowing the public to comment on the adequacy of agency peer review plans. Very few members of the public took advantage of the opportunity to provide comments on the several hundred peer review plans posted by Federal agencies over the last year. A total of nine comments were provided to agencies. We are 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. We welcome public input on this issue.

C. Response to Peer Reviews and Public Comments on Update on the Implementation of the Information Quality Act

Commenter (C) commented that this chapter provided an inadequate analysis of benefits and costs of the Information Quality Act and was deficient in that the chapter did not provide the percentage of substantive challenges and the average agency response times. The commenter recommended that OMB ask agencies for an estimate of benefits and costs, provide a section on recommendations for improvements in data quality procedures, provide information on agency response times to IQA challenges, perform an analysis on the percentage of substantive challenges. This commenter supports OMB's requirement that agencies post all information quality correspondence and suggested that OMB discuss what is being done to ensure agency compliance with the transparency requirement to post all information quality correspondence. Commenter (B) suggested that OMB create a Web site for tracking the status of requests for correction.

OMB appreciates these comments and will consider them for future chapters and updates. However, we note that it is very difficult for the agencies to calculate the benefits and costs of information changes and to tie these changes specifically to the Information Quality Act. Additionally, OMB continues to work closely with the agencies on an individual basis to ensure their compliance with transparency requirements and to help improve the timeliness of agency responses.

Commenter (B), suggested that OMB ask the Department of Justice to revisit the legal issue of whether agency responses to IQA requests for correction are not subject to judicial review. In this regard, another court recently concluded, in agreement with prior court rulings, that agency responses are not subject to judicial review. *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) (citing *Salt Institute v. Leavitt*, 440 F.3d 156, 159 (4th Cir. 2006), and *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.).

Peer reviewers (1 and 3) commented that OMB's reporting on the implementation of the Information Quality Bulletin for Peer Review would be improved by providing an indication of the total scientific disseminations each agency made during the fiscal year. That is, they suggest that if there was a denominator for each of the numbers provided in Table 3-3 it would be

possible to determine what proportion of the influential scientific information (or broader category of scientific information) that an agency disseminates goes through peer review.

Conceptually, this is a good suggestion, but it would very difficult to implement for two reasons. First, the Bulletin's definition of 'dissemination' includes scientific information that an agency uses as the basis for important policy decisions, regardless of whether the agency itself produced that information. Second, those agencies that do produce scientific information tend to produce a very large number and variety of types of disseminations every year. For those agencies, OMB thinks it is safe to assume that the items classified as "influential" scientific information are probably a small number of their total scientific disseminations. For agencies with strong systems in place (especially, NOAA, FWS, MMS, CDC, APHIS, FSIS, EPA and most of the DOT agencies), the numbers that show up in these tables are likely a reasonable representation of the disseminations that the agency determines are influential scientific information.

Table 3-3: Peer Reviews Conducted Subject to the Bulletin in FY 2006

| 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 ⁷⁵ | 19 | 8 | None | None | None | 3 |
| Department of Commerce ⁷⁶ | 19 | 3 | None | None | 6* | None |
| Department of Defense ⁷⁷ | 2 | 2 | None | None | 1 | NA |
| Department of Energy ⁷⁸ | 1 | 1 | None | None | 1 | None |
| Department of Health and Human Services ⁷⁹ | 31 | 6 | None | None | 3 | 1 |
| Department of the Interior ⁸⁰ | 51 | 1 | 1 (Waiver) | 4 | 1 | 1 |
| Department of Labor ⁸¹ | 2 | 1 | None | None | None | None |
| Department of Transportation ⁸² | 12 | 5 | None | None | None | 1 |
| Consumer Product Safety Commission | 4 | 3 | None | None | None | None |
| Environmental Protection Agency | 15 | 4 | None | None | 7 | 3 |
| Federal Communications Commission | 3 | None | None | None | None | None |
| Total | 159 | 34 | 1 | 4 | 19 | 9 |

* Incomplete count (minimum number)

⁷⁵ 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.

⁷⁶ The Department of Commerce agency reporting peer reviews in FY 2006 was the National Oceanic and Atmospheric Administration.

⁷⁷ The Department of Defense agency reporting peer reviews in FY 2006 was the Army Corps of Engineers.

⁷⁸ The Department of Energy peer reviews reported in FY 2006 were associated with climate change science.

⁷⁹ 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.

⁸⁰ The Department of the Interior agency reporting peer reviews in FY 2006 was the Fish and Wildlife Service

⁸¹ The Department of Labor agency reporting peer reviews in FY 2006 was Employee Benefits Security Administration.

⁸² 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

APPENDIX A: CALCULATION OF BENEFITS AND COSTS

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

- Rules from October 1, 1995 to September 30, 1996 appear in Table B-1 in Appendix B of this 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 this Report.

In assembling estimates of benefits and costs presented in Table 1-4, OMB has:

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

All benefit and cost estimates were adjusted to 2001 dollars using the latest Gross Domestic Product (GDP) deflator, available from the Bureau of Economic Analysis at the Department of Commerce.⁸³ In instances where the nominal dollar values the agencies use for their benefits and costs is unclear, we assume the benefits and costs are presented in nominal dollar values of the year before the rule is finalized. In periods of low inflation such as the past few years, this assumption does not impact the overall totals. All amortizations are performed using a discount rate of 7 percent, unless the agency has already presented annualized, monetized results using a different explicit discount rate.

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

⁸³National Income and Product Accounts, available at <http://www.bea.gov>

adoption of a uniform format for annualizing agency estimates allows, at least for purposes of illustration, the aggregation of benefit and cost estimates across rules; however, the agencies have used different methodologies and valuations in quantifying and monetizing effects. Thus, an aggregation involves the assemblage of benefit and cost estimates that are not strictly comparable.

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

Table A-1 below presents the unmodified information on the impacts of ten major rules reviewed by OMB from October 1, 2005 through September 30, 2006, and includes additional explanatory text on how agencies calculated the impacts for these rulemakings. Unless otherwise stated, the totals presented in Table A-1 are annualized impacts in 2001 dollars, which is the requested format in OMB Circular A-4. Table 1-4 in Chapter I of this Report presents the adjusted impact estimates for the seven rules finalized in 2005-06 that were added to the Chapter I accounting statement totals.

Table A-1: Summary of Agency Estimates for Final Rules
 October 1, 2005 to September 30, 2006 (As of Date of Completion of OMB Review)

| Rule [FR Cite] | Agency | Benefits | Costs | Other Information |
|--|---------------|--|---|--|
| Electronic Prescribing Standards [70 FR 67567] | HHS-CMS | \$222-747 million (\$2006) per year from 2060-2010 | \$93-310 million (\$2006) per year from 2006-2010 | Benefits and Costs are based on assumed one-time and ongoing costs of adopting these standards, and the percent of cost savings for each plan after adoption of the standards. CMS also assumed an approximately \$30 million transfer from Health plans to prescribers, due to the expectation that many plans will provide incentives to prescribers to offset at least some of the prescribers' initial cost of installing hardware and software. The full RIA was published in the FR preamble to the final rule. |
| Air Cargo Security Requirements [71 FR 30478] | DHS-TSA | Homeland Security | \$204-\$206 million per year | Benefits: The goal of this regulation is to protect our society from acts of terrorism involving the use of aircraft. This regulation contains provisions that would prevent unauthorized persons, explosives, incendiaries, and other destructive substances or items from being introduced into the air cargo supply chain. The full RIA is available online at http://dms.dot.gov/ . The document number is TSA-2004-19515-166. |

| Rule [FR Cite] | Agency | Benefits | Costs | Other Information |
|---|---------|--|---------------|--|
| Migratory Bird Hunting; 2006-2007 Migratory Game Bird Hunting Regulations: Early Season [71 FR 51406] | DOI-FWS | \$899 (\$734 million - \$1.0 billion) (\$2003) | 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, but did not update that estimate for the 2006-2007 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.migratorybirds.gov.</p> |
| Migratory Bird Hunting; 2006-2007 Migratory Game Bird Hunting Regulations: Late Season [71 FR 55676] | DOI-FWS | See “Early Season” benefits above. | Not Estimated | <p>See “Other Information” for Early Season rule above.</p> <p>The RIA is available online at http://www.migratorybirds.gov.</p> |

| Rule [FR Cite] | Agency | Benefits | Costs | Other Information |
|--|----------|--------------------------|----------------------|--|
| Occupational Exposure to Hexavalent Chromium [71 FR 10100] | DOL-OSHA | \$36 - \$896 million/yr. | \$244-253 million/yr | <p>Benefits: The benefit of this rulemaking is based on OSHA's estimate that the rulemaking would prevent 40-145 fatal and 5-20 non-fatal lung cancers per year. OSHA also quantified, but did not monetize, an estimated benefit of avoiding 332-1140 nasal perforations per year.</p> <p>Costs: OSHA's estimated annual compliance costs are based on installing engineering controls and the purchase and use of supplemental respirators at the new Permissible Exposure Limit.</p> <p>Other details: The rulemaking also includes an estimate of a \$5.5 million transfer from employers to employees due to a requirement that employers pay for personal protective equipment already required by other rulemakings.</p> <p>The RIA is available at http://dockets.osha.gov/search/browseDockets.asp?dm=1 under "Hexavalent Chromium (H054A)"</p> |

| Rule [FR Cite] | Agency | Benefits | Costs | Other Information |
|--|-----------|--|---|---|
| Congestion and Delay Reduction at Chicago O'Hare International Airport [71 FR 51381] | DOT-FAA | \$475.6 million (net present value from 10/06-10/08) (\$2005) | Less than \$1 million (net present value from 10/06-10/08) | <p>Key Assumptions [71 FR 51399]</p> <p>Baseline Flight Operations--Official Airline Guide (OAG) Schedule November 20, 2003 of 1,464 daily arrival flights (OAG plus 96 unscheduled).</p> <p>Daily Flight Completion Factor: 97 percent/Daily Flight Cancellation Factor: 3 percent.</p> <p>No lost revenue due to cancelled flights--All Passengers are rebooked or rerouted to their destination.</p> <p>Delay improvements are 9.6 minutes per flight and equivalent to a 32 percent improvement in delay. We derive delay improvements from MITRE's Queuing Delay Model, which measures queuing delays against the OAG flight schedule.</p> <p>For this evaluation, the effective date is 10/29/06 and the sunset date is 10/31/08. We adjust annual estimates to reflect the 1.5 days per week when the limits are not in effect (all-day Saturday and until noon on Sunday).</p> <p>Other Important Assumptions</p> <p>Discount Rate—7 percent.</p> <p>Assumes 2005 Current Year Dollars.</p> <p>Final rule will sunset October 31, 2008.</p> <p>Ground and Airborne average cost per hour--\$1,935.</p> <p>Passenger Value of Time--\$28.60 per hour.</p> <p>The full Regulatory Evaluation is available online at: http://dmses.dot.gov/docimages/pdf97/411992_web.pdf</p> |
| Average Fuel Economy Standards for Light Trucks Model Years 2008-11 [71 FR 17566] | DOT-NHTSA | <p>2008: \$782 – 968 million</p> <p>2009: \$2,015 – 2,492 million</p> <p>2010: \$2,336 – 2,857 million</p> <p>2011: \$2,992 – 3,676 million (\$2003)</p> | <p>2008: \$536 – 553 million</p> <p>2009: \$1,621- 1,724 million</p> <p>2010: \$1,752 – 1,903 million</p> <p>2011: \$2,531 million (\$2003)</p> | <p>Benefits and costs are expressed as present values over the lifetime of each corresponding model year, discounted to the year of vehicle production. The lower (upper) ends of the ranges of benefits reflect use of a 7 (3) percent discount rate. The ranges of cost estimates for model years 2008-2010 reflect the fact that manufacturers can choose between the unreformed and reformed approaches to comply with the standard for those model years.</p> <p>The full Regulatory Impact Analysis is available online at: http://www.nhtsa.dot.gov/staticfiles/DOT/NHTSA/Rulemaking/Rules/Associatedpercent20Files/2006_FRIAPublic.pdf</p> |

| Rule [FR Cite] | Agency | Benefits | Costs | Other Information |
|---|---------------|------------------------------------|--|---|
| Standards of Performance for Stationary Compression Ignition Internal Combustion Engines [71 FR 39154] | EPA-Air | \$1.36 billion in 2015 (\$2002) | \$57 million in 2015 (annualized \$2002) | The full RIA is available online at: http://www.epa.gov/ttnecas1/regdata/RIAs/ci_nsps_ria_reportfinal06.pdf |
| Review of the National Ambient Air Quality Standards (NAAQS) for Particulate Matter [71 FR 61144] | EPA-Air | \$8 – 76 billion/yr. (\$1999) | \$5.4 billion/yr. (\$1999) | The benefit and cost estimates are based on full attainment of the PM standards incremental to the full attainment of the 1997 standards. The RIA contains a detailed discussion of other effects of this rule that were not included in the monetized estimates that is too lengthy to reproduce here. The full RIA is available online at: http://www.epa.gov/ttn/ecas/ria.html |
| National Primary Drinking Water Regulations: Stage 2 Disinfection Byproducts Rule [71 FR 388] | EPA-Water | \$621 – 1,531 million/yr. (\$2003) | \$77 – 79 million/yr. (\$2003) | The full RIA is available online at: http://www.epa.gov/safewater/disinfection/stage2/pdfs/anaylsis_stage2_economic_main.pdf |

APPENDIX B: THE BENEFITS AND COSTS OF 1995-1996 MAJOR RULES

Table B-1 lists the rules that were omitted from the ten-year running totals presented in Chapter 1 of our Reports to Congress. It consists of the annualized, monetized benefits and costs of rules for which OMB concluded review between October 1, 1995 and September 30, 1996. These rules were included in Chapter 1 of the 2006 Report as part of the ten-year totals, but are not included in the 2007 Report.

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

**Table B-1: Estimates of Annual Benefits and Costs of Twelve Major Federal Rules
October 1, 1995 to September 30, 1996**
(millions of 2001 dollars)

| REGULATION | AGENCY | BENEFITS | COSTS | EXPLANATION |
|--|-----------------|-----------|---------|---|
| Meat and Poultry Hazard Analysis and Critical Control Points (HACCP) | USDA-FSIS | 76-3,055 | 109-130 | We amortized the agency's present value estimates over 20 years. |
| Seafood HACCP | HHS-FDA | 120-218 | 55-131 | We amortized the agency's present value estimates over 20 years. |
| Food/Nutrition Labeling; Small Business Exemption | HHS-FDA | 327-426 | 2 | No adjustment to agency estimate |
| Medical Devices: Quality Systems Regulation | HHS-FDA | 316-338 | 98 | We valued each fatality avoided at \$5 million and each serious injury avoided at approximately \$130,000. |
| Vessel Response Plans | DOT-Coast Guard | 44 | 305 | We valued the agency's estimated 22,000 barrels of oil prevented from being spilled per year at \$2,000 per barrel. |
| Petroleum refinery NESHAP | EPA-Air | 150-675 | 89-122 | We valued annual VOC emissions reductions at \$600-\$2,700 per ton. |
| Air Emissions from Municipal Solid Waste Landfills | EPA-Air | 65-229 | 109 | We valued annual VOC emissions reductions at \$600-\$2700 per ton. |
| Municipal Waste Combustors | EPA-Air | 71-736 | 349 | We valued SO ₂ , PM, and NO _x emissions reductions using the values in Appendix B of the 2006 Report to Congress |
| Accidental Release Prevention | EPA-Air | 185 | 109 | No adjustment to agency estimates. |
| Financial Assurance for Municipal Solid Waste Landfills | EPA-OSWER | 120 | 0 | No adjustment to agency estimates. |
| Deposit Control Gasoline | EPA-Air | 120-1,170 | 151 | We valued annual VOC and NO _x emissions reductions using the values in Appendix B of the 2006 Report to Congress. We did not value changes in CO emissions. |
| Federal Test Procedure Revisions | EPA-Air | 425-4,238 | 218-273 | We annualized VOC and NO _x emissions, which yielded average annual reductions of 350,000 tons of NO _x and 66,000 tons of VOC. We then valued these annual emissions reductions using the values in Appendix B of the 2006 Report to Congress. We did not value changes in CO emissions. |

APPENDIX C-1: LINKS FOR AGENCY INFORMATION QUALITY CORRESPONDENCE

Links to Agencies that received correction requests in FY 2006:

Department of Commerce: http://www.osec.doc.gov/cio/oipr/IQ_request_for_correction_05.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/2005percent20UPPERpercent20MSpercent20RIVERpercent20RFC/index.html>

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

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

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

Department of Transportation: <http://dms.dot.gov/cfreports/dataQuality.cfm>

Department of Transportation, Surface Transportation Board:
<http://www.stb.dot.gov/stb/InformationQualityGuidelines.htm>

Consumer Products Safety Commission: <http://www.cpsc.gov/library/correction/correction.html>

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

Links to Other Agencies IQ Correspondence Web Pages:

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

Commodity Futures Trading Commission: <http://www.cftc.gov/cftc/cftcquality.htm>

Corporation for National and Community Service:
http://www.nationalservice.gov/home/site_information/quality.asp

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

Chemical Safety and Hazard Investigation Board:
http://www.csb.gov/index.cfm?folder=legal_affairs&page=index

Defense Nuclear Facilities Safety Board: http://www.dnfsb.gov/about/information_quality.html

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

Department of Commerce: http://www.osec.doc.gov/cio/oipr/info_qual.html

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/2005percent20UPPERpercent20MSpercent20RIVERpercent20RFC/index.html>

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

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

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

Department of Housing and Urban Development:

<http://www.hud.gov/offices/adm/grants/qualityinfo/qualityinfo.cfm>

Department of Interior: <http://www.doi.gov/ocio/iq>

Department of Interior, Bureau of Land Management: <http://www.blm.gov/nhp/efoia/index.htm>

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

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

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

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

Department of Transportation: <http://dms.dot.gov/cfreports/dataQuality.cfm>

Department of Transportation, Surface Transportation Board:

<http://www.stb.dot.gov/stb/InformationQualityGuidelines.htm>

Department of Veteran Affairs: http://www.va.gov/OIT/CIO/s515/Information_Quality.asp

Equal Employment Opportunity Commission:

<http://www.eeoc.gov/policy/guidelines/index.html>

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

Farm Credit Administration: <http://www.fca.gov/informationquality.htm>

Federal Communications Commission: <http://www.fcc.gov/omd/dataquality/requests2004.html>

Federal Deposit Insurance Corporation: <http://www.fdic.gov/about/policies/#information>

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

Federal Maritime Commission:
<http://www.fmc.gov/reading/IntroInformationQualityGuidelines.asp?PRINT=Y>

Federal Reserve Board: <http://www.Federalreserve.gov/GeneralInfo/Section515/mechanism.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_OVERVIEW

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/readingroomcontents.html>

National Archives: <http://www.archives.gov/about/info-qual/requests/index.html>

National Aeronautics and Space Administration: <http://www.sti.nasa.gov/qualinfo.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/index.html>

National Labor Relations Board:
http://www.nlr.gov/about_us/public_notices/information_on_quality_guidelines.aspx

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

National Science Foundation: <http://www.nsf.gov/policies/infoqual.jsp>

National Transportation Safety Board: <http://www.nts.gov/info/quality.htm>

Nuclear Waste Technical Review Board: <http://www.nwtrb.gov/plans/plans.html>

Office of Government Ethics: http://www.usoge.gov/pages/about_oge/info_quality.html

Office of Federal Housing Enterprise Oversight:
<http://www.ofheo.gov/information.asp?section=17>

Office of Management and Budget:

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

Overseas Private Investment Corporation: <http://www.opic.gov/pubs/qualityguidelines/index.asp>

Office of Personnel Management: <http://www.opm.gov/policy/webpolicy/index.asp>

Office of Special Counsel: <http://www.osc.gov/InfoQuality.htm>

Pension Benefit Guaranty Corporation: <http://www.pbgc.gov/media/key-resources-for-the-press/content/page5274.html>

Peace Corps: <http://www.peacecorps.gov/index.cfm?shell=pchq.policies.docs>

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/>

USAID: http://www.usaid.gov/policy/info_quality/

U.S. International Trade Commission: http://www.usitc.gov/policies/info_quality.htm

APPENDIX C-2: LINKS FOR AGENCY PEER REVIEW AGENDAS

A. Cabinet-Level Departments

Department of Agriculture

http://www.ocio.usda.gov/qi_guide/qoi_officer_1st.html

Food Safety Inspection Service:

http://www.fsis.usda.gov/Information_Quality/Peer_Review/index.asp

Animal and Plant Health Inspection Service

http://www.aphis.usda.gov/about_aphis/peer_review-agenda.shtml

Office of the Chief Economist:

http://www.usda.gov/oce/peer_review

Grain Inspection, Packers, and Stockyard Inspection Administration:

<http://www.gipsa.usda.gov/GIPSA/webapp?area=home&subject=iq&topic=pr>

Forest Service:

<http://www.fs.fed.us/qoi/peerreview.shtml>

Economic Research Service:

<http://www.ers.usda.gov/AboutERS/QualityGuidelines.htm>

Agricultural Research Service:

<http://www.ars.usda.gov/Main/docs.htm?docid=8040>

Department of Commerce

http://www.osec.doc.gov/cio/oipr/pr_plans.htm

National Oceanic and Atmospheric Administration:

http://www.osec.doc.gov/cio/oipr/pr_plans.htm

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 Homeland Security

No site

Department of Health and Human Services

<http://aspe.hhs.gov/infoquality/peer.shtml>

Food and Drug Administration: <http://www.fda.gov/oc/peerreview/>

National Toxicology Program:

<http://fmp.cit.nih.gov/sif/FMPro?-DB=SIF.fp5&-Format=agenda.html&-View>

Center for Disease Control: <http://www2a.cdc.gov/od/peer/peer.asp>

Department of Housing and Urban Development

<http://www.hud.gov/offices/adm/grants/qualityinfo/infoqualityhisia.cfm>

Department of the Interior

http://www.doi.gov/ocio/iq_1.html

U.S. Geological Society: http://www.usgs.gov/peer_review/

Mineral Manangement Service:

<http://www.mms.gov/qualityinfo/PeerReviewAgenda.htm>

Fish and Wildlife Service:

http://www.fws.gov/informationquality/peer_review/index.html

Bureau of Land Management: http://www.blm.gov/nhp/efoia/peer_review.htm

Bureau of Reclamation: <http://www.usbr.gov/main/qoi/peeragenda.html>

Office of Surface Mining: <http://www.osmre.gov/Peerreview.htm>

National Park Service: under construction

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/peer.htm>

Department of Veterans Affairs

<http://www.va.gov/OIT/CIO/s515/Default.asp#PRP>

B. Other Agencies

Consumer Product Safety Commission

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

Environmental Protection Agency

http://cfpub.epa.gov/si/si_pr_agenda.cfm

Federal Communications Commission

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

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>

**APPENDIX C-3: LINKS FOR AGENCIES THAT DO NOT PRODUCE OR SPONSOR INFORMATION
SUBJECT TO THE BULLETIN**

Department of the Treasury

<http://www.treas.gov/offices/cio/information-management/infoqual.shtml>

Agency for International Development

http://www.usaid.gov/policy/info_quality/#peerreview

Corporation for National and Community Service

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

Council on Environmental Quality

No site

Equal Employment Opportunity Commission

<http://www.eeoc.gov/policy/guidelines/index.html>

Farm Credit Association

<http://www.fca.gov/informationquality.htm>

Federal Maritime Commission

<http://www.fmc.gov/reading/IntroInformationQualityGuidelines.asp>

General Services Administration

<http://www.gsa.gov/section515>

Institute of Museum and Library Services

<http://www.ims.gov/about/guidelines.shtm>

Merit Systems Protection Board

No site

National Archives

<http://www.archives.gov/about/info-qual/peer-review.html>

National Credit Union Administration

No site

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>

Nuclear Waste Technical Review Board

<http://www.nwtrb.gov/meetings/meetings.htm>

Office of Federal Housing Enterprise Oversight

www.ofheo.gov/Information.asp?Section=17

Office of Government Ethics

www.usoge.gov/pages/about_oge/info_quality.html

Office of Personnel Management

<http://www.opm.gov/policy/webpolicy/index.asp>

Overseas Private Investment Corporation

<http://www.opic.gov/pubs/qualityguidelines/index.asp>

Peace Corps

<http://www.peacecorps.gov/index.cfm?shell=pchq.policies.docs>

Patent and Trade Office

http://www.uspto.gov/main/policy/infoquality_peer.htm

Pension Benefit Guaranty Corporation

<http://www.pbgc.gov/media/key-resources-for-the-press/content/page5274.html#3>

Securities and Exchange Commission

No site

Selective Services System

No site

Social Security Administration

www.socialsecurity.gov/515/peerreview.htm

Surface Transportation Board

<http://www.stb.dot.gov/stb/InformationQualityGuidelines.htm>

APPENDIX D: PEER REVIEW AND PUBLIC COMMENTS

OMB wishes to express its sincere appreciation for the thoughtful comments we received on the draft 2007 Report. In particular, we would like to thank our invited peer reviewers: Scott Farrow (Department of Economics, University of Maryland, Baltimore County), Robert Hahn and Robert Litan (AEI-Brookings Joint Center for Regulatory Studies), and Richard A. Williams (Mercatus Center, George Mason University). Below is a listing of all the written comments submitted to OMB, and the numbers of letters we have assigned to their comments. The public and peer review comments are available for review at [Insert Link].

Peer Reviewers

1. Scott Farrow, Department of Economics, University of Maryland, Baltimore County
2. Robert W. Hahn, and Robert E. Litan, AEI-Brookings Joint Center for Regulatory Studies
3. Richard A. Williams, Mercatus Center, George Mason University

Public Comments

- A. Thomas W. Curtis, American Water Works Association
- B. Lawrence A. Fineran, National Association of Manufacturers
- C. Rick E. Melberth, OMB Watch
- D. Amy Sinden, Center for Progressive Reform

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

INTRODUCTION

This report represents OMB's twelfth annual submission to Congress on agency compliance with the Unfunded Mandates Reform Act of 1995 (UMRA). It details agency actions to involve State, local, and tribal governments in regulatory decisions that affect them, including expanded efforts to involve them in agency decision-making processes. This report on agency compliance with the Act covers the period of October of 2005 through September of 2006 (rules published before October of 2005 were described in last year's report).

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

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

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

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

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

The scope of consultation activities undertaken by Federal departments such as, Agriculture, Health and Human Services, Justice, and the Environmental Protection Agency demonstrate this Administration's commitment to building strong relationships with our intergovernmental partners based upon the constitutional principles of federalism embodied in Title II of the Act. Federal agencies have been actively consulting with States, localities, and tribal governments in order to ensure that regulatory activities were conducted consistent with the requirements of the Act. For examples of agency consultation activities, please see Appendix D.

The remainder of this report discusses the results of agency actions in response to the Act between October 1, 2005 and September 30, 2006. 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. Ten rules have met this threshold, all for their impacts on the private sector. The appendix to this report discusses agency consultation efforts. These include both those efforts required under the Act and the many actions conducted by agencies above and beyond these requirements.

CHAPTER IV: REVIEW OF SIGNIFICANT REGULATORY MANDATES

A. Review of Significant Regulatory Mandates

In FY2006, Federal Agencies issued ten rules that were subject to Sections 202 and 205 of the Unfunded Mandate Reform Act of 1995 because they require expenditures in any year by State, local or tribal governments, in the aggregate, or by the private sector, of at least \$100 million in any one year (adjusted annually for inflation).

During FY 2006, the Departments of Labor (DOL) and Health and Human Services (HHS) each issued one proposed rule, the Department of Homeland Security (DHS) issued three proposed rules, the Department of Transportation (DOT) issued one proposed and one final rule, the Department of Treasury issued one proposed rule, and the Environmental Protection Agency (EPA) issued one proposed rule and one final rule.

OMB worked with the agencies to ensure that the selection of the regulatory option for final rules fully complied with the requirements of Title II of the Act. For proposed rules, OMB often worked with the agency to ensure that they also solicited comment on alternatives. Descriptions of the rules in addition to agency statements regarding compliance with the Act are included in the following section.

Department of Labor

Occupational Exposure to Hexavalent Chromium (Preventing Occupational Illness: Chromium) (Final) This rule limits occupational exposure to hexavalent chromium (Cr(VI)) and reduces the Permissible Exposure Level (PEL) of 1 milligram per 10 cubic meters of air (1 mg/10 m³, or 100 µg/m³) reported as CrO₃, which is equivalent to a limit of 52 µg/m³ as Cr(VI) to an exposure limit of 5 micrograms of Cr(VI) per cubic meter of air (5 µg/m³), measured as an average concentration over an 8-hour workshift. The rule also adds requirements for exposure monitoring, regulated areas, protective clothing, industrial hygiene facilities, and medical surveillance.

Occupational Safety and Health Administration (OSHA) estimates that compliance with this final rule would require private-sector employers to expend about \$273-\$282 million each year. However, while this final rule establishes a Federal mandate in the private sector, it is not an unfunded mandate on State and local governments. OSHA standards do not apply to State and local governments, except in States that have voluntarily elected to adopt an OSHA-approved State occupational safety and health plan. Consequently, the provisions of the final rule do not meet the definition of a “Federal intergovernmental mandate.”

Department of Health and Human Services

Control of Communicable Diseases, Interstate and Foreign Quarantine (Proposed)

Centers for Disease Control (CDC) is committed to protecting the health and safety of the American public by preventing the introduction of communicable disease into the United States. Having updated regulations in place is an important measure to ensure swift response to public health threats. CDC proposes to update existing regulations related to preventing the introduction, transmission, or spread of communicable diseases from foreign countries into the United States and from one State or possession into another. Through this regulation, CDC proposed to require contact information to be provided by airlines on their passengers so that the passengers could be contacted by CDC should there be a need to notify them of a health concern. Additionally, CDC proposed to update the current disease list, last updated in April 2005.

The primary cost impact of the proposed rule would be the collection and maintenance of crew and passenger manifest data by air and water carriers that are likely to modify computer systems and collect passenger information to come into compliance. The benefits of the rule would be measured in terms of the number of deaths and illnesses prevented by rapid intervention. HHS' Unfunded Mandates Reform Act analysis concludes that the proposed rule will not have any significant economic impact on State, local, or tribal governments. However, the proposed rule would have a significant impact on the private sector, particularly air carriers. The costs estimated for industry exceed \$100 million/year under some options, although the actual cost might be far lower if CDC can access data already collected by other agencies.

Department of Homeland Security

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 (Proposed) This rule proposes to amend existing Bureau of Customs and Border Protection (CPB) regulations concerning electronic manifest transmission requirements relative to passengers, crew members, and non-crew members traveling onboard international commercial flights and voyages. Under current regulations, air carriers must transmit to the CPB, Department of Homeland Security. Passenger manifest information for aircraft en route to the United States no later than 15 minutes after the departure of the aircraft. This proposed rule implements the Intelligence Reform and Terrorism Prevention Act of 2004 requirement that such information be provided to the government before departure of the aircraft. This proposed rule provides air carriers a choice between transmitting complete manifests no later than 60-minutes prior to departure of the aircraft or transmitting manifest information on passengers as each passenger checks in for the flight, up to but no later than 15 minutes prior to departure. The rule also proposes to amend the definition of "departure" for aircraft to mean the moment the aircraft

is pushed back from the gate. For vessel departures from the United States, the rule proposes transmission of passenger and crew manifests no later than 60 minutes prior to departure of the vessel.

This proposed rule, if adopted as a 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. Consequently, the provisions of this proposed rule constitute a private sector mandate under the UMRA. The 10-year costs range from \$612 million to \$1.9 billion, and the benefits are an estimated \$103 million (all at the 7 percent discount rate). Thus, the non-quantified security benefits would have to be \$509 million to \$1.8 billion over the 10-year period in order for this proposed rule to be cost-beneficial. In one hypothetical security scenario involving only one aircraft and the people aboard, estimated costs of an incident could exceed \$790 million. This rule may not prevent such an incident, but if it did, the value of preventing such a limited incident would outweigh the costs at the low end of the range.

Transportation Worker Identification Credential (TWIC) Implementation in the Maritime Sector; Hazardous Materials Endorsement for a Commercial Driver's Licenses (Proposed) The Aviation and Transportation Security Act (ATSA) directs the Transportation Security Administration (TSA) to improve access control in secure areas. The Maritime Transportation Security Act of 2002 (MTSA) requires that workers with unescorted access to secured areas of vessels and facilities must be subject to a security threat assessment and hold a biometric credential needed to access secured areas. The TSA, in a joint rulemaking with the U.S. Coast Guard proposed standards for conducting security threat assessments and issuing biometric credentials to transportation workers who require unescorted access to secure areas of vessels and facilities. In addition, TSA will finalize standards for determining the comparability of threat assessments conducted in other TSA programs and by other agencies.

The economic impact on small business is yet to be determined. The proposed rule imposes no significant barriers to international trade, and does not impose an unfunded mandate on State, local, or tribal governments, but does on the private sector as there are two years with undiscounted costs in excess of the inflation adjusted \$100 million threshold. We conclude that the primary estimate of economic costs over a 10 year period for this rule are \$1,028 million undiscounted, \$918.5 million with a 3 percent discount rate, and \$802.8 million at a 7 percent discount rate. In preparing estimates, we considered ranges for some values. These ranges provide an upper estimate of \$1,062 million undiscounted and a lower range of \$995.0 million undiscounted. The benefits of the proposed rule would be an enhancement in the flow of commerce and an increase in security at vessels, facilities, and Outer Continental Shelf (OCS) facilities.

Documents Required for Travelers Departing From or Arriving in the United States at Air Ports-of-Entry From Within the Western Hemisphere. (Proposed) This amendment would require U.S. citizens who previously were exempt from presenting a passport or other authorized travel document to present such documents that denote identity and citizenship when entering the United States. The amendment would require that U.S. citizens and nonimmigrant aliens from Canada, Bermuda, and Mexico entering the United States at air ports-of-entry from Western Hemisphere countries would be required to present a valid passport or other authorized travel document that denotes identity and citizenship in circumstances where travel was previously permitted without such a document.

This proposal would not impose a significant cost or uniquely affect small governments. The proposal does have an effect on the private sector of \$100 million or more. DHS and Department of State (DOS) estimate that the cost of this rule will be approximately \$206 million annualized (7 percent discount rate) and approximately \$204 million annualized (3 percent discount rate). These estimates are in 2005 dollars from 2006 to 2016. The non-quantified benefits of the proposed rule are significant and real in terms of increased security in the air and sea environments provided by more secure documents and facilitation of inspections provided by the limited types of documents that would be accepted.

Department of Transportation

Light Truck Average Fuel Economy Standards, Model Year 2008 and Possibly Beyond (Final) This final rule reforms the structure of the corporate average fuel economy (CAFE) program for light trucks and establishes higher CAFE standards for model year (MY) 2008-2011 light trucks. The proposed Unreformed CAFE standards are: 22.5 miles per gallon (mpg) for MY 2008, 23.1 mpg for MY 2009, and 23.5 mpg for MY 2010. The Reformed CAFE standards for those model years would be set at levels intended to ensure that the industry-wide costs of the Reformed standards are roughly equivalent to the industry-wide costs of the Unreformed CAFE standards in those model years. For MY 2011, the Reformed CAFE standard would be set at the level that maximizes net benefits, accounting for unquantified benefits and costs.

This final rule will not result in the expenditure by State, local, or tribal governments, in the aggregate, of more than \$115 million annually, but it will result in the expenditure of that magnitude by vehicle manufacturers and/or their suppliers. In promulgating this proposal, NHTSA considered whether average fuel economy standards lower and higher than those proposed would be appropriate. NHTSA is statutorily required to set standards at the maximum feasible level achievable by manufacturers and has tentatively concluded that the proposed standards are the maximum feasible standards for the light truck fleet for MYs 2008-2011 in light of the statutory considerations.

Electronic Stability Control (ESC) (Proposed) This rulemaking would establish 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 71 percent to 84 percent. The requirement of ESC on cars and trucks could save thousands of lives annually.

This proposal would not result in the expenditure by State, local, or tribal governments, in the aggregate, of more than \$118 million annually, but it would result in the expenditure of that magnitude by vehicle manufacturers and/or their suppliers. Vehicle costs are estimated to be \$368 (in 2005 dollars) for anti-lock brakes and an additional \$111 for electronic stability control for a total system cost of \$479 per vehicle. The total incremental cost of the proposal (over the MY 2011 installation rates and assuming 17 million passenger vehicles sold per year) are estimated to be \$985 million 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 MY 2011 vehicles are projected to already come equipped with ESC components (particularly ABS). DOT 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. Fatalities and injuries associated with rollovers are a significant portion of this total; we estimate that the proposal would reduce 1,161 to 1,445 fatalities and 43,901 to 49,010 MAIS 1-5 injuries associated with single-vehicle rollovers.

Department of Treasury

Implementation of a Revised Basel Capital Accord (Basel II) (Proposed) As part of the Office of the Comptroller of the Currency's (OCC) ongoing efforts to develop and refine capital standards to ensure the safety and soundness of the national banking system and to implement statutory requirements, OCC is amending various provisions of the capital rules for national banks. This change involves the implementation of the new framework for the Basel Capital Accord (Basel II). OCC is conducting this rulemaking jointly with the other Federal Banking Agencies. The OCC, the Board of Governors of the Federal Reserve System (Board), the Federal Deposit Insurance Corporation (FDIC), and the Office of Thrift Supervision (OTS) (collectively, the agencies) are proposing a new risk-based capital adequacy framework that would require some and permit other qualifying banks to use an internal ratings-based approach to calculate regulatory credit risk capital requirements and advanced measurement approaches to

calculate regulatory operational risk capital requirements. The proposed rule describes the qualifying criteria for banks required or seeking to operate under the proposed framework and the applicable risk-based capital requirements for banks that operate under the framework.

The proposed rule qualifies as a significant regulatory action under the UMRA because its Federal mandates may result in the expenditure by the private sector of \$119.6 or more in any one year. The OCC's estimate of the total cost of the proposed rule includes expenditures by banking organizations and the OCC from the present through 2011, the final year of the transition period. Combining expenditures by mandatory banking organizations and the OCC provides a present value estimate of \$545.9 million for the total cost of the proposed rule.

Environmental Protection Agency

Control of Hazardous Air Pollutants from Mobile Sources (Proposed) 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. This rule will address 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, nonroad engines and vehicles, and their fuels. Previous mobile source programs for highway and nonroad 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 will then address potential changes to gasoline fuel parameters to reduce toxics such as benzene and the potential for additional vehicle controls. EPA is also considering portable fuel container controls due to their significant contribution to VOC emissions overall and the potential for exposure to evaporative benzene emissions.

This rule contains no Federal mandates for State, local, or tribal governments as defined by the provisions of Title II of the UMRA. The rule imposes no enforceable duties on any of these governmental entities. EPA has determined that this rule contains Federal mandates that may result in expenditures of more than \$100 million to the private sector in any single year. EPA believes that the proposal represents the least costly, most cost-effective approach to achieve the statutory requirements of the rule.

National Primary Drinking Water Regulations: Stage 2 Disinfection Byproducts Rule (Final) This Regulation, along with a Long Term 2 Enhanced Surface Water Treatment Rule (LT2ESWTR) that was promulgated simultaneously, is intended to expand existing public health protections and address concerns about risk trade-offs between pathogens and disinfection byproducts. This rule could affect all public water systems that add a disinfectant to the drinking water during any part of the treatment process, although the impacts may be limited to community water systems (CWSs) and non-transient non-community water systems (NTNCWSs).

EPA has determined that this rule may contain a Federal mandate that results in expenditures of \$100 million or more for the State, local, and tribal governments, in the aggregate in the private sector in any one year. While the annualized costs fall below the \$100 million threshold, the costs in some future years may be above the \$100 million mark as public drinking water systems make capital investments and finance these through bonds, loans, and other means. EPA's year by year cost tables do not reflect that investments through bonds, loans, and other means spread out these costs over many years. The cost analysis in general does not consider that some systems may be eligible for financial assistance such as low-interest loans and grants through such programs as the Drinking Water State Revolving Fund.

B. Response to Peer Reviews and Public Comments on Twelfth Annual Report to Congress on Agency Compliance with the Unfunded Mandates Reform Act

Peer reviewer (3) stated that OMB should describe in its report whether UMRA requirements were fulfilled. Specifically, they noted that the discussion of the rules that triggered UMRA did not indicate whether the UMRA requirements were fulfilled and which rules required the agency head to explain why a less costly burden was not selected.

We agree that this is a good idea and note that in our review of individual regulations we do just that. Part of our consideration during OMB's reviews of regulations meeting the UMRA definition is whether the agency complied with the UMRA requirements to, "... select the least costly, most cost-effective or least burdensome alternative that achieves the objectives of the rule" or publish an explanation of why such an alternative was not selected. As noted in OMB Circular A-4, agency "...analytical requirements under Executive Order 12866 are similar to the analytical requirements under this Act, and thus the same analysis may permit [the agency] to comply with both analytical requirements."

Consistent with the peer reviewer's comment, we will note in future reports which rules include a statement regarding why the least costly, most cost-effective or least burdensome alternative was not selected.

APPENDIX E: 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 governments⁸⁴.

Eight agencies (the Departments of Agriculture, Commerce, Education, Justice, Health and Human Services, Housing and Urban Development, and Transportation, 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 Energy, State, Treasury, and Veterans Affairs, and the Small Business Administration and the General Services Administration) do not often impose mandates upon States, localities or tribes and so have fewer occasions to consult with these governments.

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

A. United States Department of Agriculture

Animal and Plant Health Inspection Service (APHIS)

Biotechnology Regulations

APHIS is in the process of revising its biotechnology regulations for genetically engineered (GE) plants and other organisms that are potential plant pests (7 CFR 340). APHIS' Biotechnology Regulatory Services (BRS) program administers these regulations. The revision may include utilizing the expanded authority of the Plant Protection Act to broaden the scope of the regulations beyond GE organisms that are potential plant pests to include GE biological control organisms and GE plants that are potential noxious weeds. Also under consideration is a

⁸⁴ 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.

multi-tiered, risk-based permitting system to replace the current permit/notification system. BRS is also considering a rule regarding Confidential Business Information (CBI) and interactions with the States.

The regulations affect USDA, other Federal Agencies, State Departments of Agriculture, biotechnology companies, public and academic research institutions, food processors, food marketers, food commodity exporters, crop associations, biotechnology industry associations, and other public entities. APHIS-BRS makes a concerted effort to reach out to partners and parties affected by APHIS regulations to increase confidence in the effectiveness of the biotechnology regulatory system. State agencies are often on the front line as the Agency's biotechnology regulations are being implemented on a daily basis. BRS is using input from meetings and discussions with the National Association of State Departments of Agriculture (NASDA) and the National Plant Board (NPB) to shape the proposed revisions to the regulations. BRS' interaction with NPB on expanding the scope of regulations on the sharing of confidential business information (CBI) has led to progress on the development of a new rule addressing this issue.

In December 2005, PEW facilitated a meeting with NASDA in Dallas, TX, in which USDA and EPA participated. The meeting was arranged to discuss options to resolve the issue of sharing CBI with the States. Currently, CBI is withheld from the States and some States would like to have access to this information. The participants discussed several options for sharing CBI information with the States and also discussed general information needs for the States on biotechnology products. Further discussions are still needed before making a decision on sharing the information. In January and March 2006, BRS hosted workshops with the NPB to discuss ways of strengthening the relationship between Federal and State agencies with regards to biotechnology regulations.

In March 2006, BRS participated in a workshop hosted by the Pew Initiative on Food and Biotechnology and NASDA in Boulder, CO. The workshop focused on issues that arise when different agricultural production systems, in this case genetically engineered, conventional, and organic crops, are traded in domestic and international markets. The workshop explored the legal, marketing, and regulatory issues that potentially impact peaceful coexistence in the marketplace, as well as discussed and developed various options that could help facilitate the more efficient operation of an increasingly complex food marketing chain. As a next step, States will be looking at what can be done individually and collectively to help ensure peaceful coexistence.

In April 2006, BRS gave a presentation at the 81st Annual Meeting of the Eastern Plant Board in Rehoboth Beach, DE. The Eastern Plant Board is a regional division of the NPB, composed primarily of plant health officials from State Departments of Agriculture. The presentation, part of a panel session entitled "Trends and Challenges in Biotechnology," focused primarily on potential changes to APHIS' biotechnology regulations and the associated draft environmental impact statement (DEIS). The panel also discussed future research on transgenic plants and insects. The meeting was part of an ongoing effort to enhance APHIS partnership with

the States and fully consider a complete range of perspectives in the development of revised regulations. As part of this continued effort, BRS also met with the Southern Plant Board in 2006.

In May 2006, APHIS participated in a meeting sponsored by the PEW Initiative on Food and Biotechnology and NASDA in San Diego, CA. The meeting focused on the challenges and opportunities associated with the Federal Coordinated Framework for the Regulation of Biotechnology, from the perspective of the States. NASDA requested the meeting to learn more about the framework and for an opportunity to work more closely with Federal regulators. The objectives of the meeting included developing a collective understanding of the various dimensions of the Coordinated Framework, including recent developments in regulations; discussing lessons learned from State experiences with navigating the Coordinated Framework; and exploring and developing potential models and ideas for enhanced communication and collaboration between State and Federal representatives in navigating the Coordinated Framework. The meeting was also an opportunity for APHIS to continue its effort to enhance its partnership with the States.

As a result of interactions with NASDA and NPB, BRS received many diverse and helpful suggestions which are being considered in the process of revising its regulations. For example, BRS heard renewed concerns about how it handles Confidential Business Information that will be addressed in APHIS revised regulations. Another significant comment that BRS is considering is the States' need for assurance that the biotech regulations for imported commodities will not provide advantages for foreign versus domestic products.

While the consultations with stakeholder groups, NASDA, and the National Plant Board will not solely be responsible for the changes to the Agency's biotechnology regulations, their comments and feedback will contribute to the Agency's revisions to the regulations. In addition, interactions with the States have resulted in a renewed commitment and partnership between State and Federal agencies.

Plant Protection and Quarantine Program

APHIS' Plant Protection and Quarantine (PPQ) program carries out numerous activities to detect and contain, and in some cases, to manage or eradicate plant pests damaging to agricultural and environmental resources of the United States. Specific pest programs include activities to detect, contain, manage, or eradicate, among other plant pests, citrus canker (a bacterial disease), *Phytophthora ramorum* (a fungus commonly known as Sudden Oak Death), emerald ash borer (an exotic pest of ash trees), Asian longhorned beetle (an exotic pest of several hardwood tree species), Japanese beetle (a pest of more than 300 ornamental and agricultural plants), potato cyst nematode, and exotic fruit flies.

These programs are conducted cooperatively with State agencies, which share the costs with APHIS. In cases where APHIS regulations could affect Native American tribes, those

tribes are included in APHIS consultations, as for example, in the case of *Phytophthora ramorum*, where numerous Indian tribes have expressed interest in these consultations.

Operational plans and strategic action plans are prepared jointly with cooperators and reflect the respective roles of State and Federal partners. APHIS consults regularly and frequently (sometimes on a daily basis) on program strategies, methods, operations, and progress. PPQ cultivates consultations with State agencies through National Plant Board meetings, task forces, work groups and special committees to resolve issues of mutual concern. PPQ contacts and consults with tribal governments that may be affected by contemplated PPQ activities in order to resolve issues of mutual concern.

Concerns generally arise over the effects of APHIS regulations and policy on States, who are often largely responsible for enforcing the regulations under cooperative agreements. Points of concern may include availability of resources, practical obstacles to program success, coordinated national approach, and balancing the interests of stakeholders affected by quarantine actions with those who could be adversely affected by spread of the pest of concern. Tribal issues often concern the impact of regulation on tribal businesses or cultural practices.

Citrus canker: In 2006, which was the second of two unusually active years for hurricanes, citrus canker became widespread in Florida, and significant changes were made to the citrus canker regulations to quarantine the entire State of Florida. Through cooperative survey with the State of Florida, we determined that the disease had spread and established to the point that eradication was no longer a realistic option. Subsequent extensive consultation with the State and with the citrus industry led to a new strategy and management plan for overall citrus health. Once implemented, this plan will encourage sanitary and management practices throughout the citrus industry and lead to greater confidence in the disease-free status of citrus moving to other States and for export. Cooperative agreements and cost-sharing minimizes the economic and operational costs borne by Florida.

Phytophthora ramorum: APHIS continued extensive consultations throughout 2006 with the States of California, Oregon, and Washington, which produce a major portion of U.S. nursery stock, and with States that receive their nursery stock. As a result, APHIS was able to enhance APHIS regulatory strategies that protect against the interstate spread of this pest while being practical to enforce. These consultations successfully minimized the economic and operational costs to the States of implementing the regulatory program. Dialogs continued through the fiscal year with affected Indian tribes to keep them informed of program activities and discuss possible impacts. APHIS enhanced its eradication protocol to minimize the spread of *P. ramorum* in the nursery setting through considerable industry and State involvement.

Emerald ash borer: Significant changes were made in the EAB quarantine during 2006. Illinois detected EAB in the summer of 2006. Extensive detection surveys statewide in Ohio and Indiana led to the discovery of additional EAB populations in those States as well. Surveys in the Lower Peninsula of Michigan indicated that this area also was generally infested. APHIS quarantined the entire Lower Peninsula of Michigan, and the entire States of Ohio, Indiana, and

Illinois. This action was necessary to prevent the spread of EAB to noninfested areas in adjacent States. EAB was confirmed for a second time in Maryland, despite 3 years of negative surveys and eradication efforts after the detection of the insect in the State in 2003. One county in Maryland was quarantined. Through continuous consultations with the States of Ohio, Indiana, Illinois, Maryland, and Michigan, APHIS has been able to devise regulatory strategies that protect against the interstate spread of this pest while being practical to enforce given the affected industries. States are provided funds through cooperative agreements to assist in enforcement of the regulations.

Asian longhorned beetle: Through ongoing consultations in 2006, the Illinois Asian Longhorned Beetle (ALB) project worked with State and local cooperators, successfully completing program activities to ensure that ALB is no longer present in Illinois. The last remaining area regulated for ALB was deregulated in July 2006. In New Jersey, the regulated area was expanded 9 square miles in 2006 due to new detections. APHIS consulted with the State of New Jersey and local municipalities and departments before we took this action, and APHIS continues to work cooperatively towards eradication of ALB in the State and to minimize impacts on the community. To this end, the program has provided local tree care businesses and other regulated establishments a designated location where they can dispose of their regulated woody debris without charge. The debris is then taken to a nearby incinerator which produces electric power from burning. To date, 15,000 tons of wood chips have been converted to 18.6 million Kilowatt-hours of electricity, which is enough electricity to supply 10,300 households for 3 months.

Japanese beetle: During 2006, the State of Iowa was quarantined under the Japanese Beetle regulations. APHIS consulted with and obtained agreement from State regulatory officials in Iowa before taking this action. As a result of this quarantine, the interstate movement of aircraft from regulated airports in these Iowa will be regulated to prevent the artificial spread of the Japanese beetle to noninfested States where the Japanese beetle could become established (referred to as protected States).

Potato cyst nematode: Through extensive coordination with the State of Idaho, the Idaho Potato Commission, and national and regional industry organizations, APHIS was able to devise regulatory strategies designed to protect the U.S. potato industry against the interstate spread of this pest while being practical to enforce. This Federal-State-Industry coordination and cooperative effort successfully minimized the economic and operational costs to Idaho and other States of implementing the regulatory and survey program and helped to facilitate the commerce and movement of potato and potato products interstate.

Exotic fruit flies: During 2006, there were four outbreaks of exotic fruit flies in California. APHIS conducted cooperative efforts with California and other States within fruit fly supporting areas to detect and eradicate introduced exotic fruit fly populations. Cooperation with the States of California and Florida to release sterile fruit flies as a preventative measure has greatly reduced the number and size of exotic fruit fly outbreaks, thereby minimizing the impact of exotic fruit fly quarantines on producers and other regulated entities handling restricted

commodities. In a cooperative effort, if an exotic fruit fly population is detected, the State and Federal Governments establish parallel quarantines around each detection site and enforce restrictions on intrastate and interstate movement of regulated articles. None of the quarantines established in 2006 impacted any tribal possessions.

Elimination of brucellosis from bison and elk in the Greater Yellowstone Area (GYA).

Affected parties include producers of domestic livestock, State governments, and Federal agencies. Each of these entities is represented on the Greater Yellowstone Interagency Brucellosis Committee (GYIBC). Governmental representatives to the committee include the State veterinarians and directors of the State wildlife agencies from States of Wyoming, Montana, and Idaho; as well as the U.S. Department of Agriculture, Animal and Plant Health Inspection Service, Veterinary Services (APHIS/VS); the U.S. Forest Service (USFS); the National Park Service (NPS); the U.S. Fish and Wildlife Service (USFWS); and the Bureau of Land Management (BLM) as voting members of the GYIBC executive committee. There are also three nonvoting members represented on GYIBC executive committee: U.S. Geological Survey (USGS); Agricultural Research Service (ARS); and the InterTribal Bison Cooperative (ITBC).

The GYIBC holds at least two public meetings per year to discuss brucellosis elimination planning for bison and elk in the GYA. Consultation was also carried out through regular meetings of representatives of the signatories to the Interagency Bison Management Plan, which was developed for the management of Yellowstone National Park brucellosis infected bison in Montana. In addition, APHIS/VS also consults regularly with the GYA State veterinarians, representatives of GYA State wildlife agencies, and the Wyoming Brucellosis Coordination Team.

The issue of how to best approach brucellosis elimination planning, including research was discussed. Public and intergovernmental partners worked with the Federal Government to determine what research should be done as part of the plan. APHIS/VS also consulted with the public and intergovernmental agencies to determine how best to help the GYA States to regain or maintain their brucellosis Class Free classification.

The U.S. Departments of Agriculture and the Interior have agreed upon a draft GYIBC Memorandum of Understanding (MOU) to replace an expired MOU for operation of the GYIBC with the focus toward brucellosis elimination planning. The MOU will be presented to the Governors of the GYA States for their review and approval. APHIS/VS also consulted with the State of Idaho to assist them in regaining their brucellosis Class Free classification.

National Animal Identification System (NAIS).

The implementation of NAIS will affect the U.S. Department of Agriculture, other Federal agencies, State and tribal governments, and livestock producers and other stakeholders. The consultation process consisted of discussions at meetings and other events with stakeholders, including representatives from industry groups and other nongovernmental organizations, and State and tribal officials. In addition, a series of meetings, seminars, and listening sessions were held throughout the country to provide producers, cooperators, and other stakeholders further opportunity to comment and learn how the NAIS will be implemented.

Description of Issues/Concerns Raised by Public/Intergovernmental Partners:

- Financial – Producers are concerned about the costs of national identification.
- Ability to Maintain Confidentiality – Producers want assurances about who will have access to the data and how the data will be used. Their concern is that someone could use the data to harm them or their businesses. This is a voluntary program.
- Flexibility – It is important that the national system be flexible enough to accept data from existing identification systems (particularly branding systems). Also, the system needs to be flexible enough to allow producers to use it for their herd management needs.
- Liability – Some participants voiced concerns that the NAIS information would be used by individuals (other than animal health authorities) for food safety issues and that traceability of food products would increase the participants' risk of liability and financial loss from food safety issues for which they are not responsible.

Both public and private funding is required for the NAIS to be fully operational. The integration of animal identification technology standards (electronic identification, retinal scan, DNA, etc.) will be determined by industry to ensure that the most practical options are implemented, and that new ones can easily be incorporated into the NAIS. Based on producer concerns about confidentiality of data, USDA has made the program completely voluntary and continues to pursue legislation to establish a system for withholding or disclosing information obtained through the animal identification system.

B. Department of Commerce

On June 15, 2006, President Bush issued Proclamation 8031 establishing the Northwestern Hawaiian Islands Marine National Monument. The Proclamation sets forth the purposes and management regime for the Monument, as well as restrictions and prohibitions on activities in the Monument to protect Monument resources. The three Trustees responsible for management of the Monument are the Department of Commerce, through the National Oceanic and Atmospheric Administration (NOAA), the Department of the Interior, through the United States Fish and Wildlife Service (USFWS), and the State of Hawaii.

In issuing the Proclamation, the President recognized the importance of the Northwestern Hawaiian Islands as a place rich in history and of great cultural significance to Native Hawaiians. The Proclamation includes a specific permit category for native Hawaiian practices to ensure that Native Hawaiian practices may continue to be conducted in the Monument consistent with the protection of Monument resources. Since issuance of the Proclamation, the State of Hawaii has been an integral partner in the ongoing process of carrying out the Proclamation's vision for management of the Monument. As a Monument Trustee, the State of Hawaii has been an equal partner involved in and consulted with concerning all important aspects of Monument management, including the permitting of activities within the Monument and development of the MOA.

Subsequent to issuance of the Proclamation, NOAA and USFWS developed joint regulations to codify the provisions of the Proclamation. The State of Hawaii was consulted during development of the regulations and raised concerns about its responsibilities and jurisdiction within the Monument. The joint regulations included the State's language for the preamble of the regulations to address these concerns. The State, as a Monument Trustee, has also participated fully in development of the MOA.

To address the State's concerns with the codifying regulations, NOAA and FWS incorporated the language suggested by the State into the preamble of the regulations. The MOA accommodates the concerns of all the Trustees, including the State of Hawaii and will be signed by the three Trustees as equal partners in managing the monument. Further, the MOA provides specifically for the identification of culturally significant religious locations and native Hawaiian practices that may benefit Monument resources and the Native Hawaiian community. As management of the Monument continues, the Trustees will continue work together to provide for unified management in the spirit of cooperative conservation to protect Monument resources.

C. Department of Education

Part B Final Regulations

The Department published final regulations governing the program assisted under Part B of the Individuals with Disabilities Education Act on August 14, 2006 (71 FR 46540). The regulations implemented substantial statutory changes made by the Individuals with Disabilities Education Improvement Act of 2004, and restructured preexisting regulations for the program. The Department had published a notice of proposed rulemaking (NPRM) on June 21, 2005 (70 FR 35782).

Because Part B of the IDEA imposes significant requirements on the special education services available to all children with disabilities in the country, these regulations affect State

Education Agencies (SEAs), local school districts, public elementary and secondary schools, special education teachers and related service providers, children with disabilities and their parents.

In the NPRM, the Department announced a series of seven regional public meetings to solicit public comment on the NPRM. These meetings were scheduled for times and locations that would permit the wide spectrum of affected parties an opportunity to participate. Several hundred people attended each public meeting. The Department also invited written comment for a 75-day period.

In response to the invitation in the NPRM, more than 5,500 parties submitted comments on the proposed regulations. They included comments from children with disabilities, parents, teachers and related service providers, State and local agency personnel, and parent-advocate and professional organizations, and members of Congress. The comments addressed each of the major subjects covered by the NPRM, including definitions such as the new highly qualified special education teacher definition and revisions to definitions of particular special education services; new and revised State and local educational agency eligibility requirements such as provisions concerning the participation of private school children with disabilities in special education services; provisions governing evaluations, eligibility determinations, individualized education programs and educational placements, due process and discipline procedures for children with disabilities; new provisions governing Federal and State monitoring and enforcement; and changes to the funding requirements.

The comments were reviewed and considered in developing the August 2006 final regulations. The preamble to the final regulations contains a lengthy *Analysis of Comments and Changes* (71 FR 46547-46743) detailing the specific changes requested and the changes made in the final regulations.

Title I Final LEP Regulations

On September 13, 2006, the Department published final regulations (71 FR 54188) that amended regulations under Title I of the Elementary and Secondary Education Act of 1965 (Title I) to provide States with additional flexibility regarding State, LEA, and school accountability for the achievement of limited English proficient (LEP) students. The final regulations permit a State to exempt “recently arrived” LEP students from one administration of the State’s reading/language arts assessment. A State may also exclude the scores of “recently arrived” LEP students on the State’s mathematics assessment and reading/language arts assessment (if taken) from determinations of adequate yearly progress (AYP). A “recently arrived” student is a student with limited proficiency in English who has attended schools in the United States for less than 12 months. Finally, a State may include in two AYP determination cycles the scores of former LEP students who no longer have limited English proficiency.

These final regulations affect SEAs, LEAs, public elementary and secondary schools, and LEP students. In developing the regulations, Department staff consulted with individuals from these constituencies as well as researchers knowledgeable about assessing LEP students and advocates for LEP students.

The need for the Title I LEP regulations was raised to the Department by State and LEA officials who were concerned that LEP students who recently arrived in U.S. schools with little or no understanding of English could not reasonably demonstrate their knowledge on a reading/language arts assessment administered in English. These officials also noted that, by definition, once LEP students gain sufficient proficiency in English, they exit the LEP subgroup; as a result, a school or LEA does not receive credit for its efforts in raising the academic achievement of these students with respect to AYP for the LEP subgroup. Based on the concerns raised, the Department convened a meeting with State and LEA officials, researchers, and national advocacy groups to learn more about the issues involved in assessing LEP students, balanced by concerns of advocates for ensuring that all LEP students are held to high academic achievement standards and included in accountability. The Department also afforded interested parties the opportunity to provide written comments on the notice of proposed rulemaking and received comments from approximately 50 parties.

In response to the NPRM, approximately 50 parties submitted comments. Although generally favorable to the basic concept in the NPRM of allowing States flexibility in assessing “recently arrived” LEP students, the comments raised a number of issues, including the definition of a “recently arrived” LEP student; the number of years a “recently arrived” LEP student should be exempt from a State’s reading/language arts assessment; whether a “recently arrived” student should also be exempt from a State’s mathematics assessment; and the appropriateness of including former LEP students in the LEP subgroup for accountability purposes.

The information obtained through the public comment period, including the meeting with State and local officials, researchers, and national advocacy groups, informed Department staff about the issues that needed to be resolved in the final regulations. Based on this input, the Department revised slightly the definition of a “recently arrived” LEP student to include a student who has not been in U.S. schools for at least 12 months. The Department did not, however, expand the number of years a State could exempt a “recently arrived” LEP student from its reading/language arts assessment out of concern that doing so could reduce a school’s incentive to instruct the student in academic content. The Department also did not permit a State to exempt a “recently arrived” student from the State’s mathematics assessment because English language proficiency is not a prerequisite to participating in State mathematics assessments to the same extent as it is to participating in reading/language arts assessments. The Department believes the final regulations reflect a balance in input from State and local officials concerned about their schools’ missing AYP because of “recently arrived” LEP students and advocacy groups concerned about ensuring that LEP students receive content knowledge as they gain English proficiency.

Academic Competitiveness Grants

On July 3, 2006 (71 FR 37990), the Department published interim final regulations with a request for comments implementing 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 (Publ. L. 109-171), enacted on February 8, 2006, 20 U.S.C. 1070a-1 (HERA). The interim final regulations established regulations to implement the ACG and National SMART Grant programs.

ACG regulations affect college students and their parents, institutions of higher education, State educational agencies, and public and private secondary schools. Prior to publishing the interim final regulations, the Department held several meetings with affected constituencies, including Chief State School Officers and urban superintendents, to discuss what to include in the regulations. These meetings, hosted by senior officials at the Department, solicited input from groups interested in high school issues and the linkage to college.

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 comments informed the regulations for the first two years of the program, and resulted in policy to indicate that Education intends to raise the level of rigor under this program in years three and later.

D. Department of Health and Human Services

Flexibility and Innovation in Child Welfare Services

Provisions of the Social Security Act authorize the Department of Health and Human Services to effect approval for as many as ten States per year to conduct demonstration projects involving the waiver of certain requirements of the title IV-E foster care program. The projects are intended to test new approaches to the delivery and financing of child welfare services. The child welfare waiver demonstration projects provide States with greater flexibility to use title IV-E funds for a range of child welfare services in addition to foster care in order to facilitate improved safety, permanency and well-being for children. (Normally title IV-E funds may only be used to pay for foster care maintenance payments and related allowable administrative costs.) All projects must be cost-neutral to the Federal Government and are required to include a rigorous evaluation conducted by an independent evaluator.

While there has been public interest in child welfare waiver demonstrations, waiver requests must be submitted by a State's child welfare agency. Thus, the Children's Bureau within Administration for Children and Families (ACF) in HHS works primarily with State agencies on the child welfare waiver demonstrations. States applying for waivers, however, must seek public input on their proposals before they are approved.

ACF has engaged in considerable consultation and discussion with State representatives regarding child welfare demonstration proposals. General technical assistance has been provided to interested States prior to submission of proposals and extensive dialogue occurs during the negotiation of waivers. Consultation occurs primarily through conference calls, issue papers and correspondence. ACF leaders and staff have also met in person with State representatives when requested.

ACF was successful in working with the State of Florida to approve the first ever Statewide child welfare waiver demonstration in March 2006. In addition, some States have raised concern about the expiration of the child welfare waiver authority.

Currently, 15 States have active waiver demonstrations, involving 19 demonstration components. (Some States have more than one approved waiver demonstration project and some waiver agreements involve more than one type of service intervention.) Through timely technical assistance and negotiations with States, HHS was able to complete an expeditious review and approval of six of the currently approved projects. Over the coming years, these projects will promote improved outcomes for vulnerable children and families in the affected States and will also make an important national contribution to the evidence base in child welfare policy and practice.

Food safety — E. coli Outbreak in Spinach

The Lettuce Safety Initiative was an activity under the "2004 FDA Produce Safety Action Plan." It was developed in summer 2006 in response to recurring outbreaks of *E. coli* O157:H7 in fresh lettuce. This initiative was developed to: 1) assess current industry approaches and actions to address lettuce safety and further advance those efforts; 2) ensure early consumer alerts and respond rapidly in the event of an outbreak; 3) document observations of practices that potentially lead to contamination and use these data to help develop guidance /policy that will minimize opportunities for future outbreaks; and 4) consider appropriate regulatory action when warranted. In September 2006, in response to an *E. coli* outbreak in spinach, this initiative was expanded to include spinach.

On September 14, 2006, FDA issued an alert to consumers of an outbreak of *E. coli*, possibly related to bagged, fresh spinach. FDA, CDC, and State and local governments from the 8 affected States worked together to determine the cause and scope of the problem. In total, the outbreak involved approximately 200 cases of illness and 3 deaths due to *E. coli* infection. Twenty-six States and one Canadian province were affected.

FDA had developed the Lettuce Safety Initiative in cooperation with the State of California Department of Health Services and Department of Food and Agriculture, because of recurring outbreaks of *E. coli* O157:H7 traced back to produce grown in that State. During the 2006 outbreak linked to spinach, all affected States participated in the investigation.

As part of a larger FDA Produce Safety Action Plan, FDA held many meetings and constituent briefings on produce safety which involved FDA, CDC, USDA, State and local governments, consumers, academia, and relevant trade associations. Issues that were raised during the various food safety consultations included the need for enhanced communication and coordinated media activities, time zone difference that may affect that coordination, cultural and language differences, variations in State laws, the need to identify how produce becomes contaminated with pathogens and the speed and accuracy needed in investigations and trace backs of this nature.

The first illness linked to consumption of fresh bagged spinach was reported on August 20, 2006, and peak of illnesses were reported between August 26 and September 12. FDA was notified on September 13, 2006. Immediately, FDA, CDC, California and other State officials began holding daily conference calls to share information, and coordinate efforts. Field investigation teams included experts from USDA, CDC, FDA, and the State of California. These teams inspected and collected samples from facilities, evaluated animal management practices, water use, and the environmental conditions.

As a result of Federal-State cooperation, within a month of FDA receiving the first report of the *E. coli* outbreak in spinach, FDA and the State of California were able to narrow the investigation to four specific fields in four ranches.

Through these investigations, FDA has identified many possible factors that contribute to the contamination of fresh produce. FDA is working with the State of California and industry to promote measures that will minimize the potential for contamination of fresh produce.

Health status disparities affecting American Indians and Alaska Natives

The Department of Health and Human Services (HHS) and Indian Tribes share the goal of eliminating health and human service disparities among American Indians and Alaska Natives, and of ensuring that access to critical health and human services is maximized. To achieve this goal, and to the extent practicable and permitted by law, it is essential that federally recognized Indian Tribes and the HHS engage in open, continuous, and meaningful consultation. The importance of such consultation was affirmed through a 2004 Presidential Memorandum.

During Fiscal Year 2006, HHS leadership worked closely with Indian tribal governments and tribal organizations, such as the National Congress of American Indians, the National Indian Health Board, the Tribal Self-Governance Advisory Committee, the Direct Service Tribes Advisory Committee, the American Indian Higher Education Consortium, the National Indian Child Welfare Association, the National Council on Urban Indian Health, as well as a number of locally-based governmental and non-governmental tribal groups.

Consultation with Indian tribes took the following diversity of forms at HHS during FY '06 :

- 1st Annual Divisional Budget and 8th Annual Tribal Budget Consultation Sessions: HHS agencies engaged Tribes in an annual conversation about budget priorities. Through this process, Tribes have been able to state their funding priorities to HHS. On March 11, 2006 HHS hosted the 1st Annual Divisional Budget Consultation Session. This was a new process as outlined in the Revised Tribal Consultation Policy. This session allowed Tribes to engage the Divisions on a more detailed conversation about their specific budgets. On May 17-18, 2006, HHS held its Eighth Annual Budget Consultation Session. This session was one and one-half days at the request of tribal leaders. As a result, support for tribal programming has increased by 5 percent each year for the past three years, and funding has been able to be targeted to those areas of greatest need, as defined by Tribes.
- Regional Tribal Consultation Sessions: In 2006, HHS Regional Directors coordinated its 4th annual year of Regional Tribal consultation sessions. Seven sessions were conducted in the field with one encompassing four regions all were coordinated with IHS Area Directors and supported by IGA. The sessions were attended by over 800 people and had over 145 Tribes represented at the sessions.
- Tribal Leaders Roundtables on Meth Abuse: In 2006, HHS hosted three Tribal Leader Roundtables across the country to listen to their issues and concerns on the rising use of methamphetamines in tribal communities. HHS awarded \$1,175,100 in funds to the American Association of Indian Physicians (AAIP) and its partners to address the outreach and education needs of Native American communities on methamphetamine (meth) abuse. Tribal leaders have identified meth use as one of their highest priority health issues, and called for Federal and State assistance to conduct outreach and education and help reduce the toll that methamphetamine abuse is taking on their communities.
- Pandemic Influenza Planning and Preparedness in Indian Country: In May 2006, HHS hosted a National tribal Leader Pandemic Influenza Preparedness Summit. The focus of the meeting was to answer questions and raise awareness to the National Strategy for Pandemic Influenza issued by President Bush on November 1, 2005. The meeting facilitated discussion between tribal experts and representatives from State and local health departments on how to work together to prepare and respond to threats to HHS' communities.

- Centers for Medicare and Medicaid Services (CMS) Tribal Technical Advisory Committee (TTAG) During 2006, TTAG met in-person twice in Washington, D.C. at HHS Headquarters. Key issues discussed at these sessions included issues for TTAG operations with a major focus on implementation of the Medicare Modernization Act, as well as numerous Medicaid issues.

The highest priority identified at all tribal consultation sessions was the need to increase resources for Indian tribes. In addition, tribes sought to increase access to HHS programs and health services; enhanced consultation and communication with HHS; and recruitment and retention of care providers and the rising issue of Methamphetamine Abuse in Indian Country. Tribes also expressed specific interest in health promotion and disease prevention; Medicare and Medicaid; emergency preparedness and homeland security; health and human service facilities construction, and reauthorization of the Indian Health Care Improvement Act.

As a result of this process, tribal access to HHS resources improved. In 2006, HHS resources that were provided to tribes or expended for the benefit of tribes increased to approximately \$4.660 billion. This is an increase of approximately \$95 million or 2.09 percent over the 2005 amount of \$4.565 billion. The increase came in both appropriated funding as well as increased tribal access to non earmarked funds and increases in discretionary set asides.

E. Department of Housing and Urban Development

Working with Stakeholders on Revisions and Updates to the Consolidated Plan Regulations of State and Local Governments

On February 9, 2006 (71 FR 6950), HUD published a final rule streamlining and clarifying the consolidated plan submission regulations for community planning and development programs at 24 CFR part 91 so that the plans are more results-oriented and useful to communities in assessing their own progress toward addressing the problems of low-income areas. The rule also eliminated obsolete and redundant provisions and made other changes that conform the regulations to HUD's public housing regulations that govern the Public Housing Agency (PHA) Plan. The consolidated plan also serves as each jurisdiction's planning document for the use of Community Planning and Development formula grant programs funds. The final rule took into consideration comments received on the December 30, 2004, proposed rule (69 FR 78830). The proposed rule resulted from an extensive consultation process that involved public interest groups, State and local governments, grantees, and other stakeholders.

On March 14, 2002, HUD's Office of Community Planning and Development (CPD) convened a national planning meeting to introduce the concept of the Consolidated Plan Improvement Initiative. In attendance were public interest groups, grantees, and other stakeholders, along with staff from HUD Headquarters and field offices, and staff from the

Office of Management and Budget (OMB). At a meeting of these stakeholders, participants agreed that addressing the issues of streamlining and performance measurement would be best served by small working groups that represent the full range of people involved in and affected by the consolidated plan, including grantee practitioners, public interest groups, HUD staff, and other stakeholders. Six working groups were created to assess alternative planning requirements, examine and suggest performance measures, and identify communities that would be willing to test pilots of alternative planning procedures. Representatives from the following national groups participated in the working groups: Council of State Community Development Agencies, National Community Development Association, National Association for County, Community and Economic Development, National Association of Housing and Redevelopment Officials, and National Low Income Housing Coalition.

Representatives of State and local governments participated in eight pilots that tested alternative planning procedures. One pilot looked at streamlining the consolidated plan by referencing existing documents to avoid requiring redundant information. Another pilot evaluated alternative means of satisfying non-housing community development plan requirements. A third pilot addressed alternative formats for submission of consolidated plans, action plans, and performance reporting. A fourth pilot explored ways to enhance the citizen participation process. A fifth pilot involved development and use of templates. The sixth pilot involved coordination of consolidated plan and PHA plan. A seventh pilot explored the development and review of tools to submit consolidated plans, track results, and report performance. An eighth pilot documented useful practices for streamlining and performance measurement. After completion of the pilots, the general view of the groups participating was that the consolidated plan must be a concise, action-oriented management tool that would be more understandable to the public and more useful to decision makers in the community.

The national planning meeting and the pilot testing of alternative planning procedures helped HUD determine how the consolidated planning process and regulatory requirements might be streamlined, made more results-oriented, and ultimately made more useful to communities in addressing the needs of their low-income residents and areas. The consultation resulted in streamlining and clarifying changes to the consolidated plan regulations of State and local governments.

Working with the Manufactured Housing Consensus Committee to Develop Amendments to the Manufactured Home Construction and Safety Standards

The National Manufactured Housing Construction and Safety Standards Act of 1974 (42 U.S.C. 5401-5426) authorizes HUD to establish and amend the Federal Manufactured Home Construction and Safety Standards codified in 24 CFR part 3280. The Act was amended in 2000 by expanding its purposes and creating the Manufactured Housing Consensus Committee (MHCC). On November 30, 2005, HUD published a final rule amending the Federal Manufactured Home Construction and Safety Standards by adopting certain recommendations made to HUD by the Manufactured Housing Consensus Committee. The final rule took into

consideration comments received on the December 1, 2004, proposed rule (69 FR 70016). HUD developed the proposed rule in consultation with the MHCC, which was supported by an Administering Organization (the National Fire Protection Association) (NFPA) and comprised of 21 members representing industry, government agencies, and consumers.

The MHCC held its first meeting in August of 2002 and began work on reviewing recommendations for revisions to the Manufactured Home Construction and Safety Standards previously submitted to HUD by the NFPA. These recommendations were developed based on procedures for consensus committees developed by the American National Standards Institute. The MHCC developed its own priorities and submitted revised versions of the NFPA recommendations to HUD as proposed revisions to the Manufactured Home Construction and Safety Standards.

The MHCC made recommendations on simplifying requirements for whole-house ventilation; amending the term “firestopping” to “fireblocking;” streamlining the process for implementing alternative body and frame testing procedures; amending the design live load testing criteria; amending the thermal protection requirements; amending the plumbing system requirements; amending the heating, cooling, and fuel burning system requirements; amending the electrical system requirements; and updating other standards incorporated by reference.

HUD reviewed the proposed revised Construction and Safety Standards recommended by the MHCC and was in agreement with almost all of them. The proposed rule was published for public comment, and in the final rule, HUD identified those MHCC proposals that were not accepted by HUD, returned to MHCC for further consideration, or modified by HUD in light of public comments received. The final rule improved various aspects of the Manufactured Home Construction and Safety Standards.

F. Department of Justice

Community Oriented Policing Services (COPS)

The COPS program involves information sharing between the COPS Office and State, local, and tribal law enforcement agencies to promote community policing knowledge and address emerging concerns within the law enforcement field.

State, local and tribal law enforcement agencies are all affected by the continuing demands placed on them with regard to community policing, crime prevention, homeland security, and ethics and integrity to name a few current topics of interest. Gaining access to this information in the most efficient and cost effective way is of paramount importance.

COPS has a history of working closely with State, local, and tribal agencies. Since its inception in 1994 through the Violent Crime Control Act, COPS has consulted regularly with professional law enforcement organizations, such as the International Association of Chiefs of

Police, National Sheriffs Association, the Police Executive Research Forum, the Police Foundation, and NOBLE on current issues facing law enforcement. COPS also maintains regular contact with intergovernmental organizations such as the U.S. Conference of Mayors, the National League of Cities, and the National Association of Counties, which provides the perspective of local government on law enforcement issues. For more than a decade COPS has conducted research and evaluations with local police departments to identify barriers and challenges to their implementation of community policing. COPS consultation with State and local government is reflected in the training provided through the Regional Community Policing Institutes, best practices publications and other problem-specific guides, and targeted initiatives. COPS Office representatives attend conferences, meetings and workgroups throughout the year, as well as hosting one-on-one meetings with law enforcement officials to remain current on the issues and concerns facing agencies today and to put in place any policies or programs that may help address such needs. Additionally, the COPS Office Director, as a former law enforcement professional, enjoys a unique relationship with his law enforcement peers. Representatives of police groups as well as chiefs and sheriffs maintain direct contact with the COPS Director and have the opportunity to share their suggestions and concerns with him candidly.

During conferences, meetings and workgroups, COPS has been encouraged to make efforts to reach more participants than can be represented on site at such events. In an effort to reach a broader audience of practitioners and interested parties, the COPS Office implemented a policy of providing information on a wide range of topics through electronic means. Webcasts and conference calls were established to address emerging needs and reach a maximum number of agencies with little or no cost to those agencies. Additionally, COPS established two surveys to be implemented in FY06. The American Customer Satisfaction Index (ACSI) will be posted on the COPS website in FY06. This survey will assist COPS in targeting areas of improvement for better dissemination of information to the public. The Community Policing Capacity/ Customer Satisfaction Survey will focus on COPS Office performance in meeting the mission to advance community policing by assessing the impact of COPS Office grant resources and knowledge resource products (training/technical assistance and publications) at increasing the capacity of grantees and knowledge resource recipients to implement community policing strategies.

COPS National Policing Conferences provide valuable information to those who attend. Additionally, COPS provides a variety of knowledge products and workshop information for attendees to share with those unable to attend. COPS continues to host webcasts on a variety of topics including methamphetamine interdiction and reduction as well as hiring and gangs. By logging into a designated webcast (similar to a TV show broadcast over the Internet) participants can join law enforcement officers, local government leaders, and community members for a discussion on current law enforcement issues identified by law enforcement practitioners.

The Office of Community Policing Services (COPS Office) hosts conference calls to reach a maximum number of law enforcement professionals with pertinent information. COPS is developing a pilot series of conference calls to discuss specific grant management topics of

interest to award recipients. The five subject areas are: 1) Legal Requirements: Retention, Nonsupplanting, and Allowable Costs; 2) Staying in Grant Compliance / Preparing for an Audit; 3) What Is Community Policing?; 4) Maintaining an Active Grant: Modifications, Extensions, and Related Grant Management Topics; and 5) Grant Closeout Process: Programmatic and Financial Issues. Each conference call has a maximum of 50 phone lines available.

The COPS Office continues to expand and diversify the audiences reached through partnerships with other agencies, employing technology and remaining accessible to law enforcement practitioners nationwide.

G. Transportation

Federal Transit Administration (FTA)

Circulars Addressing Access Programs (Elderly Individuals and Individuals with Disabilities Circular (Section 5310), Job Access and Reverse Commute Circular, and New Freedom Circular) - the process for all three circulars has been conducted as a single process.

States, local governments and/or governmental authorities may apply for grants for these programs and therefore, are the entities affected by the guidance documents. FTA published *Federal Register* notices and held public meetings.

FTA conducted extensive outreach in developing its circulars for these programs. First, FTA held initial listening sessions in Washington, DC in September, 2005. Then, FTA requested comments related to the Section 5310, JARC and New Freedom programs in a notice published on November 30, 2005 (70 FR 71950), and held listening sessions in five cities around the country. Subsequent to that notice, FTA published in the *Federal Register* on March 15, 2006 (71 FR 13456), proposed strategies for implementing these programs and requested comments on those strategies. In addition, FTA conducted an all-day public meeting on March 23, 2006, and held a number of meetings and teleconferences with stakeholders, which included State and local governments. To ensure that FTA heard from a broad range of stakeholders and interested parties, FTA extended the comment period of the March 15, 2006, *Federal Register* notice through May 22, 2006. FTA received more than 200 comments from State departments of transportation, trade associations, public and private providers of transportation services, metropolitan planning organizations (MPOs), individuals and advocates. Finally, FTA published the proposed circulars on its website (www.fta.dot.gov) and a *Federal Register* notice (71 FR 52610) on September 6, 2006, seeking public comment on the proposed circulars. FTA received an additional 70 comments in response to the September 6, 2006, notice and proposed circulars.

A number of issues were raised by commenters, including the amount of funding available for certain activities, eligible activities to be funded by grants, and how FTA plans to administer the programs. All issues/concerns will be addressed in a future *Federal Register* notice and in the final guidance documents.

In some cases, FTA's suggested strategies/policies were changed in response to commenters. For example, FTA modified the definition of a coordinated plan in response to comments received from State and local governments. In other cases, FTA explained why it would not change its policy decision.

Section 5311 Nonurbanized Area Formula Program and FTA Tribal Transit Program

States, local governments and or government authorities and tribes may apply for grants for these programs; these are entities affected by the guidance documents. FTA published *Federal Register* notices and held public meetings.

FTA conducted extensive outreach in revising the Section 5311 circular and developing and implementing the new Tribal Transit Program. FTA held initial listening session for the Section 5311 program in November of 2005, in Washington DC. For the Tribal Transit Program FTA held a listening session in October 2005, in Washington DC and presented at various national tribal meetings and conferences during the months of October thru December 2005. On July 31, 2006 FTA published a *Federal Register* notice responding to listening session comments and proposed its revised Section 5311 circular. In March 2006, FTA published a *Federal Register Notice* regarding proposed grant program provisions for the new tribal transit program and announced two public meetings that were subsequently held on April 4, 2006, in Denver, Colorado, and on April 7, 2006, Kansas City, Missouri. FTA received 26 written comments and published a second *Federal Register* notice in August 2006 responding to comments received; the notice also announced funding availability, and solicitation of grant applications for FY 2006 tribal transit program funds. FTA published the proposed circular and tribal transit program solicitation process on FTA's website (www.fta.dot.gov). FTA received 95 grant applications in response to the August 2006 *Federal Register* notice.

A number of issues were raised by commenter's regarding reporting, intercity bus consultation, the process for awarding grants, funding availability, local match, eligible activities and how FTA plans to administer the program. The Section 5311 comments raised will be address in a *Federal Register* notice to be published in March 2007. All issues for the Tribal Transit Program were addressed in an August 2006 *Federal Register* notice (71, 157).

FTA implemented a two year intercity bus pilot program as a direct result of comments received by stakeholders and FTA modified its local match policy, produced a separate Master Agreement and certification and assurances as a result of the comments and concerns raised during tribal public outreach sessions and written comments.

H. Environmental Protection Agency (EPA)

Consultation Mechanisms, General Outreach Activities and Communication Aids

EPA has several mechanisms to help State, local, and tribal officials learn about its regulatory plans and to let them know how they can engage in the rule-development process. For example, it distributes reprints of the semi-annual Regulatory Agenda to more than 300 State, local, and tribal government organizations and leaders. EPA also participates in a Federal Government-wide State and local governments website. 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 U.S. 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
- 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.

EPA 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

The Office of Prevention, Pesticides and Toxic Substances (OPPTS) has 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 that leads to new policies or changes to existing Federal policies. Here are a few of these OPPTS outreach mechanisms:

The Office of Pesticide Programs (OPP) in OPPTS uses the State Federal 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 us to discuss issues including regulations in progress. One example of results from consulting with SFIREG was the formation of joint EPA-State workgroup to address a number of issues and projects.

Over the past several years, OPP consulted and received significant input from the Pesticide Program Dialogue Committee (PPDC), which 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 Committee 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 committee has provided a forum for meaningful dialogue and collaboration on addressing new policies or changes to existing Federal policies.

Reflecting consultations with a variety of stakeholders through the PPDC, OPPTS finalized a rule which established procedures for the periodic review of pesticide registrations once every 15 years. For example, during these communications, one of the Agency's State partners expressed a concern that, as part of registration review, OPP should consider the effects of a given pesticide on water quality. The Agency has agreed to consider a pesticide's effects on water quality during registration review, although no changes to the rule were required to do so.

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 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. It 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 and 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 Outreach Activities

EPA's National Center for Environmental Innovation (NCEI), in the Office of Policy, Economics, and Innovation (OPEI), routinely provides 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 programs engaged States in creating a more performance-based environmental regulatory system

Performance Track recognizes and rewards facilities that demonstrate strong environmental performance, beyond current requirements. Currently, the program has about 400 members. Over 20 States have active performance-based environmental programs similar to Performance Track. The national Performance Track program works closely with its State counterparts. In FY 2006, NCEI continued to consult with States to address regulatory issues that can hinder smart growth at the local level, and through industry-specific partnerships improved environmental performance in specific industry sectors.

Through the Sector Strategies Program, NCEI and other stakeholders focused on tailored approaches for 13 sectors that are comprised of 780,000 facilities, contribute \$2.1 trillion to U.S. GDP (19 percent), and employ 19 percent of workers in the United States. In FY 2006, EPA worked closely with States to implement a policy on the role of environmental management systems in Federal environmental regulations and permits. This policy provided a framework to implement and evaluate alternative uses of EMSs in permits and regulations.

During FY 2006, NCEI provided grant resources to State regulatory agencies to implement innovative strategies and approaches. NCEI continued to expand its State Innovation Grants Program, selecting six projects for funding from the 2006 competition. These projects reflected NCEI's strategic investment in assisting States implement innovation in environmental programs, specifically:

- the expansion (2 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);
- the further testing of Environmental Management Systems (EMS) in permitting

(1 State/project) to help business 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 the 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, and statistically-based inspections and measurement to assess the environmental performance of facilities and overall sectors. In FY2006, 15 States pursued ERP in 10 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.

Local and Small Government Outreach

EPA has also developed various materials intended to help small governments more easily understand Agency regulations.

- **Profile of Local Government Operations**: The Profile 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.
- **Local Government Environmental Assistance Network (LGEAN)**: EPA helps support this Internet-based information service (that has parallel toll-free voice and fax-back options). LGEAN provides a first stop for local government officials with questions about environmental compliance. The site contains information from EPA and eight participating nongovernmental organizations. Users can ask questions of experts, consult with their peers, review and comment on developing regulations, and find the full text or summaries of State and Federal environmental statutes. LGEAN alerts users to hot topics and new developments in environmental compliance, tells them where to find technical and financial support, and provides them with a grant writing tutorial.
- **Small Government Agency Plan**: 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. The agency 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.

- Newsletter/Internet Site for Small Governments: 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.
- Guide to Federal Environmental Requirements for Small Governments: EPA also publishes and distributes the small communities guide, 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.
- Regional Guides to Federal Environmental Requirements for Small Governments: EPA Region VIII publishes and distributes 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.

Office of Solid Waste and Emergency Response

Resource Conservation and Recovery Act Burden Reduction Initiative: Final Rule.

On April 4, 2006, EPA, in accordance with the goals of the Paperwork Reduction Act, promulgated changes to the regulatory requirements of the Resource Conservation and Recovery Act (RCRA) hazardous waste program to reduce the paperwork burden these requirements impose on the States, EPA and the regulated community. EPA estimated that the total annual hour savings under the final rule would range from 22,000 hours to 27,500 hours per year. This rulemaking streamlined our information collection requirements, ensuring that only the information that is actually needed and used to implement the RCRA program is collected and the goals of protection of human health and the environment are retained.

The Burden Reduction rule was a deregulatory activity in that it reduced the amount of paperwork that needed to be generated by the States, EPA and the regulated community. Costs were saved rather than added, hence EPA determined that the final rule did not contain a Federal

mandate that may result in expenditures of \$100 million or more by State, local and tribal governments, in the aggregate, or by the private sector in any one year. In addition, the rule contained no regulatory requirements for small governments. Thus, it was determined that the final rule is not subject to the requirements of Sections 202, 203, and 205 of the UMRA.

While not formally subject to UMRA, EPA held extensive consultations with the State Waste Management Association (ASTSWMO) to ensure that concerns of State program implementers were addressed. These consultations largely occurred before October 2005.

States expressed concern because in some areas where EPA thought it was reducing burden on States, EPA was in fact merely shifting burden to State cleanup authorities. In the final regulation, EPA retained requirements identified by States as necessary to ensure that burden was not simply shifted to State cleanup programs.

Criteria for the Safe and Environmentally Protective Use of Granular Mine Tailings

Known as “Chat” Final Rule, this rule establishes criteria for the protective use of chat in transportation construction projects funded in whole or in part with Federal funds. Affected parties include the States of Oklahoma, Missouri, and Kansas, as well as owners (both private and tribal) of chat piles located within the Tri-state mining district. Other affected parties are users of chat in asphalt and concrete.

During the development of the proposed rule (71 FR 16729, April 4, 2006) and the final rule scheduled for promulgation in June 2007, EPA consulted with State environmental agencies and departments of transportation in Oklahoma, Missouri, and Kansas. EPA also consulted with the U.S. Department of Transportation Federal Highway Administration (FHWA) and the U.S. Bureau of Indian Affairs.

As required under the APA, EPA consultation took place formally during the proposal’s notice and comment period. EPA also conducted numerous meetings with FHWA, and conducted a site visit to the Tar Creek Superfund site where EPA staff met and held discussions with tribal representatives and environmental staff from the three affected States. In addition, EPA consulted with the Quapaw Tribe of Oklahoma in specific with the chat piles on tribal lands.

Chat owners and Tribes are concerned that any rule could adversely impact the use of chat in road construction. State Highway departments do not want additional rules that would supersede their materials specifications. FHWA does not want the rule to add additional burdens to their management of Federal transportation funds.

Consultation has led to clarifying the proposal’s scope so that it does not adversely affect existing Federal or State highway materials specifications. As a result of tribal consultations, the proposed rule was consistent with BIA efforts to encourage the sale of chat. The proposal was drafted so that it would be consistent with existing BIA MOUs with EPA. EPA did not change the proposal based on these consultations, since they confirmed the existing

information.

Underground Storage Tank Guidelines and Strategies

Required by the Energy Policy Act of 2005, these documents included: (1) Tribal Strategy; (2) Guidelines for delivery prohibition and secondary containment; and (3) Reports to Congress.

In the process of developing these documents, EPA consulted with States, Tribes and other Federal Agencies. EPA set up workgroups comprised of State, tribal, and EPA HQ and regional representatives. Workgroups reviewed drafts and provided suggestions on how to resolve issues, including limiting the scope of the guidelines to what was required by the statute, providing States with flexibility to implement the guidelines, and providing certainty to the regulated community.

As a result of the consultation process, EPA provided additional flexibilities in how States could structure their underground storage tanks regulatory programs.

Office of Prevention, Pesticides and Toxic Substances (OPPTS)

Periodic Pesticide Review

On August 9, 2006, EPA published a final rule that established procedures for the periodic review of each pesticide every 15 years (known as registration review), as required under Section 3(g) of the Federal Insecticide, Fungicide and Rodenticide Act (7 USC 136a(g)). The registration review program primarily affects pesticide registrants. Inter-governmental partners may be affected in that they have enforcement responsibilities or may themselves be users of pesticides.

EPA consulted stakeholders, including intergovernmental partners, in October 2006 meeting of the Pesticide Program Dialogue Committee (PPDC) which is an advisory committee established under the Federal Advisory Committee Act. Additionally, the Agency provided updates to SFIREG regarding the development of the new program.

The issues raised by participants in the consultation included the following; The design of the registration review program reflects input from consultation. Federal policies were changed as follows:

- Criteria for scheduling reviews. During the consultation, stakeholders reached agreement that the age of the pesticide's last review was a surrogate for risk because science issues that are considered now may not have been considered in the earlier review. Also, known risks of pesticides were recognized and dealt with during reregistration. Furthermore, the Agency has a separate procedure for managing emerging risks. Registration review schedules will be based on the date of the last comprehensive review.
- Public participation. The rule incorporates the pre-review comment period suggested by the stakeholders.

- Consideration of water quality issues in registration reviews. With respect to the issue raised by the State of California, the Agency agreed that, during the scheduled review, a pesticide's effects on water quality would be considered.